

Outline of ESRD Core Survey Process

Presurvey Preparation:

- Review the most current dialysis facility report following “Data Tools” worksheet guidance; note how facility is ranked on the State Profile/Outcomes list
- Contact the ESRD Network about quality concerns
- Review facility complaint & survey history
- Copy Entrance Conference Materials list from the “Data Tools” worksheet

Introductions: Contact the person in charge; explain purpose of the survey; present them w/ Entrance Conference Materials list to complete w/in 3 hours for Entrance Conference

Environmental “Flash” Tour: Observe the 4 patient-related areas below; ASK staff about the facility “culture of safety” in all 4 areas:

- **In-center dialysis patient treatment area:** Observe 25% (min 3) occupied dialysis stations including the patients, their vascular accesses & surroundings of the stations; check availability of functionality of emergency equip

Triggers:

- Dummy drip chambers present (V400, 403)
- Vascular accesses covered, not consistently uncovered/corrected by staff (V407)
- No RN on duty (V759)
- Poor staffing to meet patients’ needs (V757)
- Blood spills not cleaned up; equip &/or surfaces spattered with blood (V122)
- HD machine transducer protectors wetted with blood not changed (V120)
- Insufficient space to prevent cross-contamination & use emergency equip (V404)
- No functional AED/defibrillator, oxygen, suction, emergency medications, Ambu bag (V413); insufficient or unavailable emergency evacuation supplies (V415)
- Hemodialysis machines in obvious poor repair (V403)
- If dialyzer reuse, noticeable strong germicide odors (V318)
- Disrespectful communication or actions toward patients (V452, 627)
- Failure to offer patients privacy & confidentiality (V454)

- **Water treatment/dialysate preparation area:** Observe carbon system, chlorine testing equip & reagents, current total chlorine test, RO & DI monitoring & dialysate proportioning ratios

Triggers:

- Carbon system: absence of 2 or more carbon tanks w/sampling port between (V192)
 - Current total chlorine test not done, reagents not sensitive to 0.1 mg/L, expired or don’t match testing equip (V196)
- RO: absence of functioning H₂O quality monitor & audible alarm in tx area (V200)
- If DI present: absence of functioning resistivity monitor & alarm visible & audible in tx area, absence of automatic divert-to-drain or auto cut-off valve, DI not monitored 2x/d (V202, 203)
- Water distribution equip in obvious disrepair or contaminated state (V403)
- Acid & bicarb concentrates of different proportioning ratios present (V249)
- Acid or bicarb mixing & distribution equip in disrepair or contaminated state (V403)

- **Reuse room:** Observe condition of equip, dialyzer storage & dialyzer refrigerator, if present

Triggers:

- Stored dialyzers aesthetically unacceptable (V343); not protected from unauth access (V321)
- Reprocessing room or equip in obvious disrepair (V318, 403)
- Dirty dialyzers kept at room temperature >2 hrs (V331)
- Dialyzer refrigerator temperature not monitored (V331)

- **Home dialysis training area:** Observe the physical layout, infection control & availability of emergency equip with method for summoning assistance

Triggers:

- Insufficient space to prevent cross-contamination between patients (V404)
- Insufficient patient privacy (V406)
- Blood /PD effluent spills not cleaned; equip or surfaces visibly spattered (V122)
- Absence of functional emergency resuscitation equip or immediately available (V413)
- No method for summoning immediate assistance (V402)

Triggers for extending the tour to other areas:

- Evidence of serious lack of environmental maintenance that has the potential to impact patient safety, e.g., large areas of water damage, mold presence in patient-related areas; uneven/broken floor surfaces creating multiple trip hazards where patients ambulate (V401, 402)

Entrance Conference: with the facility administrative person

- Explain purpose & timeline of survey; Ask questions from “Entrance Conference Questions”
- Obtain current facility outcomes on completed Entrance Conference Materials List
- Review & discuss the current facility outcomes with the administrative person
- Compare the current facility outcomes in “% Met Goal” column of Entrance Conference Materials List with applicable “Threshold for % Met Goal” in “Clinical Outcomes Threshold Table 1” in “Data Tools” worksheet
- Determine the data-driven focus areas for survey clinical reviews (areas where thresholds not met & need for improvement is indicated)

Observations of Hemodialysis Care & Infection Control Practices:

- Observe direct care staff delivering care to HD patients using observational checklists for:
 - Pre-dialysis vascular access care & initiation of hemodialysis
 - Discontinuation of a patient’s HD tx & post-dialysis vascular access care (CVC & AVF/AVG)
 - Cleaning & disinfection of the dialysis station between patients
 - Preparation of the dialysis machine & extracorporeal circuit
 - Dialysis supply management
 - Medication preparation & administration

Triggers:

- Observed trends of breaches in infection control patient care practices:
 - Hand hygiene & glove use (V113)
 - Supplies taken to station not disposed, disinfected or dedicated (V116)
 - Clean dialysis supplies not protected from potential contamination (V119)
 - Breaches in aseptic practices for CVC (V147) or vascular access care (V550)
- Not adequately disinfecting the HD station/equip between patients (V122)
- Not testing hemodialysis machine alarms (V403)
- Not testing dialysate pH/conductivity w/ independent method or staff unaware of acceptable parameters (V250)
- Not performing reprocessed dialyzer germicide tests (V350, 351, 353) or patient/dialyzer identification by 2 people (V348) when patient is at the station
- Not priming reprocessed or dry pack dialyzers per DFU (V352, 403)
- Not assessing patients before & after tx or monitoring during tx per facility policy (V504, 543, 550, 551, 715)
- Medications not prepared in a clean area away from the dialysis stations (V118)
- Single dose vials punctured more than once or used for multiple patients (V118)

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- Multidose vials punctured with previously used syringe or needle (V143)
 - Poor aseptic technique (V143)
 - Medications for multiple patients taken to a patient station (V117)
 - Medications prepared/administered by unqualified personnel (V681)
- **Review Facility Isolation practices:** *If there is an HBV+ patient on in-center HD; Observe isolation room/area/equip/supplies; Observe care as above if possible; Review staff assignments for current week; Ask staff about assignments when HBV+ patient is dialyzing*
- Triggers:**
- HBV+ patient(s) not isolated (V110, 128, 129)
 - Observed trends of breaches in infection control practices (V113, 116, 117, 119, 121)
 - Staff assigned/delivering care to HBV+ patient & susceptible patients (V110, 131)
 - When 1 RN on duty, poor infection control separation between care to HBV+ & susceptible patients (V131)
 - Isolation equip not dedicated for use on HBV+ patients (V130)
 - Non-HBV+ patient(s) dialyzing in isolation room/area when HBV+ patient is on in-center HD census (V110, 128, 130)
- **Verify dialysis treatment prescription delivery:** *Compare the dialysis prescription/orders with delivered treatment for 4-5 patients (dialysate, dialyzer, BFR, DFR)*

Triggers:

- 1 or more patients not dialyzed on ordered prescription (V543, 544)

Patient Sample Selection:

- **Review patient-specific info from Entrance Conference Materials List**
- **Select 10% of total # of patients on census** (min 4, max 10) representing all modalities offered, using criteria below:
- “Unstable” patients
 - New admissions <90 days
 - Involuntary discharges in past 12 months, not previously investigated by State Agency
 - LTC residents receiving home dialysis at the LTC facility
 - Not meeting goals in the data-driven-focus areas for the survey
 - Observed w/concerns or involved in a complaint to be investigated
- **Record the patient sample w/rationale used for selecting them** (as listed above)

Water Treatment & Dialysate Review: *Review the critical water treatment components with the person(s) responsible for the activity & daily monitoring:*

- **Observe the total chlorine test; interview about maximum allowable total chlorine; actions taken for breakthrough; amount of carbon (EBCT) present; validating on-line chlorine monitor, if present**

Triggers:

- Absence of 2 or more carbon tanks with sample port between (V192), insufficient carbon EBCT-verify this by interview or record review, surveyors not expected to calculate (V195)
 - Observed total chlorine test result greater than maximum allowable level; test done incorrectly or with incorrect reagents/equip (V196)
 - Staff unaware of max allowable level of 0.1 mg/L total chlorine & breakthrough procedures (V260)
- **Observe the reverse osmosis (RO) unit, water quality monitor & alarm; interview about monitoring RO function by % rejection & water quality by TDS or conductivity**

Triggers:

- Absence of RO % rejection & product water TDS or conductivity monitor & alarm audible in patient tx area (V200)
- **Observe DI, if present; Interview about DI & if it is included in back-up plan; Ask about automatic divert-to-drain or auto cut-off valve, minimum resistivity, actions if resistivity <1 megohm (STOP dialysis), ultrafilter after DI**

Triggers: (if DI is part of back-up plan, all items below should be included in plan)

- Absence of functional resistivity monitor/alarm, visible & audible in patient treatment area or not monitored 2x/day (V202, 203)
- Absence of a functional automatic divert-to-drain or auto cut-off valve (V203)
- Staff unaware of accurate monitoring, minimum allowable resistivity of 1.0 megohm or actions for DI tank exhaustion i.e., STOP dialysis (V260)
- No ultrafilter post DI (V204)

- **Interview person(s) responsible for dialysate mixing/testing & microbiological monitoring about proper dialysate mixing, acid batch testing, timeframe for bicarbonate use, “spiking”; microbiological sample sites & techniques, timing, frequency of cultures on each HD machine**

Triggers:

- Water distribution system not disinfected monthly (V219); Water/dialysate samples not drawn before disinfection (V254); each HD machine not cultured at least annually (V253)
- Staff unaware of correct dialysate mixing, acid batch testing procedures (V260)

➤ **Review facility water/dialysate oversight logs:**

- Total chlorine tests-2 months; Product water chemical analysis-12 months
- RO monitoring % rejection & product water TDS or conductivity-2 months
- DI, if present or used in past 12 months: resistivity readings 2x/day-2 months
- Microbiological results of water (including reuse room) & dialysate-6 months
- Practice audits of staff conducting water, dialysate testing & procedures-12 months

Triggers:

- Total chlorine >0.1 mg/L & no documentation of appropriate actions taken (V197)
- Chemical analysis of product water not done at least annually (V201)
- Irregularities, trends of omitted tests (V178, 196, 199, 213, 252, 253)
- Microbiological results exceeding action/maximum levels & no documentation of appropriate actions taken (V178, 180)
- Practice audits of staff conducted < annually (V260)

Dialyzer Reprocessing/Reuse Review: *Observe the high risk components of dialyzer reprocessing & interview the reuse technician:*

- **Transportation of used/dirty dialyzers** to the reprocessing room/area
 - **Pre-cleaning procedures** rinsing, header removal/cleaning
- **Ask about germicide mixing, storage & spill management; dialyzer labeling/similar names warning; pre-processing before use; water quality & water pressure at pre-rinse sink**
- **Review 12 months of documentation of facility oversight of reuse program:**
- **QA audits:** obs of staff reprocessing, setting up for patients’ dialysis & dialyzer labeling
 - **Reprocessing equip PM**
 - **Adverse events/dialyzer complaint log**

Triggers:

- Improperly performed pre-cleaning or header removal/cleaning (V334)
- Water used for pre-cleaning **not** purified to AAMI standards (V333)
- Absence of functional water pressure gauge at pre-cleaning sink (V332)

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- Germicide not stored, mixed or handled per manufacturer's DFU (V339)
- Reuse tech interview w/inadequate knowledge of key patient safety areas (V309, 319, 320, 328, 345)
- Dialyzers not transported in a sanitary manner (V331)
- Dirty/used dialyzers at room temperature for >2 hours before reprocessing (V331)
- QA audits listed not done or incomplete (V362-368)
- Noticeable strong germicide odors or patient/staff complaints (V318)
- Serious adverse events related to dialyzer reprocessing/reuse without documentation of appropriate actions taken to prevent future similar events (V355, 356, 635)

For centralized reprocessing, refer to the current CMS Survey & Certification guidance

Dialysis Equipment Maintenance:

- **Interview machine maintenance personnel** about HD machine manufacturer's DFU for PM i.e., prescribed intervals & operating hours for PM
- **Review 12 mos PM logs for 10% of HD machines** (min. 3) for compliance with manufacturer's DFU –include home HD machines maintained by the facility in the 10% sample
- **Review 2 mos logs for calibration of equip used for machine PM & pH/conductivity testing**

Triggers:

- Trends of non-adherence to HD machine manufacturer's directions for PM (V403)
- No calibration of pH & conductivity meters or equip calibration meters or not per DFU (V403)
- Observations of serious lack of maintenance of ancillary equip that has the potential to impact patient safety (V403, 626)

Home Dialysis Training & Support Review: If the dialysis facility provides only home dialysis training and support, the survey must include all applicable survey tasks, e.g., Environmental Tour, Water/dialysate review and Dialysis Equipment Maintenance (if applicable to the equipment in use), Personnel Record Review, and QAPI Review

- **Interview the home training nurse(s)** about patient candidacy evaluation, training, demo of comprehension, IDT support & QAPI oversight of home training & support programs
- **Observe the direct care of home dialysis patient(s)** if the opportunity arises during the survey when a home dialysis patient is being treated or trained at the facility, observe the care.
- **Interview home dialysis patients** during Patient Interviews; if not at the facility, ask the home training nurse to contact the patient to alert that the surveyor will be calling to interview.
- **Review medical records of home dialysis patients** during Medical Record Review

Triggers:

- Home training nurse(s) lack knowledge of training patients/caregivers or monitoring patients
- Patient/caregiver interviews identify concerns (V581, 585, 586, 592)
- Medical record reviews of home dialysis patients identify concerns related to training or monitoring home dialysis patients (V585, 586, 593-595)
- Not evaluating home program outcomes separately in QAPI (V628)
- If care was observed, refer to the triggers for infection control in Observations of HD Care

Patient Interviews:

Interview the sampled patients, minimum of 4 patients interviewed. If <4 sampled patients can be interviewed, select additional alert patients to interview for total of at least 4. For home patients, ask nurse to alert patient about interview. **Refer to the Core Survey Patient Interview worksheets.**

Triggers:

Patients express concerns regarding:

- Patients' rights & responsibilities (V451)

- Education re transplant options & all dialysis modalities & settings (V451, 453, 458)
- Disrespectful treatment from staff (V452)
- How to prevent infections & protect their dialysis access (V562)
- The safety & comfort of physical environment of facility (V401, 402)
- Disaster preparedness & emergency evacuation procedures (V409, 412)
- Communication with IDT & involvement in planning their care (V501, 541)
- Proficiency of staff in delivering safe, adequate care (V681, 713)
- Problems due to inadequate numbers of qualified trained staff (V757-759)
- Culture of Safety: freedom to report care concerns, make suggestions, ask questions, or file a grievance/complaint without fear of reprisal (V465-467, 627)
- Adequate training & IDT support of home dialysis patients & caregivers (V585, 592)

Medical Record Review: All medical record reviews are focused reviews focusing on the care provided in the area/rationale used for sampling the patient

- **Review the medical records of all sampled patients** (10% census as selected at Patient Sample Selection)
- **For ALL sampled patients, review the dialysis prescription/orders, medication orders, & the documentation of dialysis delivery** (2-3 wks HD tx records; 8-12 wks PD flowsheets)
 - **For in-center HD:** looking for machine safety checks, treatments delivered as ordered, BP/fluid management, patient monitoring per policy
 - **For home HD:** looking for staff monitoring patient's adherence to orders, BP/fluid management, machine safety checks
 - **For PD:** looking for staff monitoring patient's adherence to orders, BP/fluid management
- **Patients w/poor outcomes in data-driven focus areas: review parts of medical record about THAT area** (e.g., 3 mos of THAT lab result, progress notes, medication orders, care plans, etc.)
 - Looking for facility actions for monitoring, recognizing the poor outcomes, & addressing it through taking actions to help patient reach outcome goals
- **Unstable patients: review IDT activities during the 2 most recent assessment/plan of care periods in progress notes, orders, assessments, plans of care**
 - Looking at the functionality of the IDT for addressing the reasons patient was deemed unstable
- **Newly admitted patients <90 days: review documentation in first weeks at facility**
 - Looking for initial nursing evaluation & orders prior to 1st tx, surveillance for TB, HBV, offered vaccinations & medical, psychosocial & training (home dialysis) needs met
- **Home HD patients: review water/dialysate quality testing appropriate to equip in use**
- **For Involuntarily discharged patients & home dialysis LTC residents follow the current CMS Survey & Certification guidance for review**

Triggers:

- Absence of a functional IDT process that monitors, recognizes & addresses barriers to attainment of identified outcome goals in clinical & psychosocial areas
- Patient/caregiver interviews indicate lack of functional patient education program & patients' rights concerns - *Extend review to documentation of patient education & patients' rights*
- Incomplete, inaccurate, inaccessible or insecure medical records (V726)
- Concerns identified in other survey tasks which can be investigated further through medical record review to support or dispel findings

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Personnel Interviews: *Interview in-person or by phone: med director, master's social worker, registered dietitian, 2-3 nursing staff (min. 1 RN & 1 PCT) & nurse manager (if necessary). Refer to the Core Survey Interview worksheets. Note that the water/dialysate, reuse, equipment maintenance & home training staff are interviewed during those survey tasks.*

Triggers:

- Concerns identified from personnel or patient interviews or other survey tasks that indicate the need to extend the questioning areas of personnel or interview more personnel to support or dispel findings

Personnel Record Review:

- **Review the facility-completed** "Personnel File Review" worksheet
- **Select a minimum of 3 personnel files** to review/compare to facility documentation for accuracy

Triggers:

- Personnel lack required qualifications or competency verification (V410, 681)
- 1 or more personnel files validated indicates inaccurate facility-submitted documentation
- PCTs listed w/ no certification expiration date: *check for hire date w/in 18 mos* (V695)

Quality Assessment & Performance Improvement Review: *Prepare for QAPI review by communicating with survey team about areas of concern. Determine the focus areas to review during Segment II Performance Improvement (i.e., data-driven focus areas & survey findings)*

- **Review the QAPI documentation for the past 6 months while interviewing the facility-based responsible person**

Segment I: Monitoring care & facility operations

- **Clinical & operational indicators:** **Review** (briefly) facility QAPI dashboard or summarizing info to verify that all expected clinical & operational indicators are being monitored -**refer to table/list of indicators in "QAPI Review Worksheet"**
- **Oversight of technical operations & practice audits:** **Review QAPI documentation of review/discussion/audits of:**
 - **Water/dialysate quality**-monthly cultures, annual water chemical analysis, visual audits of staff conducting testing/operating equip
 - **Dialysis equip**-monthly review of HD machine PM/repairs
 - **Dialyzer reuse/reprocessing**-QA audits done at specified intervals

Segment II: Quality Assessment & Performance Improvement in 3 critical priority areas & data-driven focus areas & survey findings (areas of risk) **Review/interview re QAPI activities for the 3 critical priority areas & focus areas specific to this survey.**

- **Mortality review:** **Review** documentation of QAPI analysis & discussion about mortality occurrences, causes, & trends. *If mortality is ↑, performance improvement strategies for addressing contributory factors related to facility care.*
- **Infection prevention/control: Review & discuss 4 aspects of program:**
 - **Infection occurrence tracking/trending/surveillance:** *all positive cultures recorded w/sufficient info; trends recognized & addressed*
 - **Vaccination: high-risk disease management:** *Refer to vaccination info from Entrance Conference Materials list; all patients tested for HBV & TB; all susceptible patients staff offered HBV vaccination; patients offered pneumococcal & seasonal influenza vaccines.*
 - **Staff education & audit for infection control:** **Review** visual audits of staff while caring for patients; *infection control education & each staff member visually audited at least annually; applicable staff included in performance improvement plan development*

- **Patient education for infection prevention:** **Ask** about patient education & engagement for personal care & expectations of staff delivering care

- **Medical error/adverse occurrence/clinical variance tracking & investigation system:** **Review log** for past 6 mos. **Note:** *The adverse event log review is NOT intended as a source for citations except as related to QAPI process. Select an event/occurrence to "follow" through the QAPI process with a responsible person.*

- **Data-driven focus areas & survey findings:** **Review** the QAPI activities for prioritizing, recognizing the problem existed, implementing performance improvement strategies, monitoring for improvements, &, when goals still not met, revising & implementing revised plans to attain & sustain improvements.

Segment III: Culture of Safety

Review/interview about the presence of a facility-wide culture that assures patient safety through open communication for all patients & staff, clear expectations communicated to staff, and an effective system for reporting & investigating adverse events/errors

- **Risk identification and reporting:**

- **Ask** what events are reported at the facility & compare with list on table in "ESRD QAPI Review Worksheet"; how "near misses"/"close calls" are reported & investigated;

- **Staff engagement review:**

- **Ask** how administration supports open, non-judgmental communication with/among all levels of staff; how/what staff are educated about reporting concerns & suggestions for improvement; how staff are given clear expectation of their duties, & how all levels of staff are involved in the facility QAPI activities

- **Review staff suggestion/complaint log** to ensure there is a functional & responsive system in place for staff to freely voice concerns without fear of retribution

- **Patient engagement review:**

- **Patient health outcomes, physical & mental functioning:** **Ask** how scores from patient physical & mental functioning surveys (e.g., KDQOL-36) are tracked & trended in QAPI; what the threshold is for patient refusals.

- **Review QAPI Team analysis/discussion/action for patient QOL survey outcomes**

- **Patient grievance/complaint/suggestion system:** **Ask** how staff are educated on what patient voiced issues to report & how to respond professionally; how patients are encouraged to freely speak up, self-advocate, and voice concerns w/o fear of retribution;

- **Review patient grievance/complaint/suggestion log:** "follow" a complaint; ask them to show how it was investigated, resolved & result reported to patient

- **Patient satisfaction:** **Ask** how patients' satisfaction/perceptions of care are assessed. **Review** summary of most recent patient satisfaction survey. *If negative trends in patient responses were identified, ask how that information was used to improve care.*

Triggers: The QAPI program does not:

- Administer oversight of all facility operations: monitor all areas & conduct practice audits as required in the CfC (V132, 260, 362-368, 403)
- Recognize & address risk areas where performance improvement is indicated (V625-640)
- Follow up on performance improvement plans, resulting in improvements not attained or sustained (V638)
- Promote a culture of quality & safety (V627)

Decision Making: **Meet with survey team** to discuss survey findings, refer to ESRD decision-making tools, and make copies of facility documents as needed

Exit Conference: **Verbally present findings** in accordance with SOM and State procedures