

Outline of ESRD Core Survey Process

▲ Presurvey Preparation:

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

Introductions: Contact the person in charge; explain purpose of the survey; present them w/ Entrance Conference Materials/Clinical Outcomes Tables to complete & return w/in 3 hours

Environmental "Flash" Tour: Observe 4 patient-related areas listed; 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 & functionality of emergency equipment

Triggers:

- Dummy drip chambers present in treatment area (V400, 403)
- Vascular accesses covered, not consistently uncovered/corrected by staff (V407)
- No RN on duty (V759)
- Evidence of 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 observed poor repair (V403)
- If dialyzer reuse, noticeable 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 0.1mg/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 stop valve, DI not monitored 2x/d (V202, 203)
- Water distribution equip in observable 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)
- Dialyzers not stored w/n germicide manufacturer's temperature range (V345)
- Reprocessing room or equip in observable disrepair (V318, 403)
- Dirty dialyzers kept at room temp >2 hrs; dialyzer refrigerator temp not monitored (V331)

- **Home dialysis training area:** Observe the physical environment, infection control, availability of emergency equipment & method for summoning immediate 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 immediately available emergency resuscitation equipment (V413)
- No method for summoning immediate assistance (V402)

Triggers for extending the tour to other areas:

- Evidence of serious lack of environmental maintenance w/ potential to impact pt. safety, e.g., large areas of water damage, mold, uneven floor surfaces in pt.-related areas; (V401, 402)

▲ Entrance Conference: with the facility administrative person

- Obtain & Review current facility information/outcomes on completed Entrance Conference Materials/Clinical Outcomes Tables
- Explain purpose & timeline of survey; Ask questions from "Entrance Conference Questions"
- Compare the current facility outcomes in "% of (HD or PD) Pts with" column of Clinical Outcomes Tables with applicable "US Thresholds" in Clinical Outcomes Threshold Table in current FY ESRD Core Survey Data Worksheet
- Discuss concerns & areas from DFR that have improved with the administrative person
- Determine the data-driven focus areas for survey clinical care reviews (areas where national 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:
 - Initiation of hemodialysis w/central venous catheter (CVC)
 - CVC exit site care
 - Discontinuation of hemodialysis & post-dialysis care of CVC
 - Initiation of hemodialysis w/AVF or AVG
 - Discontinuation of hemodialysis w/AVF or 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:
 - Poor hand hygiene & glove use practices (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 AVF/AVG care (V550)
- Not adequately disinfecting the HD station/equip between patients (V122)
- Use of dummy drip chamber to set up HD machine for treatment (V400, 403)
- Not testing hemodialysis machine alarms per manufacturer DFU (V403)
- Not testing dialysate pH/cond per manufacturer DFU or staff unaware of 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 or monitoring during tx per facility policy (V504, 543, 550, 551, 715)

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- Medications not prepared in a clean area away from the dialysis stations (V117)
 - Single dose vials punctured more than once or used for multiple patients (V118)
 - 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)
 - Not disposing needles in Sharps containers (V121)
- **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,)
 - Observed trends of breaches in infection control practices (V113, 116, 117, 119, 121)
 - Staff assigned/delivering care to HBV+ patient & susceptible patients (V110, 131)-for exceptions, refer to Core Survey Process
 - 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/Clinical Outcome Tables**
- **Select at least 10% of patients on census (min 4) w/ all modalities offered w/criteria below:**
- Not meeting goals (“outliers”) in the data-driven-focus areas for the survey
 - “Unstable” patients
 - New admissions <90 days
 - LTC residents receiving dialysis treatments at the LTC facility
 - Observed w/concerns
 - Involved in a complaint to be investigated: limited to ≤25% of pt. sample
 - Involuntarily discharged in past 12 months, not previously investigated by SA
- **Record the patient sample w/criteria used for selecting them**

▲ Water Treatment & Dialysate Review: Review critical water treatment components with on-site person(s) routinely responsible for the activity & daily monitoring:

- **Observe total chlorine test; interview about maximum allowable total chlorine; actions taken for breakthrough; amount of carbon (EBCT) present. See notes in Core Survey process re the use of block carbon with portable RO units, the use of and on-line chlorine monitors.**
- Triggers:**
- Absence of 2 or more carbon tanks with sample port between (V192), insufficient carbon EBCT-verified by interview or record review (V195)
 - Total chlorine test result >0.1mg/L; done incorrectly or w/ incorrect reagents/equip (V196)
 - Staff unaware of correct testing, max level of 0.1mg/L total chlorine & breakthrough procedures (V260)

- **Observe 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; readings not recorded daily (V199, 200)
- **Observe DI, if present; Interview about DI & if it is included in back-up plan; Ask about automatic divert-to-drain or stop 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 must be included in plan)
- Absence of functional resistivity monitor/alarm, visible & audible in patient tx area or not monitored 2x/day (V202, 203); No ultrafilter post DI (V204)
 - Absence of a functional automatic divert-to-drain or stop 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)
- **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 b4 disinfection (V254); sampling not per CfC (V253,255,258); HD machines not cultured at least annually (V253)
- Staff unaware of correct dialysate mixing, acid batch testing procedures “spiking”, duration of bicarbonate usability, etc. (V229,233, 235, 236, 260)

➤ 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 >0.1mg/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, 180, 196, 199, 200, 202, 203, 213, 252, 253)
- Culture results exceeding action/max levels & no doc of appropriate actions taken (V178, 180)
- Practice audits of staff not conducted at least 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

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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)
- Germicide not stored, mixed or handled per manufacturer's DFU (V321,339)
- Reuse tech w/inadequate knowledge per interview (V309, 319, 320, 328, 330, 345)
- Dialyzers not transported in a sanitary manner (V331)
- Dirty/used dialyzers at room temperature for >2 hours before reprocessing (V331)
- Reprocessed dialyzers stored for extended periods (V345)
- Reprocessing equip not maintained/repared per DFU &/or not documented (V316,317)
- QA audits listed not done or incomplete (V360-368)
- 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 (V355-357, 635)

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

▲ Dialysis Equipment Maintenance:

- *Interview machine maintenance technician 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)
- Obs serious lack of maintenance of ancillary equip w/potential to impact pt 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, Dialysis Equipment Maintenance (as applicable to the equipment in use), Personnel Record Review, and QAPI Review

- *Interview home training nurse(s) re 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*
- *Interview home dialysis patients during Patient Interviews*
- *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 patient monitoring (V585, 586, 593-595)
- Not evaluating home program outcomes separately in QAPI (V626, 628)
- If care observed, refer to triggers for infection control in Observations of HD Care

▲ Patient Interviews: *Interview sampled patients, minimum of 4 patients; If <4 sampled patients can be interviewed, select additional alert patients to interview for total of at least 4. For phone interviews with home dialysis patients, ask nurse to alert patient about interview.*

Triggers:

AVF=arteriovenous fistula; AVG=arteriovenous graft; BFR=blood flow rate; CVC=central venous catheter; DFR=dialysate flow rate; DFU=directions for use; DI=deionization; EBCT=empty bed contact time; HD=hemodialysis; PCT=patient care technician; PD=peritoneal dialysis; PM=preventative maintenance; RO=reverse osmosis; TDS=total dissolved solids ▲ Indicates a Core Survey worksheet for the task
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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 related to the criteria used for sampling the patient*

- *Review medical records of all sampled patients (10% census selected at Pt Sample Selection)*
- *For ALL sampled patients, review dialysis prescription & medication orders, & dialysis treatment records (2-3 wks HD tx records; 8-12 wks PD flowsheets)*
 - *In-center HD: looking for machine safety checks, treatments delivered as ordered, BP/fluid management, patient monitoring per policy*
 - *Home HD: looking for staff monitoring patient's adherence to orders, BP/fluid management, machine safety checks; water/dialysate quality testing per equip in use*
 - *PD: looking for staff monitoring patient's adherence to orders, BP/fluid management*
- *Patients w/poor outcomes ("outliers") in data-driven focus areas: review medical record related to THAT area : Looking for IDT actions in monitoring, recognizing the poor outcomes, & addressing it w/interventions to help patient reach outcome goals*
- *Unstable patients: review IDT documentation during 2 most recent assessment/plan of care periods: Looking at functionality of the IDT for addressing issues deeming patient 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*
- *Patients observed w/concerns: Follow the concern*
- *Patients involved in complaint being investigated: Follow applicable complaint process*
- *Involuntarily discharged patients: Refer to guidance in ESRD Core Survey Process*
- *LTC residents receiving their dialysis treatments at the LTC: Follow CMS SCG guidance*

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

▲ Personnel Interviews: *Interview facility-based (not corporate-based) staff: med director, master's social worker, registered dietitian, 2-3 nursing staff (min. 1 RN & 1 PCT) & nurse manager. Water, reuse, equip main & home training staff interviewed during those survey tasks.*

Triggers:

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- Concerns identified from personnel or patient interviews or other survey tasks indicating need to expand questioning areas or interview more personnel to support or dispel findings

▲ **Personnel Record Review:** Review the facility-completed “Personnel File Review” worksheet or equivalent

- **Select a minimum of 3 personnel files to review/compare to facility documentation for accuracy and/or follow up on concerns from survey**

Triggers:

- Personnel lack required quals, training, or competency verification (V410, 681, 684-696)
- 1 or more personnel files validated indicates inaccurate facility-submitted documentation
- PCTs w/o current certification : check for hire date w/in 18 mos (V695)

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

Note on Facility-Based (not Corporate-Based) QAPI: The review of the facility QAPI program must be limited to the information for only the facility being surveyed, and conducted with facility-based (on-site) administrative personnel. The expectation of a facility QAPI program is for ongoing engagement of facility-based staff in monitoring all clinical outcomes of the patients they provide care to and monitoring facility operations of their individual facility. The facility-based staff are expected to recognize when performance improvement is needed in any area, and respond with performance improvement actions individualized for the unique aspects of that facility and its patient population, and aimed at achieving improved patient safety and quality care.

- **Communicate** with survey team about areas of concern. Determine focus areas for review during Segment II (i.e., data-driven focus areas & survey findings)
- **Review QAPI documentation for 6 months; Interview the facility-based responsible person**

Segment I: Monitoring care & facility operations

- **Clinical & operational indicators:** Review (briefly) facility QAPI summarizing info to verify all expected clinical & operational indicators are being monitored-per table/list of indicators in “QAPI Review Worksheet”
- **Oversight of technical operations & practice audits:** Review QAPI documentation of review/evaluation/audits and performance improvement actions, when indicated in:
 - 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: QAPI Activities in 3 critical priority areas & data-driven focus areas & survey findings (areas of risk) Review/interview re QAPI activities in:

- **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; Dialysis-related infection rates routinely calculated, and acted upon (vascular access, PD catheter, peritonitis)
 - Vaccination: high-risk disease management:** Refer to vaccination info from Entrance Conference Materials; 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:** Ask how staff are visually audited for infection control pt care practices; Review visual audits of staff while caring for patients;

At least annual infection control education & visual practice audit for each staff member; 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: 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 the facility-based responsible person.
- **Data-driven focus areas & survey findings:** Review 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 facility-based responsible person 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 & compare with list on table in 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 (HRQOL) are tracked & trended in QAPI; what the threshold is for patient refusals.
 - Review QAPI Team analysis/discussion/action for patient HRQOL 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 the facility-based responsible person to show how it was investigated, resolved & result reported to patient; You may wish to interview the patient, if indicated
 - **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)
- Make substantial efforts to establish and maintain a facility-wide culture of safety (V627)

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

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