

Outline of the Basic ESRD Survey Process

Task 1 – Presurvey Preparation onsite:

- To select facilities to survey, use: Outcomes List; Dialysis Facility Reports (DFRs); complaints/concerns/FDA alerts; time since last survey
- Create or load the survey shell in ASPEN, import to STAR, & enter the specific facility data in STAR under “Presurvey Preparation” section
- Contact the applicable ESRD Network for current information related to compliance with Network goals, complaints, monitoring (V772)
- To focus each survey, use DFRs and other facility-specific data available:
 - Note if there are programs for home hemodialysis, peritoneal dialysis, dialysis in nursing homes, reuse
 - Make notes (on paper or in STAR) of lower than expected outcomes in any area: anemia management, dialysis adequacy, mortality, fistula rate, catheter rate, hospitalization rate, hospitalizations for septicemia, deaths from infection
- Develop specific questions for patient & staff interviews; note areas of QAPI to review
- For a complaint survey, outline specific survey tasks to review; specific questions to ask

Task 2 – Introductions at the facility

- Introduce the members of the team to the person in charge of the patient care area
- Briefly explain purpose of visit
- If survey team composition allows, & facility administrative person is on-site, the Team Leader may wish to proceed with entrance conference (Task 4)

Task 3 – Tour & Observations of Care:

Record your findings under the applicable sections of STAR

3a-Environmental tour: Tour areas: Note that this is an initial tour; many of the areas will be inspected in more depth during those survey tasks. Tour & observations are ongoing throughout the survey

Observe all areas for cleanliness/sanitary conditions (V111, 122, 401); free of hazards (V402):

- **Waiting room:** chair surfaces intact (V403) space for wheelchair storage (V402)
- **Patient restrooms:** functional emergency call method (V402)
- **Reuse room:** overall condition of equipment (V316); storage & aesthetic appearance of reprocessed dialyzers (V321, 343); no noticeable germicide odors (V318)
- **Water treatment area:** restricted access (V184); general condition of equipment (V401, V403); two carbon tanks (V192); chlorine/chloramines test done (V196); reagents in-date, appropriate for test (V196)
- **Dialysate preparation area:** general condition of mixing & delivery systems (V231, V232, 401, 403); individual jugs clean (V243)
- **Supply storage:** sufficient, non-expired supplies on-site (V401); correct temperature control for germicides (V338)
- **Infectious waste storage:** restricted access (V121)
- **Home training area:** sufficient space (V404); handwashing sink (V114)
- **Hemodialysis patient treatment area:**
 - **Note:** There should be no “dummy drip chambers” present in the patient treatment area. The use of these to set up dialysis machines for patient use is hazardous to

patient safety. If these are observed in the patient treatment area, it should be considered as an immediate & serious threat to patient health & safety (V403).

- **General:** sufficient space (V404); staff can see all patients & their vascular accesses at all times (V407); patient privacy maintained (V406); comfortable temperature for patients (V405); patients treated respectfully (V452)
- **Emergency medical equipment:** AED/defibrillator, Ambu bag, oxygen, suction, medications available & ready for use (V413)
- **Staffing:** adequate for patient load (V757); RN present (V759); machine alarms set/responded to (V403)
- **Isolation room/area:** in use for hepatitis B+ (HBV+) patients (V128); dedicated supplies (V130); staff caring for HBV+ patients only caring for HBV immune patients (V131)
- **Dialysis treatment records/dialysis prescriptions:** Rx administered as prescribed, check treatment records for blood flow rate, dialysate, dialyzer type, etc. match to machine settings (V541, 543, 544); treatment sheets show safety checks: machine alarms, pH/conductivity (V403, 250); reprocessed dialyzer germicide presence (V350, 351), residual (V353), patient ID by 2 persons (V348); patient/machine monitoring per policy (V715)
- **Medication preparation area:** away from patient station (V117); single dose vials = single use (V118); predrawn syringes labeled with patient name & contents

3b-Observation of hemodialysis patient care: Observations are on-going throughout survey

Observe initiation &/or termination of dialysis treatments, focusing on:

Infection control practices: If there is a high hospitalization rate for septicemia or conversions to hepatitis, spend extra time observing infection control practices:

- Hand hygiene & glove changes b/t patients & b/t dirty & clean tasks (V113); patients wear gloves to hold sites (V113)
- Items taken to station disinfected, dedicated, or disposed (V116)
- Cleaning/disinfecting machines/chairs/equipment between patients (V122)
- PPE appropriate to task worn, i.e., gowns, gloves, eye/nose protection (V115)
- Meds prepared & administered w/aseptic technique (V143); single dose vials = single use (V118)
- Wastes/sharps properly handled & disposed (V121)
- Blood spills - no dried blood spills; all spills cleaned immediately (V122)

Patient care:

- Patients evaluated pre & post tx; patients and machines monitored per policy during tx; unstable = more frequent monitoring (V543, 715)
- Observe pre & post dialysis access care, e.g., proper skin prep prior to cannulation, aseptic technique used for CVC use & dressing changes (V147)

Dialysis machine & dialyzer use

- **Dialysis machines:** being prepared per manufacturer’s DFU (V403); are safety checks performed, i.e. alarms tested, dialysate pH/conductivity with independent method (V403, 250)
- **Reprocessed dialyzers:** all preprocessed b4 first use (V335); labeled with pt name b4 first use (V328); sufficient germicide contact time (V349); meet aesthetic requirements

Outline of the Basic ESRD Survey Process

(V347); tested for germicide presence (V350, V351); primed per manufacturer's DFU (V352), & tested for germicide residual (V353)

- o **Note:** Watch carefully. It is easy to miss the testing for presence/residual germicide. Be sure that the testing methods are specific to the task & sufficiently sensitive, appropriate test strips are used
- o Reprocessed dialyzers IDd by 2 persons prior to treatment initiation (V348)
- Non-reuse dialyzers primed per manufacturer's DFU

3c-Emergency equipment: Use STAR menu for ancillary equipment

- Review emergency equipment for function (i.e., AED/defibrillator, Ambu bag, oxygen, airways, suction, medications) (V413)
- Staff emergency preparedness: resuscitation equipment & procedures (V409, V411); fire/emergency evacuation procedures (V409)
- Emergency evacuation supplies present and in date (V408)
- Fire extinguishers are present & evacuation routes posted (V417)

Task 4 – Entrance Conference: with administrative personnel

- The Team Leader should use STAR to record facility specific information
- Review the purpose of visit, the survey process, & anticipated time schedule
- Discuss issues noted during presurvey in data reports
- Provide form CMS-3427 for completion-explain that section 27 is to be used for listing SNFs where patients are receiving dialysis
- Request facility specific information-refer to entrance conference questions in STAR or entrance conference worksheet
- Request reference materials (P&P etc): provide reference materials list
- Request patient specific information for selecting a sample: this information is on the reference MAT list:
 - Current patient census separated into modalities, with admission dates
 - Current hemodialysis patient listing by shifts with any isolated pts IDd (seating chart)
 - Aggregate list of individual patients' labs (Kt/V, URR, Hgb, TSAT%, ferritin, albumin, Ca⁺, PO₄, PTH) for the previous quarter
 - Infection logs for past 6 months
 - Hospitalization logs for 6 months
 - Vascular access information as reported to the ESRD Network
 - Pediatric patients
 - Residents of Long Term Care facilities
 - Any involuntary discharges since last survey

Task 5 – Patient Sample Selection:

- Select 10% of patient population for record review &/or interview; select at least 5 if census <50; maximum of 15 if census >150
- Select patients to include all modalities provided (in-center HD, home HD, PD)
- Use patient specific information obtained during entrance conference when selecting patients for review, focusing on any areas of concern. Selection may include lab "outliers", infections, repeated "dialysis-related" hospitalizations, patients who have

been dialyzed with CVCs >90 days, pediatric patients, residents of SNFs, involuntarily dc patients

- Consider including patients identified w/concerns during tour & observations of care

Task 6 –Water Treatment & Dialysate Preparation:

Use STAR &/or the CfC "Water and dialysate quality" to guide your survey of the water treatment & dialysate preparation systems

6a-Observation of water treatment equipment/interview with water treatment personnel

- Talk to the person doing the work to assess level of knowledge
- Refer to the STAR water treatment review section &/or worksheet for interview
- Walk through water treatment components while interviewing staff
 - General: materials compatibility (V212); organization/schematic (V187); distribution system w/continuous flow during hours of operation (V211)
 - Required water treatment components:
 - o Carbon adsorption: 2 tanks w/sample port b/t & minimum 10 min EBCT (V192, 195)
 - o Reverse Osmosis: continuously monitored, alarms in treatment area, >90% rejection rate (V199, 200)
 - o DI: if no RO or as polish: resistivity monitoring/alarms (V202); auto divert-to-drain (V203); followed by UF filter (V204)
 - Standard water treatment components/set up & monitored per RD52/CfCs: sediment filter (V188); softeners (V190, 191); cartridge filters (V189); ultraviolet irradiator (V214, 215); UF filter (V207); holding tank: conical base, followed by bacterial control device (V208, 209)
 - Observe water testing for chlorine/chloramines: observe in "real time;" sample from correct port, test performed accurately, reagents sensitive to test & in date (V196); staff aware of maximum allowable levels & actions for "breakthrough" (V197, 260)

6b-Review of water treatment logs

- Chemical analysis: review 12 months: done at least annually/may vary by equipment in use (V201, 206, 177)
- Microbial surveillance: review 6-12 months: monthly samples for CFU & LAL just prior to disinfection, from various sample sites (V213, 254); within AAMI limits, actions taken if elevated (V178, 255)
- Chlorine/chloramine testing: review 3-6 months: tests recorded prior to each shift (V196); actions taken if maximum levels exceeded (V197, 270)
- Daily logs: review 3-6 months: daily monitoring recorded of: softeners/hardness (V191); RO/DI parameters (V199, 202)

6c-Review of dialysate preparation & delivery

Determine what systems are used for mixing & delivery of acid & bicarbonate concentrates

- Batches mixed on site: try to observe mixing & transfer: mixing per manufacturer DFU (V226); batch tested & verified (V229); bicarb not overmixed (V234) & storage time minimized (V233); all concentrate containers/tanks clearly labeled (V228)
- Central delivery: outlets clearly labeled/color coded (V245, 246, 247); disinfection of bicarb mixing & delivery system per manufacturer DFU & at least weekly (V239)

Outline of the Basic ESRD Survey Process

- Individual jugs: “spiked” dialysate clearly labeled (V236); bicarb jugs rinsed daily (V243), & disinfected weekly (V244)

Task 7 - Reuse:

“Reprocessing” refers to the processes of cleaning & germicide instillation, “Reuse” refers to the clinical use of the reprocessed dialyzer

Use STAR menu for Reuse &/or the reuse technician interview guide to conduct & record the reuse survey; talk to person doing the reprocessing to evaluate knowledge & training

7a-Observations of reprocessing procedures/interview with reuse personnel

- Reuse room clean, sanitary, safe (V318); chemicals stored properly (V319); no noticeable germicide vapors (V318); vapor testing supplies available (V318)
- PPE appropriate to task available/used (V320)
- Inspect reprocessed/stored dialyzers for aesthetics (V343); labeling e.g., dialyzer labels intact, filled out, legible, not obscuring manufacturer label (V327, 329); similar names alert (V330); storage time within facility policy or germicide manufacturer DFU (V345)
- Observe complete reprocessing procedures for at least 2-3 dialyzers
 - Labeling done pre-use (V328); measurement of original total cell volume (V335)
 - Transporting to reuse room; clean & sanitary, reprocessing initiated timely, ≤ 2 hrs. reprocessing or refrigeration (V331)
 - AMI water only (V314)
 - Pre-rinse: water pressures monitored (V332); header cleaning w/ stream of water, reassemble wet w/ germicide (V334)
 - Testing: Leak/blood path integrity (V337); total cell volume (V336)
 - Filling with germicide: germicide potency correct (V341); caps disinfected (V340)
 - Exterior surface cleaned w/germicide solution (V342)
 - Reprocessing info recorded (V326)
 - Discarded in infectious waste when failed tests (V344)
- Set up for clinical use: *This is addressed in Task 3b, Observations of HD patient care*

7b-Review of reuse logs:

- Reprocessing logs: review logs for several patients-complete, legible, secure (V326)
- Germicide vapor testing: review last 3; performed per policy within limits (V318)
- Cultures/LALS: review 6-12 months of water cultures done in reuse room-within limits (V205, 314); sample sites per policy (V314)
- PMs/repairs: of reprocessing equipment-per manufacturer’s DFU or at least semiannual (V316); equipment tested after repairs (V317)
- QA: required practice audits performed (V362-368); reviewed in QAPI (V635)

7c-Centralized reprocessing: on-site review of tasks 7a & 7b is required at the centralized reprocessing location

- Policies & procedures at user ESRD facility for transportation & clinical use of dialyzers (V306)
- Transporting used & reprocessed dialyzers safely (V331)

Note: Any deficient practices in centralized reprocessing locations affect all user ESRD facilities; Condition-level findings must be cited for all user facilities.

Task 8 – Machine Operation/Maintenance: Use STAR menus to review

- Review PM & repair logs for a sample of dialysis machines (25% or a minimum of 5) for previous 12-18 months; were manufacturer’s instructions for PM intervals followed, electrical leakage tested per DFU (V403)
- Interview the technician responsible for machine maintenance: method staff uses to alert bio-med of machine breakdown; machines awaiting repair pulled from service & machine tested for function prior to return to use (V403)
- Review dialysate culture results for 12 months: at least 2 machines monthly, each machine at least annually (V180, 253, 255); done prior to disinfection (V254)
- Ancillary equipment: documentation of calibration/PM/repairs of scales, pH/conductivity meters, eyewash stations, generators (if present), infusion pumps, blood glucose monitors, AED/defibrillator, etc. (V403)

Task 9 – Home Training Department Review:

9a-Observation of home training area: sufficient space for training with equipment & afford patient privacy (V404, V406); basic emergency supplies or a method for summoning immediate assistance (V413); training materials on site: geared for patient understanding (V453); cover required topics (V585)

9b-Interview with home training nurse(s): refer to STAR staff interview or worksheet for interview with home training nurse.

Note: medical record reviews for home patients are included in Task 11.

Task 10 –Patient Interviews:

- Use STAR patient interview menus or patient interview guide; interview 2-4 patients completely; for remaining sample, focus interview questions on areas of concern identified during observations, other interviews or record reviews
- Home &/or in-center patients may be interviewed by phone, if necessary or if they prefer

Task 11-Medical Record Review:

Use the STAR medical record menu or medical record review worksheets to guide & record medical record review. Review 3-7 sampled patients’ records completely; focus the remaining record reviews on the care concerns specific for that patient and as identified in other records or during the survey. Refer to the Measures Assessment Tool (MAT) for current standards.

- Patient assessment & patient plan of care development: completed by the IDT in the required areas (refer to STAR Clinical Record Review section & medical record review worksheet)
- Implementation of patient plan of care: review the following components of the record:
 - Physician's orders: prescribed treatments & medications administered as ordered (V543, 544, 546, 547)
 - Laboratory values for 3-4 months: identified patient-specific & facility goals for dialysis adequacy (V544), anemia (V547), nutrition (V545) & renal bone disease management (V546) achieved; or actions taken to revise the plan of care (V559)
 - IDT progress notes: show involvement of all IDT team members to evaluate the patient & address pertinent issues in the patient's care (V501, 541); patient seen by ESRD physician, APRN or PA at least monthly & periodically during dialysis (V560)

Outline of the Basic ESRD Survey Process

- Dialysis treatment records for in-center & home HD patients & home dialysis flow sheets for PD patients, to determine compliance with dialysis prescriptions (V541, 543, 544), medication & treatment orders (V543, 544, 545, 546, 547), safety checks for reprocessed dialyzers & dialysis machines (V403, 250, 348, 350, 351, 353), pre & post-tx assessments & periodic monitoring during dialysis (V504, 543)
- Patient education: emergency preparedness (V412); dialysis mgmt, infection control; modalities; vascular access (V562); home care training content (V585); discharge & transfer policies (V568, 569)

Task 12– Personnel Interviews:

- Refer to the STAR section for staff interviews or worksheets for interviews with the reuse technician, water treatment personnel, & home training nurse.
- Interviews with medical director, social worker, dietitian, nurse manager, & administrator should be guided by potential findings identified during the survey to clarify issues & gather additional information.
- If there are poor clinical outcomes, findings pertinent to the medical director’s role, or potential Condition level findings, interview the medical director.

Task 13 – QAPI:

Refer to the STAR section for QA/QI Review; data entered during presurvey activities will appear at these screens.

13a: QAPI documentation/interview: See MAT for expected targets

Review minutes/QAPI records over the last 6–12 months; interview the nurse manager about the QAPI program. Areas for which data must be continuously monitored include:

- Dialysis adequacy (V629)
- Medical injuries/errors (V634)
- Nutritional status (V630)
- Dialyzer reuse program (V635, 362-368)
- Mineral metabolism (V631)
- Patient satisfaction & grievances (V636)
- Anemia management (V632)
- Infection control (V637)
- Vascular access (V633)
- Technical functions (water/dialysate, equipment) (V627)
- Look for prioritization for those areas which affect patient safety (V639, 640); action plans aimed at performance improvements; & actions taken to improve care when outcomes were poor; monitoring for improvement; improvement made/sustained (V638)
- If home modalities are provided, QAPI must review these modalities; PD data should be reviewed separately (V628)

13b: Emergency preparedness review: also use information gathered in pt/staff interviews V408 requires implementation of processes & procedures for the following:

- Fire: emergency evacuation, reporting & responding to a fire;
- Power failure: manual return of the extracorporeal circuit, emergency phone communication & lighting

- Water supply interruption/equipment failure: plan for providing dialysis in the event the water supply is contaminated or the water treatment system is inoperable (V182); HVAC system failure
 - Natural disasters: that may be anticipated in the geographical area-must address the specific physical aspects of the facility, rather than general corporate procedures
 - Care-related emergencies: such as cardiac arrest, air embolus, adverse drug reactions, suspected pyrogen reactions, accidental germicide infusion, profound hyper/hypotension, significant blood loss
- Documentation of staff training at least annually (V409); patient education program (V412); annual re-evaluation of procedures (V415); annual contact with local disaster management agency (V416)

Task 14 –Personnel Record Review:

- Refer to the STAR section for Personnel Record Review
- Review the files of nurse manager, social worker, dietitian, home training nurse, medical director & a representative sample of nurses, patient care technicians, reuse technicians, & water treatment system technicians.
- Include files of staff identified with concerns during survey
- Review files for: minimum qualifications/training/competencies (V682-696, 410); PCT certification (V695); health screenings (V126, 127, 310); emergency/disaster training (V409)
- Review PCT training & certification program (V693, 694, 695)

Task 15 – Decision Making:

- Use STAR pre exit conference menu. Review Form CMS-3427. Application for Certification, for accuracy & completeness
- Use STAR to “review all findings”; uncheck potential tags to choose best tags; if STAR is not available, review your findings, determine what deficient practices you have evidence to cite. Discuss the findings with the survey team (if applicable) to determine what to cite & the level of citation, and if further interviews, reviews or observations are indicated; contact your state agency if indicated
- **If at any time during the survey, practices are identified which present serious hazards to patient health & safety, consider review of Appendix Q for determination of an IJ situation & contact state survey agency & CMS RO**

Task 16 – Exit Conference: Use STAR exit conference menu

- Verbally present findings, follow State procedures & SOM
- Explain: When the facility may expect to receive the 2567; when the plan for correction is due; what should be included in the plan for correction; the requirement for a date of correction for each deficient practice statement; the potential for a revisit if this is a possibility