

Flow-QC Hemodialysis Monitoring Protocols



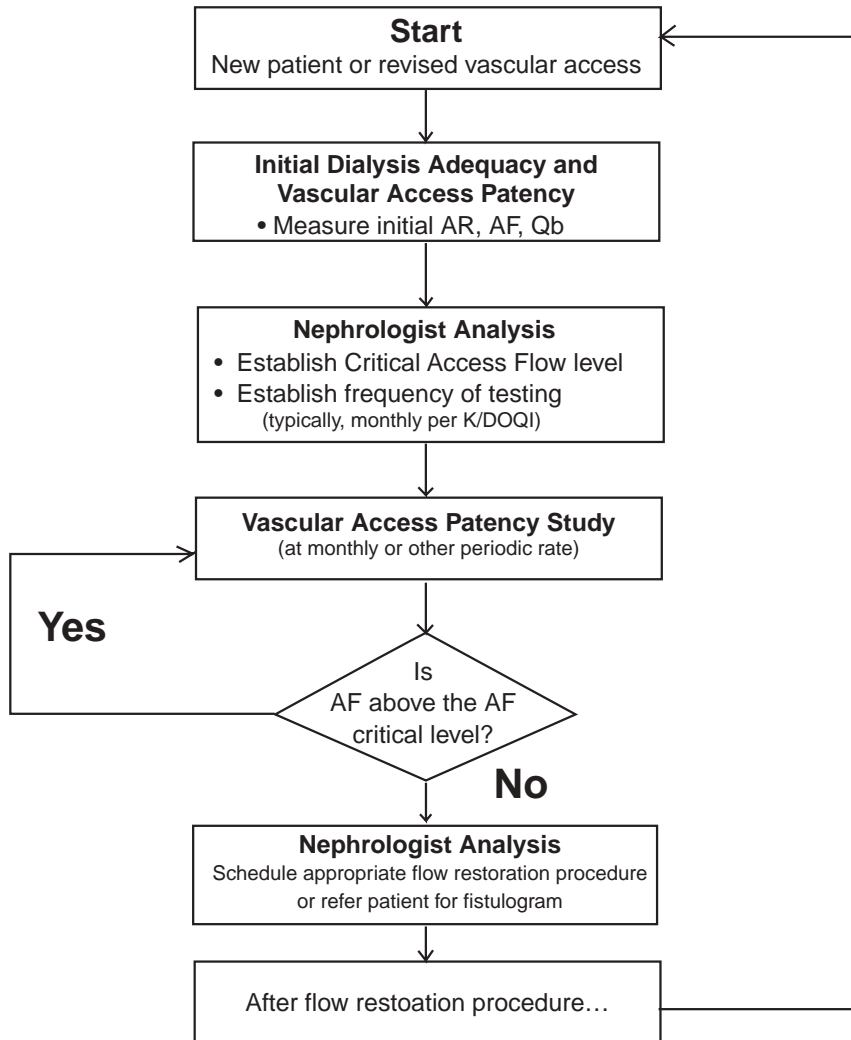
Transonic Flow-QC Hemodialysis Monitoring, when considered with an ESRD patient's medical history, type of vascular access, Kt/V prescription, as well as staff resources and a physician's preferences, creates an opportunity to customize an individual's treatment in order to:

- Optimize dialysis delivery
- Prolong the life of the vascular access
- Maintain the patient's cardiovascular health

The Transonic Flow-QC Monitoring Protocol (outlined on page 18) includes an initial **Dialysis Adequacy Flow Study** followed by periodic **Access Patency Monitoring**. The flow chart outlines a general protocol where the nephrologist sets a critical access flow level. As soon as flow drops below the critical access flow threshold, or falls below 1000 ml/min and exhibits a drop more than 25% during a 4-month period, an additional diagnostic study such as angiography is scheduled. Thereafter, monthly access flow surveillance is performed in compliance with K/DOQI Guidelines.

The **Cardiac Function Study Program** (page 34) introduces a protocol for ongoing management of an ESRD patient's cardiac health. For additional information about Flow-QC Cardiac Function Protocols, refer to the Transonic companion booklet, *Cardiac Function Assessment during Hemodialysis*.

FLOW-QC PROTOCOL FOR AV GRAFTS & FISTULAE



Flow Chart 1: Flow-QC Protocol includes an initial Adequacy Study followed by periodic Access Patency surveillance to track the progression of stenosis in AV grafts and fistulae.

A. Hemodialysis Adequacy Flow Protocol

As patients with new vascular accesses begin hemodialysis, a baseline **Dialysis Adequacy Flow Study** should be performed to confirm dialysis delivery and set vascular access parameters.

Delivered Blood Flow

Prescribed delivered blood flow is first verified by comparing the reading of delivered blood flow on the front of the Flow-QC monitor to the setting on the dialysis machine. It is not uncommon to see a difference between the two, especially at high blood pump settings. This may be due to the size of the access needle because larger needles (16G) deliver flow more efficiently than smaller diameter needles (15G). Under-delivery of prescribed blood flow may also be due to needle placement in the access. The arterial needle tip may be close to the vessel wall. If the arterial needle does not face the incoming access flow (needle is down rather than up), it may be difficult to achieve a high delivered blood flow. Access conditions may also limit the delivery of prescribed delivered blood flow.

One way to diagnose large differences in delivered blood flow between the pump and the monitor is to turn the blood pump speed to 200 ml/min. At this speed, pump errors due to high negative pressures are negligible and the monitor's delivered blood flow reading should correspond to the dialysis pump setting. If the readings agree, it can be concluded that the deviations at the high pump settings were due to one of the factors listed above.

If the readings do not agree at the low pump setting, check the tubing selection on the computer screen to make sure it matches the tubing you are using to dialyze the patient. The ultrasound dilution sensors are sensitive to differences in tubing brands and the accuracy decreases if the sensor is not calibrated for the tubing being used. In general, the accuracy of the Transonic delivered flow reading is $\pm 6\%$. Other possible causes for discrepancies in readings of the pump and the hemodialysis monitor could be that the dialysis machine is out of calibration or the arterial needle tip is too close to the vessel wall.

Access Recirculation

The second step in the Flow-QC Hemodialysis Adequacy Flow Study is measurement of Access Recirculation performed at the patient's prescribed Qb setting (Flow Chart 2, page 22). Most patients have 0% access recirculation in A-V accesses. Before the advent of Flow-QC technology, it was assumed that all patients had some degree of recirculation because screening technologies could not separate cardiopulmonary recirculation from vascular access recirculation (Fig. 4, page 9). This produced an over-estimation of a patient's true access recirculation. Because Flow-QC Monitoring can separate cardiopulmonary recirculation from true Access Recirculation, **0% recirculation is the norm for a healthy A-V access.**

If any recirculation is reported, the measurement must be confirmed by a second measurement. If the second measurement reports 0% recirculation, a third measurement is advised. This third measurement is the deciding "vote" on whether or not the access exhibits recirculation. In some cases, when recirculation < 5% (borderline recirculation), it is recommended that pump flow be increased to confirm recirculation. Figure 11 demonstrates the theoretical appearance of recirculation at a variety of measured access flows when delivered blood flow (Qb) is set at 400 ml/min. At a Qb of 400 ml/min, access recirculation theoretically appears at an access of 400 ml/min. When access flow is 300 ml/min and Qb is 400 ml/min, 100 ml/min must be drawn from the venous return to account for the deficit at the arterial needle, and recirculation equals 100/400 ml/min or 25%.

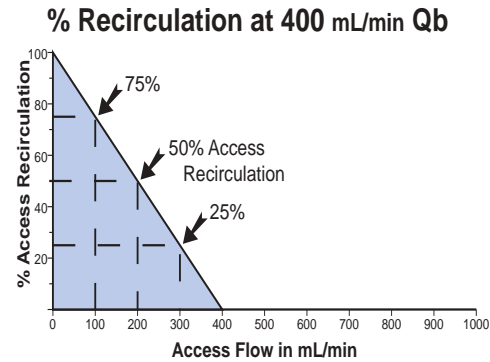


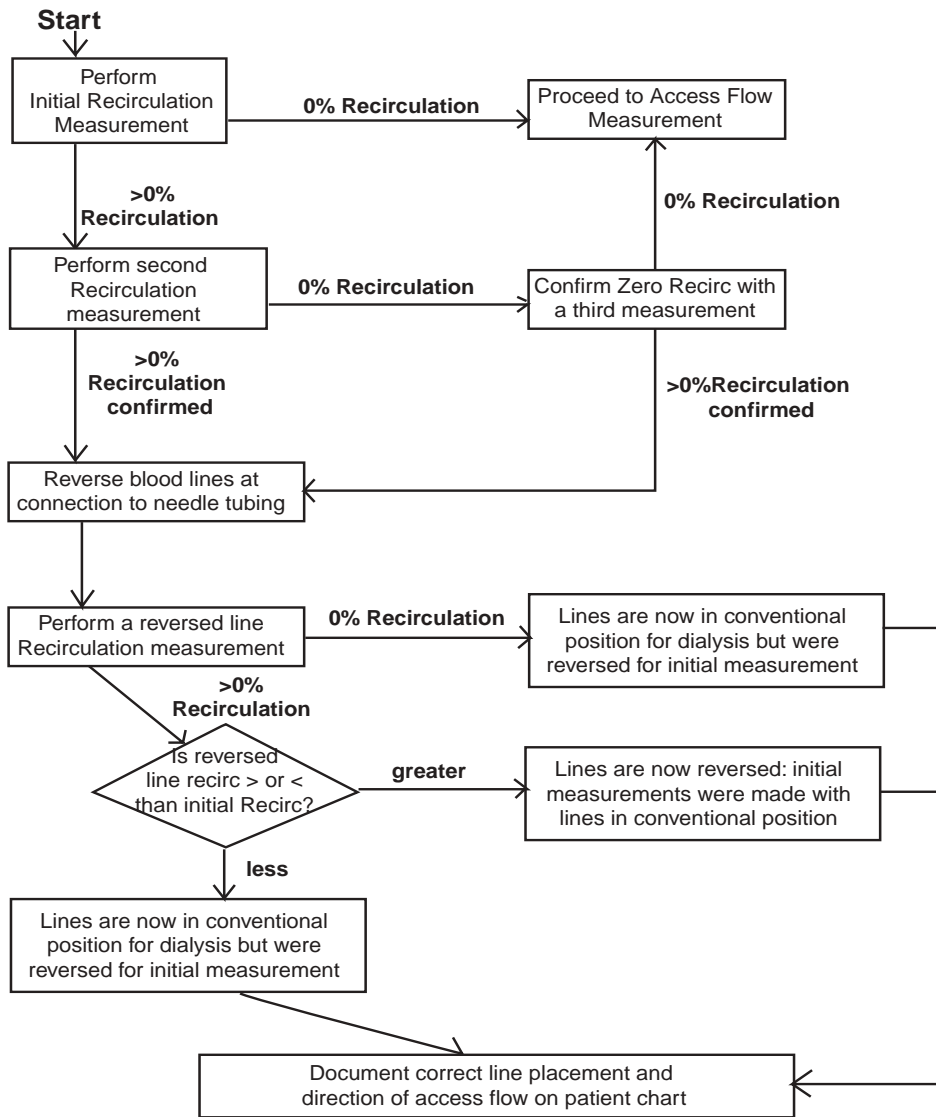
Fig. 11: Recirculation (Theoretical): When delivered blood flow (Qb) is 400 ml/min, access recirculation theoretically appears at an access flow of 399 ml/min or anything below the delivered blood flow. If measured access flow is 300 ml/min, there is theoretically 25% recirculation; at 200 ml/min measured access flow, 50% recirculation; at 100 ml/min measured access flow, 75% recirculation.

When a repeat measurement confirms the presence of recirculation, two possibilities exist.

- 1. The blood lines are inadvertently reversed with respect to conventional dialysis line orientation.** Examine whether the venous needle is placed upstream from the arterial needle with respect to the direction of the access flow (this is the line orientation used by the Krivitski Method to intentionally induce recirculation). Then repeat the recirculation measurement after intentionally cross-connecting the arterial line to the venous needle and vice-versa. If the result is “0% recirculation,” or if the recirculation percentage is less than the first for the same Q_b , the lines have been inadvertently reversed for the first measurement and the second line position is correct. Document this correct line position on the patient record to prevent future occurrences of inadvertent line reversal.
- 2. Access recirculation is due to low access blood flow.** When the second recirculation measurement is higher than the the first, the blood lines are now in the reversed orientation and first recirculation measurement should be the recirculation of record for the session (Flow Chart 2, page 22).

Access Flow Measurement (AF): The final step in the initial Hemodialysis Adequacy Flow Study is an initial access flow (AF) measurement. This measurement is important in establishing the access monitoring schedule as described in the following section.

RECIRCULATION PROTOCOL



Flow Chart 2: When the initial recirculation measurement confirms 0% recirculation, proceed directly to an access flow measurement. When recirculation is present, a series of steps is presented to identify the cause.

Nephrologist Analysis

After the Dialysis Adequacy Flow Study has been completed, the nephrologist integrates the results with other patient factors into a proactive quality care management program for the patient in order to:

- Provide optimum delivery of the dialysis prescription.
- Identify access concerns that require further investigation.
- Establish an early stenosis onset detection program.

During the initial dialysis adequacy analysis, all three Flow-QC parameters (delivered blood flow, recirculation and vascular access flow) are evaluated in relation to their “normal” dialysis conditions.

1. A **delivered blood flow** that is not within 10% of the dialysis pump setting may be compensated for by setting the prescribed Qb higher on the machine, or setting the pump speed with the monitor’s Qb as a reference at the beginning of each treatment. The needle size and needle placement should also be evaluated.
2. **0% recirculation** is expected in a healthy access. Recirculation unaccounted for by line reversal is a serious indication that a patient’s access may at risk for thrombosis because recirculation is known to be a late predictor of access dysfunction.
3. A **high rate of access flow** is necessary to maintain access patency. This high access flow and its mechanical shear force delay stenosis and thrombosis by working against the body’s clotting mechanisms.

B. Vascular Access Monitoring Program

The K/DOQI Guidelines formally recognizes that periodic access flow monitoring, as part of a comprehensive vascular access program, is an effective tool for predicting declining access health. Decreasing levels of flow over time or flows below a known danger level foreshadow impending access failure.

When establishing a vascular access monitoring program, the nephrologist first establishes an **Access Flow Trending Threshold**: a rate of flow where the access is at higher risk of failure. The nephrologist also sets a **Critical Access Flow Threshold** below which flow restoration procedures must be performed to preserve access patency.

Figure 12 presents a guideline for Access Flow Trending and Critical Flow thresholds for adult patients with artificial grafts. Figure 13 presents a similar guideline for patients with fistulae. K/DOQI guidelines recommend monthly monitoring to diagnose the onset of stenosis. For vascular access grafts, the Critical Flow Threshold is 600 ml/min or access flow of less than 1000 ml/min if flow drops 25% or more over the course of four months. For native fistulae, the thresholds are analogous to graft thresholds, but recent publications suggest that a critical flow threshold of 500 ml/min is more effective. Some clinicians use 800 ml/min for the a flow trending threshold with monitoring at two-month intervals. Nephrologists should draw upon their clinical experience and consider a patient's history (Figure 14, page 26) when setting flow thresholds. The level should be set high enough to permit proactive action before access failure.

Access flow screening in a patient at risk must be frequent enough to produce several data points over the period of patency deterioration. If the possibility exists for an access to completely stenose over a four-month period, measurements every four weeks should be adequate, providing that the criteria for intervention are sufficiently conservative and a flow restorative procedure can be scheduled without delay.

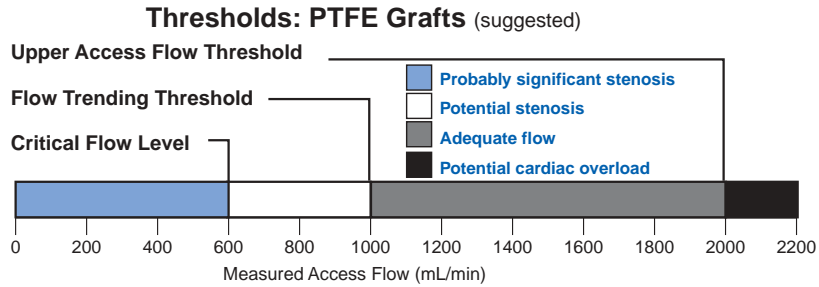


Fig. 12: PTFE Grafts Access Flow Level Guidelines (from K/DOQI and publications), **Adult Patients:** The Critical Level is 600 ml/min. The Flow Trending Threshold is 1000 ml/min, and the potential for cardiac overload exists at flows of over 2000 ml/min. Actual flow levels should be tailored for each patient by the nephrologist.

The **Critical Access Flow** threshold for grafts (Fig. 12) is 600 ml/min and 500 ml/min for fistulae (Fig. 13). Flows at or below the critical level set by the physician are indicative of significant stenosis and require immediate attention. The stenosis should be verified by a fistulagram and the appropriate flow restorative procedure performed.

A third threshold established by the nephrologist is the **Upper Access Flow Threshold**. In both grafts (Fig. 12) and fistulae (Fig. 13), this level is 2000 ml/min. Above 2000 ml/min, the patient may be at risk for cardiomegaly or other symptoms resulting from cardiac overload. Cardiac output measurements should

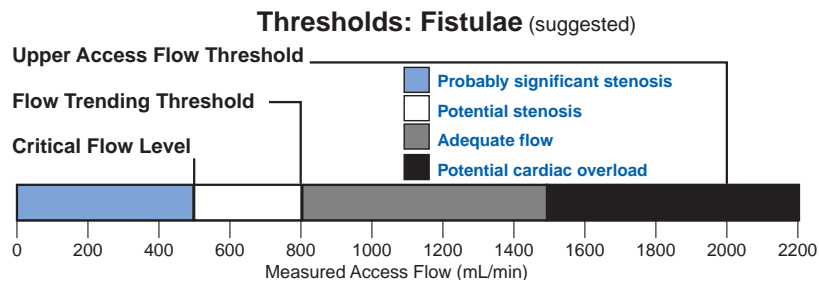


Fig. 13: Access Flow Level Guidelines for Fistulae, Adult Patients: The Critical Level is 500 ml/min, Flow Trending Threshold is 800 ml/min, and the potential for cardiac overload exists at flows of over 2500 ml/min. Actual flow levels should be tailored for each patient by the nephrologist.

Transonic Flow-QC

be performed when flow levels are above this upper threshold. The ratio between Access Flow (AF) and Cardiac Output (CO) is an important clinical indicator. When AF is over 20% of CO, the nephrologist generally performs additional tests, requests periodic monitoring and/or reduces access flow by banding the access. With AV grafts, banding is generally not recommended.

Patients whose flow falls between the upper and lower thresholds have adequate flow levels. In grafts.(Fig. 12) this ranges from 1000 - 2000 ml/min and in fistulae (Fig. 13), it ranges from 800-2000 ml/min.

After a monitoring schedule has been established, access flow measurements should follow the prepared plan. After each series of measurements, each patient's data should be examined as part of the patient's chronological history (Fig. 14). When a patient's access flow is below the Critical Flow Threshold, the software automatically alerts the clinician. Patients who fall into the high risk or critical categories defined by the threshold and critical access flow should be brought to the attention of a nephrologist. The nephrologist can schedule an examination or initiate appropriate flow restoration procedures.



Fig. 14: Patient History: As shown in the example above of one patient's access measurement history, the onset of stenoses were identified twice by a decrease in flow below 600 ml/min, the Critical Flow Threshold. The patient underwent a corrective intervention, indicated by the inverted arrows, and an immediate increase in access flow resulted.

Multidisciplinary Vascular Access Care Program

To proactively address access-related morbidity among hemodialysis patients, hemodialysis providers are implementing multidisciplinary vascular access care programs (VACP). One such example is the Gambro VACP, a comprehensive, proactive team approach to hemodialysis vascular access care designed to:

- improve all vascular access-related outcomes;
- prolong vascular access life, and
- reduce hospitalization costs associated with vascular access.¹³

The overall benefits of VACP are to:

- improve quality, cost, and satisfaction outcomes;
- provide seamless delivery of optimal vascular access care, and
- empower the nephrologist in delivery of vascular access care.

The Process Implementation Model (pages 28,29) describes the process, timetable for implementation and core competencies. The assessment phase first evaluates the current access care and baseline data. This is accompanied by a thorough and ongoing educational phase to develop vascular access core competency among all team members. The heart of VACP, though, is a fully integrated and proven access monitoring program and referral process. Vascular access flow monitoring is the cardinal protocol of the entire program. The objectives of VACP monitoring, evaluation and surveillance protocol are to:

- detect and intervene when significant access stenosis is suspected to prevent access thrombosis;
- prolong access life;
- prevent inadequate dialysis;
- reduce access-related morbidity and hospitalizations, and;
- decrease the number of missed dialysis treatments.

¹³Duda, C.R., Spergel, L.M., Holland, J., Tucker, C.T., Bander, S.J., Bosch, J.P., "How a Multidisciplinary Vascular Access Care Program Enables Implementation of the DOQI Guidelines,"Nephrology News and Issues, April 2000: p. 13-16.

Vascular Access Care Program

PHASE	PROGRAM	DEFINITION
Assessment Phase	Assessment	Evaluation of the current access care delivered by a multidisciplinary team in a Dialysis Facility and the collection of vascular access baseline data for subsequent comparison.
Education Phase	Education	Thorough and ongoing process to develop VA care core competency of all team members.
Monitoring Phase	Monitoring	Prospective VA monitoring techniques performed on each patient monthly and following any access intervention.
Diagnosis Phase	Diagnosis	Identify patients at risk for vascular access by completing a fistulagram or other diagnostic test to identify stenosis or other cause of access dysfunction. Provides information necessary to determine whether an intervention should be radiologic or surgical.
Radiologic or Surgical Intervention	Intervention	The phase when the patient actually undergoes a procedure to correct the diagnosed access complication.
Documentation of VACP Indicators	Documentation	The VACP documentation requirements and process.
CQI to achieves Outcomes and Best Demonstrated Practices	CQI	The GAMBRO Continuous Improvement Process (CIP) which enables monthly analysis of data and benchmarking of VA performance criteria.

Process Implementation Model¹⁴

PURPOSE	CORE COMPONENTS	TIME LINE
Standardizes assessment criteria and provides VA benchmarks for the continuous improvement process (CIP).	<ol style="list-style-type: none"> 1. Assess clinic staff and patient for vascular access care behavior and knowledge 2. Assess each patient's access each treatment 	1 st Month and Ongoing
Assure that all members of the VA Care team are knowledgeable and capable of providing VA care.	<ol style="list-style-type: none"> 1. Access Care Basics and Techniques 2. How to apply VACP in my Center 3. Access evaluation techniques to assess potential stenosis 4. When to refer for further diagnosis 	1 st Month and Ongoing
Designed to detect access dysfunction early and to permit sufficient lead time for a planned access intervention as well as assess the "success" of any completed access intervention (radiological or surgical).	<ol style="list-style-type: none"> 1. Identifies patients at risk with access problems 2. Defines access intervention required 	1 st Month and Ongoing
Provides a clear "road map" for any subsequent access intervention.	<ol style="list-style-type: none"> 1. Identifies patients at risk with access problems 2. Defines access intervention required 	1 st Month and Ongoing
Intervention is planned and delivered specifically to correct a diagnosed access problem.	<ol style="list-style-type: none"> 1. per Radiology 2. per Surgery 	Ongoing per diagnosis
Facilitates the tracking of each patient's VA history and ensures center-specific and national data are collected, monitored and trended.	<ol style="list-style-type: none"> 1. Access status for each patient each treatment 2. Access Clinical Indicators for each patient each treatment 	Ongoing per intervention and flow
Evaluates each Centers own standards of care against the national goals and benchmarks to promote each Center CIP to achieve best-demonstrated practices in VA care.	<ol style="list-style-type: none"> 1. Trend and analyze VACP Clinical Indicators each month 2. Maintain and monitor center-specific VA care improvement. 	Ongoing per monthly CQI meeting process

¹⁴Ibid.

Other components of the program include the diagnosis phase which identifies patients at risk for vascular access stenosis or other cause of access dysfunction in order to determine whether an intervention should be radiologic or surgical. During the intervention phase the patient actually undergoes a procedure to correct the diagnosed complication. Finally, documentation of VACP indicators is essential for the success of the continuing quality improvement (CQI) process. CQI recommends monthly analysis of data and benchmarking of vascular access performance criteria.

Such a multidisciplinary access management program implement K/DOQI guidelines and have been found to prolong access life, prevent inadequate dialysis and reduce access-related morbidity and hospitalizations.

Minimizing Access Flow Surveillance Errors

The K/DOQI guidelines clearly address multiple issues that should be considered in the implementation of access surveillance programs. However, published data^{15,16,17} and numerous personal communications suggest that some simple rules are not being applied consistently during access flow data analysis. The following recommendations are advised to improve outcome quality:

1. For AV grafts, use both K/DOQI-recommended thresholds including the absolute threshold of 600 ml/min and the dynamic threshold of a 25% decrease within 4 months. Use of both these thresholds should decrease false-positive rates. The dynamic threshold may be more predictive of stenosis. Using only one threshold may not be as effective and may lead to a misleading message about the effectiveness of flow surveillance.¹⁸

¹⁵McDougal G., Agarwal, R., "Clinical Performance Characteristics of Hemodialysis Graft Monitoring," *Kid Int'l* 2001; 60: 762-766.

¹⁶Desoto D.J., Ram, S.J., Faiyaz, R., Bitk, C.G., Paulson, W.D., "Hemodynamic Reproducibility during Blood Flow Measurements of Hemodialysis Synthetic Grafts," *Am J Kid Dis* 2001; 37: 790-796.

¹⁷Atray, N.K., Paulson, W.D., "Blood Flow Surveillance of Hemodialysis Grafts: Insight from Two Case Reports," *Sem Dial* 2002; 15: 370-374.

¹⁸McDougal G., Agarwal, R., "Clinical Performance Characteristics of Hemodialysis Graft Monitoring," *Kid Int'l* 2001; 60: 762-766.

2. It is generally recommended that access flow measurements be performed during the first two hours of a dialysis session. However, this approach may not always avoid hypotensive episodes or other nonbaseline situations. If a 20-30% decrease in flow is observed, it may be the result of significant stenosis or a decrease in systemic pressure. If a significant decrease in mean arterial pressure (MAP) has been observed, the patient's previous access flows and MAPs should be reviewed.^{19,20} Before the patient is referred for angiography, the access flow measurement should be repeated at the patient's next session to confirm that the decrease also exists when patient's MAP is in its normal range.
3. Flow measurements should be performed at least once a month in AV grafts to avoid thrombosis events.²¹
4. For native fistulae, outcomes could possibly improve by decreasing the absolute threshold to 500 ml/min.^{22,23,24} This threshold takes into account that fistulae have long life spans with lower flows, and that the initial access flows at distal locations (anatomical snuffbox) generally are lower.

¹⁹Desoto, D.J., Ram, S.J., Faiyaz, R., Bitk, C.G., Paulson, W.D., "Hemodynamic Reproducibility during Blood Flow Measurements of Hemodialysis Synthetic Grafts," *Am J Kid Dis* 2001;37: 790-796.

²⁰Atray, N.K., Paulson, W.D., "Blood Flow Surveillance of Hemodialysis Grafts: Insight from Two Case Reports," *Sem Dial* 2002; 15:370-374.

²¹Ibid.

²²Bouchouareb, D., Saveanu, A., Bartoli, J.M., Olmer, M., "A New Approach to Evaluate Vascular Access in Hemodialysis Patients" *Artif Org* 1998; 22: 591-595.

²³Tonelli, M., Jindal, K., Hirsh, D., Taylor, S., Kane, C., Henbrey, S., "Screening for Subclinical Stenosis in Native Vessel Arteriovenous Fistulae," *J Am Soc of Nephrol* 2001; 12: 1729-1733.

²⁴Atray, N.K., Paulson, W.D., "Blood Flow Surveillance of Hemodialysis Grafts: Insight from Two Case Reports," *Seminars in Dialysis* 2002; 15:370-374.

Pediatric Access Flow Monitoring

Pediatric dialysis is an emerging field. In 2003, 4,500 U.S. children and adolescents will undergo treatment for end stage renal disease, many of whom will receive kidney transplants within two years. Approximately 60% of this population is less than 12 years old. The remaining 40% are adolescents. Since patients range from neonatal to teenagers, the blood tubing used to dialyze these patients comes in several sizes and configurations. Transonic Flow-QC software is equipped to normalize access flow for children. To adjust for patient size, the raw access flow is corrected for body surface area and is reported in mL/min/1.73m². Transonic recommends the use of standard H4D sensors on Transonic Flow-QC tubing sets inserted between the smaller blood lines and needle lines of young children.

Goldstein *et al* report that ultrasound dilution (UD) is a valid indicator of access flow in children^{25,26,27} “When the uncorrected flow value reported by UD is corrected for patient body surface area, UD is predictive for the presence or absence of severe AV graft stenosis, regardless of patient size.’ A corrected access flow of less than 700 ml/min/1.73m² was considered highly predictive of stenosis in pediatric hemodialysis patients.

There are no current standards for dialysis treatment for children. A large percentage of children on dialysis are treated through a catheter. For these patients, the Transonic Flow-QC monitor can measure delivered blood flow and recirculation. Transonic recirculation measurements optimize catheter functions by identifying catheter dysfunction and determining the optimum blood pump speed to customize dialysis prescription, determining which flow direction is most efficient and whether recirculation is present in the catheter.

²⁵Goldstein SL, Allsteadt, A, “Ultrasound Dilution (UD) Is a Simple Non-Invasive Technique for Measuring Access Flow and Is Reliable To Monitor for Vascular Access Stenosis in Children Receiving Hemodialysis.” HD148

²⁶Goldstein, SL, Allsteadt, A, “Ultrasound Dilution Evaluation of Pediatric Hemodialysis Vascular Access,” Kidney Int. 2001;59(6): 2357-60. HD177A

²⁷Goldstein, SL, Allsteadt, A, Smith CM, Currier, H, “Proactive Monitoring of Pediatric Hemodialysis Vascular Access: Effects of Ultrasound Dilution on Thrombosis Rates,” Kidney Int. 2002 ;62(1):272-5.HD261A

C. Cardiac Function Measurements

Transonic Flow-QC[®] cardiac output measurements enable ongoing surveillance of the cardiovascular health of ESRD patients as they undergo the stress of hemodialysis. Effective cardiac function management depends on a routine screening program, such as Central Hemodynamic Profiling (CHP) depicted in Figure 15. Specific cardiovascular parameters provide nephrologists with early indications of deteriorating cardiac conditions so that treatment can be immediately initiated.

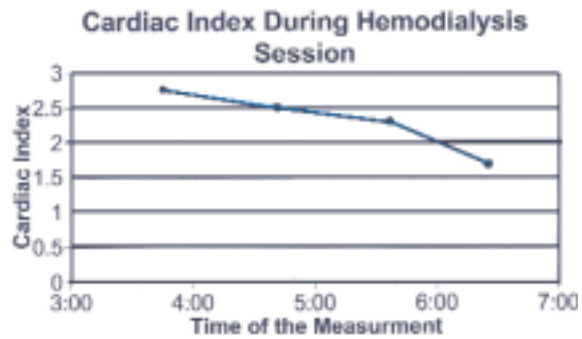
Fig. 15: Central Hemodynamic

Profiling (CHP): CHP tracks

the response of the heart to the stress of hemodialysis to detect early indications of cardiovascular failure. A CHP Study consists of hourly cardiac output measurements throughout the hemodialysis treatment. Transonic Flow-QC[®] Cardiac Output software

automatically calculates the Cardiac Index (CI). If CI drops below 2 L/min/m² during treatment, the hemodialysis prescription should be reviewed and adjusted immediately (e.g. dialysis prescription, ultrafiltration, medications, etc.). After adjustments are made, another CHP Study is performed during the next dialysis session. If this profile is stable and in the appropriate range, the patient's cardiac status can then be monitored as scheduled.

Courtesy of Dr. T. Tucker, Brunswick, GA



Cardiac Function Assessment during Hemodialysis, a companion booklet, presents the Flow-QC[®] protocol for cardiac management. An effective management program can be performed by a trained nurse for review by a nephrologist and should consist of baseline and follow-up tests. Nephrologists, should design an individual testing program for each patient, based on the patient's medical status and needs.