

➡ **Quality Assessment & Performance Improvement (QAPI) Review:** ▲

Purpose - To verify that the facility's QAPI program is sufficiently comprehensive and robust to monitor all facility operations/services, recognize when performance improvement is indicated, take actions to attain and sustain improvements, and support a facility-wide "Culture of Safety" that assures optimum patient safety

The QAPI review is divided into 3 General Segments of review:

Segment I: Monitoring care and facility operations to verify that the facility QAPI program has sufficient infrastructure, and continuously monitors all areas as expected, including in the technical areas. ***Note:** The Quality assessment and performance improvement activities for critical priority areas, and the data-driven focus and survey findings areas for this facility will be reviewed in more detail during Segment II of the QAPI review.*

- **Clinical and operational indicators:** A brief look to assure all expected indicators and areas pertinent to dialysis care are continuously monitored.
- **Oversight of technical operations and practice audits** to verify the presence of consistent QAPI oversight of water/dialysate, equipment maintenance/repair, and dialyzer reuse programs through review of outcomes and practice audits.

Segment II: Review of Quality Assessment and Performance Improvement in three critical priority areas for ALL facilities and in the data-driven focus areas and survey findings areas of this facility survey. This involves a detailed look into the facility's QAPI activities for recognizing issues, prioritizing, and addressing the critical priority and problematic areas to attain and sustain improvements.

- **Mortality review:** Looking at the QAPI activities for evaluating and trending patient deaths, and efforts implemented to address adverse trends potentially related to care received at the facility.
- **Infection prevention and control:** A review of the facility program for infection occurrence tracking/trending, vaccination, personnel infection control education and visual auditing, and patient education in infection prevention, toward the goal of reduction of patient infection rates.
- **Medical error/adverse occurrence/clinical variance tracking and investigation system** to verify the presence of an effective system for responding to events, investigating, and addressing causal factors to prevent occurrence or recurrence. During this review, you will "follow" an error/event and the facility performance improvement actions as recorded in the facility system.
- **Data-driven focus and survey findings areas:** following through with the focuses and findings of the survey, to determine what the facility QAPI activities were for recognition of the problems/risks, and actions taken to address them.

Segment III: Culture of Safety Review: Verifying the presence of a facility-wide culture that assures patient safety. The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors, open blame-free communication between all levels of staff and patients, communication of clear expectations of staff, and complete staff and patient engagement to assure that everyone at the facility is committed to identifying and mitigating any risks to patients. The culture of safety review has 3 components:

- **Risk identification and reporting:** Looking to see that an effective program exists to identify all risks to patients and facilitate liberal reporting of those risks, including “near misses”/“close calls” to allow comprehensive investigation and mitigation of risks.
- **Staff engagement:** Looking at the facility's communication systems and role expectations among all levels of staff. You will review the facility staff complaint/suggestion log.
- **Patient engagement:** Looking at the facility program for assessing and addressing patients' mental and physical health outcomes. You will also review the facility patient grievance/complaint/suggestion system by “following” a patient complaint through the process.

Preparation for QAPI Review: Although portions of the QAPI review may occur throughout the survey, the bulk of the QAPI review should be conducted toward the end of the survey to enable focus of the review during Segment II on the facility's QAPI performance improvement activities in the critical priority areas, data-driven focus areas, and survey findings areas. Conducting the review after most of the survey is completed allows you to determine if the facility has identified the same concerns and what performance improvement actions they have taken to address them. *Prior to conducting the QAPI review, the survey team should communicate, discuss the survey findings, and make a list of areas in addition to the critical priority ones you will focus on during Segment II.*

Review the QAPI documentation for the last 6 months in the areas listed in Segments I, II, and III below. Interview the responsible facility-based person.

Segment I: Monitoring Care and Facility Operations

➤ **Clinical and operational indicators monitored**

Review the QAPI documentation to verify that the facility's QAPI program includes active involvement of all expected administrative, patient care and technical staff and that the QAPI Team monitors at a minimum all the expected areas of patient clinical management and facility operations. Refer to table of indicators in the “ESRD Core Survey QAPI Review Worksheet.” Note that not all areas listed in the table are expected to be monitored monthly.

This is not a detailed review, but a brief look at the facility's QAPI dashboard or other summarizing documentation. You will review the facility QAPI performance improvement activities in the critical priority areas, survey data-driven focus areas and survey findings/concerns areas in more detail during Segment II.

- Expect to see that the facility is routinely monitoring and trending all of the expected areas. For the clinical areas, that the facility has identified outcome goals which reflect community standards from the current Measures Assessment Tool (MAT). The QAPI documentation must show the active involvement of all personnel necessary to adequately address and resolve problems/issues, including all members of the interdisciplinary team, i.e., medical director, nurse manager, masters-prepared social worker, registered dietitian, and other personnel such as technical staff and patient care staff (V626, 628).

➤ **Oversight of technical operations and practice audits:**

Review the facility's QAPI documentation to ensure routine audits in these areas are conducted and discussed, as required in the Conditions for Coverage:

- **Water and dialysate quality**
 - Review of monthly water and dialysate cultures/endotoxin results, annual product water chemical analysis, and other microbiological monitoring as indicated for the equipment in use (V628)
 - Audits at least annually of staff mixing dialysate concentrates; testing dialysate pH/conductivity; testing water for total chlorine and microbiological sample collection (V260)
- **Dialysis equipment**
 - Review of monthly dialysis machine, equipment and ancillary equipment maintenance and repair (V628)
- **Reuse**
 - Review and verification that all required reuse audits are conducted at the applicable intervals and adverse occurrences related to reuse addressed (V635)

Segment II: Review of Quality Assessment and Performance Improvement in three critical priority areas for ALL facilities and in the data-driven focus and survey findings areas of this facility survey (identified areas of patient risk).

For ALL facilities, review the mortality, infection prevention and control, and medical error/adverse occurrence investigation systems (i.e., critical priority areas). Individualize your review of the data-driven focus areas and survey findings pertinent to this facility survey. In all areas, conduct a sufficiently detailed review to determine the quality and effectiveness of the facility QAPI Team actions for addressing problematic areas and attaining and sustaining improvements in outcomes.

➤ **Mortality review:**

Review, with the responsible facility-based person, the QAPI documentation for evaluation of the facility mortality data. Focus the discussion on the analysis and trending of causes of patient deaths and the relationship to the care received at the facility.

For all facilities, ask: What information do you collect about patient deaths? How does the QAPI Team conduct analysis of individual patient deaths, and recognize trends in causes and contributory factors to deaths?

- Expect to see evidence that the facility reviewed and evaluated all patient deaths, and analyzed trends in causes of patient deaths (V628).

For facilities with poor mortality outcomes as noted from the Dialysis Facility Report review during Presurvey Preparation: Ask: What trends in causes of mortality have you identified?

How did you investigate them? What performance improvement strategies have you implemented to address the high mortality ratio and/or adverse trends?

- Expect to see, for identified trends in cause of deaths, that the QAPI Team investigated the issues and conducted focused QAPI review on the aspects of care related to specific-cause categories. Examples are: for high rates of deaths due to **infection causes** the QAPI Team should have looked at the CVC rate and CVC reduction efforts, hospitalization patterns, water/dialysate cultures, staff compliance with infection control practices, etc.; for high rates of death due to **cardiac causes** the QAPI Team should have looked at HD ultrafiltration rates, length of HD treatments, the use of low potassium (“0K+” or “1K+”) dialysate, patients' serum bicarbonate levels, etc.
- **Infection prevention and control:** Infections are a leading cause of death in dialysis patients, and protection from infection is vital to their health and safety. This review is intended to assure that the facility’s QAPI activities facilitate a multifaceted and effective facility-wide program for the prevention, detection, and management/control of infections, with the goal of minimizing or eliminating healthcare associated infections (HAI) acquired at the facility.

Review the past 6 months of QAPI documentation in these areas:

- **Infection occurrence tracking/trending/surveillance:** *Ask:* What types of infections do you record? What information do you record about each infection?

Review the infection tracking logs.

- Expect to see that all positive culture results, dialysis access, blood stream infections (BSI), and peritonitis episodes, if applicable, are recorded with sufficient information for each (i.e., patient name, date, infecting organism, culture site, antibiotic use); That trends in infections were recognized, evaluated/investigated, and performance improvement strategies implemented and monitored for effectiveness (V637).
- **Vaccination: high risk disease management:** *Refer to the facility vaccination information obtained from the Entrance Conference Materials List. Ask:* The responsible person to show you the QAPI documentation of oversight for surveillance and vaccinations including:
 - Hepatitis B patient surveillance and susceptible patients and personnel offered vaccination (V125-127)
 - Tuberculosis surveillance of patients on admission or exposure
 - Influenza vaccinations offered to patients and personnel seasonally
 - Pneumococcal pneumonia vaccination offered to patients
- Expect to see evidence of active QAPI oversight of the high risk disease surveillance and vaccination programs listed above. If trends of lapses in surveillance or vaccination were identified, that the QAPI Team took meaningful actions to investigate the problem, implement performance improvement plans, and monitor them for effectiveness V637).

- **Staff education and visual practice audits for infection control:** *Ask:* What are staff taught about the prevention of infections in dialysis? How often are they re-educated in infection prevention? How often do you visually audit personnel infection control practices? If you identify a problem when auditing staff, how do you involve the staff in the development and implementation of the solution?

Review the documentation visual audits of personnel infection control practices while delivering care to patients.

- Expect to see evidence of active staff education and at least annual verification of competency for infection prevention and control by visually auditing each direct care staff member. There should be evidence of actions taken toward improvement when lapses in practices were observed, i.e., applicable staff involved in the investigation into issues surrounding the practices such as low staffing, and development and implementation of improvement plans, rather than not just counseling or reeducating (V637, 142).
- **Patient education for infection prevention:** *Ask:* How are patients educated about infection prevention? How are patients encouraged to be engaged in knowing what infection prevention actions (e.g., changing gloves, hand hygiene, cleaning/disinfecting equipment) they and/or staff should follow? How are the patients encouraged to speak up if they have concerns about personnel infection control practices?
- Expect to see that the facility's infection prevention and control program includes educating patients and families about strategies for remaining infection-free (V637, 562, 585).
- **For facilities with high rates of infection, high rates of CVC >90 days, or patterns of survey findings in infection control:** *Ask:* What investigation have you conducted into your facility's problematic infection issue? What QAPI strategies have you implemented to improve the problem? What improvements have you achieved?
- Expect to see that a facility with high patient infection rates has fully investigated for trends and causes of the infections, including but not limited to staff care practices, water/dialysate and dialyzer reprocessing sources. For high rates of CVC>90 days, there should be evidence of meaningful strategies implemented for reducing CVC rates. When reductions in infection rates or CVC >90 days rates are not attained, there should be evidence of revisions and changes in performance improvement actions until improvements are achieved (V637).
- **Medical error/adverse occurrence/clinical variance tracking and investigation system:** The intent of this review is to ensure that there is an effective QAPI system in place for reporting, investigating, and responding to errors/occurrences. **The error/occurrence log is not intended as a source for survey citations except as related to the QAPI process.** *Tell the responsible person that you will be reviewing the facility error/occurrence log with them.*

Review the facility error/occurrence log for the past 6 months: Select one error/occurrence to “follow” along with the responsible person. You may randomly select the error or select one pertinent to concerns identified during the survey (e.g., you observed staff not identifying patients' reprocessed dialyzers as required, and select an error to follow when a patient was dialyzed on another patient's dialyzer). Look at the reporting of the error/occurrence, the investigation into the circumstances and possible cause(s), and QAPI Team actions to prevent future similar occurrences.

- Expect to see evidence that the facility thoroughly investigated the error/occurrence by looking at why it happened, including interviews with all applicable staff to determine what circumstances surrounded it, and involved those staff members in the development of the plan for resolution. There must be evidence that the facility implemented a meaningful action plan to mitigate factors that contributed to the error/occurrence, monitored the plan for effectiveness in preventing recurrence, and, if a similar error/occurrence happened, revised and implemented the revised plan (V634).

➤ **Data-driven focus areas and survey findings areas:** *Using your list of QAPI focus areas, Review those data-driven focus areas and survey findings areas in more detail with the responsible facility-based person.*

Ask: How does the QAPI Team prioritize their performance improvement activities? How did the QAPI Team recognize the focus area problem/issue and investigate the root/multiple cause(s)? What actions did they take for improvement, and how were the actions and subsequent outcomes monitored to assure improvements were attained and sustained? If improvements were not attained, what actions did the QAPI Team take?

For each data-driven focus area and survey finding area you reviewed:

- Expect to see evidence that the facility QAPI Team:
 - Prioritized performance improvement activities to assure the areas with the highest potential for impacting patient safety were given priority and aggressively addressed in a timely manner (V639)
 - Routinely monitored the focus area, recognized that a problem/opportunity for improvement existed, thoroughly investigated root/multiple causes of the issues, and developed and implemented performance improvement plans
 - Monitored the performance improvement plan to attain and sustain improvements, or, if goals were still not achieved, revised the actions until improvements were attained and sustained (V626, 628-637)

Segment III: Culture of Safety

In healthcare, lessons show that true patient safety is only achieved through the implementation of a facility-wide “culture of safety.” The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors/risks, open blame-free communication between all levels of staff and patients, and clear expectations of staff practices. A culture of safety supports complete staff and patient engagement and assures that everyone at the facility is

committed to identifying and mitigating any risks to patients. This segment includes reviews of the following 3 areas:

- **Risk Identification and Reporting:** To verify that there is an effective system in place for reporting all errors/occurrences, “near misses”/“close calls,” and potential risks to patients

Ask: How do you define medical errors/adverse occurrences/clinical variances? What occurrences are staff expected to report? **Compare:** the answer (list of occurrences) with the list in the section “Medical error/adverse occurrences/clinical variances” from the table included in the “ESRD Core Survey QAPI Review Worksheet” to ensure that these occurrences, at a minimum are recognized as potentially hazardous and are included in the facility reporting and investigation system.

Ask: How do you ensure staff report “near misses” and “close calls” when an error/adverse occurrence/clinical variance did not actually occur, but was averted? How do you track and investigate near misses/close calls? **Note:** The evaluation of near misses/close calls has been shown to be a rich source of error/adverse occurrence prevention and highly effective for improving patient safety.

- Expect to see that the facility medical error/adverse occurrence/clinical variance reporting system includes all expected error/occurrences, and staff education for reporting defined occurrences and near misses/close calls (V634)

- **Staff Engagement Review:** To verify the presence of open communication between all levels of facility staff where all staff are engaged in the QAPI processes and encouraged to voice concerns without fear of retribution

Ask: How do you ensure open communication with all levels of staff? How are staff educated about and encouraged to freely report errors/occurrences/clinical variances, and near misses/close calls without fear of retribution? How are staff encouraged to voice concerns about or ideas for improvements in their work environment? How do you engage all levels of staff in QAPI activities? How are staff suggestions, concerns, and complaints recorded and responded to?

Review the Staff Suggestion/complaint log: Look for evidence that the facility has an organized, facility-based system in place for staff to submit written or verbal suggestions for improvement, communication of concerns about their work environment, and complaints.

- Expect to see evidence that the facility administration educates and encourages staff to make suggestions and voice concerns and complaints about their work environment. There should be evidence that administrative personnel recognize and acknowledge staff concerns in a timely, non-judgmental manner, conduct substantive investigation into the concerns, and include applicable staff in resolution to the issues (V627).

➤ Patient Engagement Review

Patient health outcomes, physical and mental functioning review: To verify that the facility QAPI Team is focused on patients' psychosocial status by regular monitoring through the administration and use of an age-appropriate standardized survey that assesses the patients' physical and mental functioning

Ask: How do you track and trend eligible patients' scores in an age-appropriate standardized physical and mental functioning survey, e.g., KDQOL-36? What is your facility's threshold for patients completing and refusing the survey annually? **Note:** *Although it is expected that a few patients may refuse to participate in the assessment of their physical and mental functioning, high refusal rates, e.g., >20% would indicate a problem which should be recognized and addressed by the QAPI Team.*

Review the QAPI documentation related to patient physical and mental functioning outcomes monitoring.

- Expect to see that the QAPI Team tracks and trends the % of eligible patients who complete and refuse the physical and mental functioning survey, and track and trend the scores on a facility level.
- If the trends showed facility-level scores declined or an increase in the refusal rate, there should be evidence that the QAPI Team recognized a problem existed, investigated the possible causes, and took meaningful actions to address the issue(s) and attain improvements (V628).

Patient grievance/complaint/suggestion system: To verify that the facility QAPI Team is "listening" to the patients, and that a patient grievance/complaint submission system is in place that encourages patients to feel free to express concerns without fear of reprisal. *If the patient interviews indicated trends of concerns about reluctance to speak up, plan to spend more time reviewing this area with the responsible person. Tell the responsible person you will be reviewing the patient grievance/complaint suggestion log with them.*

Ask: How are staff taught to respond to patients' voiced concerns? What types of patient concerns do you educate and expect staff to report and record?

Ask: How are patients educated about and encouraged to freely speak up and voice suggestions and complaints/grievances without fear of retribution or retaliation? How are their concerns, verbal or written suggestions, and complaints/grievances recorded and responded to? What is your facility's system for communicating with the patient and reporting the resolution to him/her?

Review the patient suggestion/complaint/grievance log with the responsible person. Select one patient suggestion/complaint/grievance to review how it was investigated, resolved, and the result communicated to the patient.

- Expect to see that the facility management and staff encourage patients to verbalize suggestions and concerns, in addition to written complaints/grievances. Staff should be

educated how to respond professionally to patients' verbalized concerns and to report them to their supervisor for recording and follow up (V627).

- There must be evidence that the patient's concern you reviewed was recorded, the circumstances investigated, mutually acceptable resolution reached, and the result communicated to the patient (V636, 465, 765).

Patient Satisfaction Survey: To verify that the facility routinely assesses the patients' satisfaction with the facility and care received and acts upon the identified opportunities to improve care.

Ask: How do you assess patient satisfaction/perceptions of care at this facility?

Review summary information of the most recent patient satisfaction survey results. If trends in negative patient responses were identified, **ask:** How did you utilize that information to improve programs or care delivery (V636)?

Note: In the chronic dialysis setting where patients are encouraged to speak freely without fear of reprisal, patient voiced concerns, suggestions and complaints/grievances are expected and indicate the presence of a culture of safety. If the facility responsible person states there are no patient suggestions, verbalized or written concerns or complaints/grievances, this may be a cause for concern and indication of an absence of open communication and culture of safety (V627).

Triggers for citation in QAPI:

The QAPI program does not:

- Administer oversight of all facility operations including monitoring all areas and conducting practice audits as required by the CfC (V132, 260, 362-368, 403)
- Recognize and address risk areas where facility outcomes and/or survey findings indicate performance improvement is needed/indicated (V625-640)
- Follow up on performance improvement plans, resulting in improvements not attained or sustained (V638)
- Promote a facility-wide culture of safety (V627)-*Consider the survey team's interviews with patients, staff and administrative personnel, along with the above reviews in the Culture of Safety QAPI Review Segment III, to determine if meaningful efforts are being made to promote a facility-wide culture of safety.*

Extending the QAPI review should be conducted if there are serious pervasive deficient practices identified during the survey which have not been recognized and/or adequately addressed by the QAPI program. Extending the QAPI review should include investigation into the facility's compliance with the Conditions for Coverage of Medical Director and Governance. This may include interviews with the facility administrator, medical director, and governing body members to determine what administrative failures have contributed to the pervasive problems, through lack of adequate staff and/or resources (V754, 756, 757); lack of staff training and education (V713, 715, 760, 761, 763); and/or lack of involvement or leadership of the medical director (V712, 714).

