

Outline of the Basic ESRD Survey Process

Task 1 – Presurvey Preparation offsite: If using STAR, refresh your memory in its use

- To select facilities to survey, use: Mission and Priority Document (MPD), Outcomes List; Dialysis Facility Reports (DFRs); complaints/concerns, involuntary discharges/transfers; FDA alerts; time since last survey; Network suggestions
- Create or load survey shell in ASPEN; for STAR, enter specific facility data under “Presurvey Preparation;” print Entrance Conference materials list; print optional worksheets at www.cms.gov/GuidanceforLawsAndRegulations/05_Dialysis.asp if not using STAR
- Contact the applicable ESRD Network for current information related to compliance w/Network goals, complaints, monitoring (V772)
- To focus each survey, use DFRs, facility file (if avail); other facility-specific data available:
 - Note if there are programs for home HD, PD, dialysis in nursing homes, reuse
 - Note in STAR or on paper any “worse than expected” outcomes in any area: anemia management, dialysis adequacy, mortality, fistula rate, catheter rate, hospitalization rate, hospitalizations for septicemia, deaths from infection, transplant waitlist
- 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 team members 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 proceed w/entrance conference (Task 4) while team member(s) go to Task 3

Task 3 – Tour & Observations of Care:

Begin the tour as soon as possible. Tour & observations are ongoing throughout the survey. In STAR, record your findings under the applicable sections.

3a-Environmental tour: Note: This is a first look; many of the areas will be inspected in more depth during other survey tasks. 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)
- **Hemodialysis patient treatment (tx) area:**
 - **Note:** There should be no “dummy drip chambers” in the patient tx area. Using these to set up dialysis machines for patient use is hazardous to patient safety (V400, 403)
 - **General:** sufficient space between patient chairs (V404); staff can see all patients, their vascular accesses & bloodline connections at all times (V407); patient privacy provided (V406); comfortable temperature for patients (V405); patients treated respectfully (V452)
 - **Emergency medical equipment:** AED/defibrillator, Ambu-bag, oxygen, suction (V413)
 - **Staffing:** adequate for patient load (V757); RN present (V759); machine alarms set (V403)/responded to (V757)
 - **Isolation room/area:** must use for hepatitis B+ (HBV+) pts (V128-129); dedicated machine, equipment, supplies (V130); sink readily available (V114); staff caring for HBV+ pts only caring for HBV+ & HBV immune pts (V110, 131)
 - **Dialysis treatment records/dialysis Rx:** Administered as prescribed, compare tx records/orders for fluid removal, BFR, dialysate, dialyzer type w/machine settings (V543, 544); tx records show machine alarms/safety checks (V403), pH/conductivity (V250); patient monitored during treatment (V543); dialysate supply labeled (V245-247)

- **Reuse safety:** reprocessed dialyzer germicide presence/absence (V350, 351); patient/dialyzer ID'd by 2 persons, documented (V348)
- **Medication preparation & storage area:** away from patient station (V117); single dose vials = single use (V118); predrawn syringes labeled w/patient name, contents (V681); multidose vials labeled when opened (V143); appropriately refrigerated (V143, 403)
- **Water treatment area:** restricted access (V184); general condition of equipment (V182, 401, 403); two carbon tanks (V192); chlorine/chloramine test done; reagents in-date & sufficiently sensitive (V196)
- **Dialysate preparation area:** general condition of mixing & delivery systems (V231, 232, 403); individual jugs clean (V243); dialysate proportioning ratios match (V248)
- **Supply storage:** sufficient supplies on-site (V403, 754); non-expired meds (use indicated POC tag)
- **Laboratory area:** separated from clean area (V117)
- **Reuse room:** condition of equipment (V316); storage & aesthetic appearance of reprocessed dialyzers (V321, 343); no noticeable germicide odors (V318); appropriate PPE used (V320)
- **Infectious waste storage:** restricted access (V121,142)
- **Home training area:** sufficient space; restricted access 4 exchanges (V404); h/w sink (V114)

3b-Observation of hemodialysis patient care:

Observations should be ongoing throughout the survey, to include initiation &/or termination of treatments. Observe 1-2 staff/stations at a time. Watch carefully, it's easy to miss seeing specific tasks. Focus on these areas:

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 between patients, between dirty & clean tasks & patients/others wear gloves to hold sites (V113) ; sufficient # accessible h/w sinks (V114)
- Appropriate PPE used:, gowns, gloves, eye/nose/mouth protection (V113, 115)
- Staff: no eating or drinking in pt tx area (V115), no supplies in pockets (V119)
- Items taken to station disinfected, dedicated, or discarded (V116); no common cart to stations, supplies kept sufficient distance away (V117, 119)
- Cleaning/disinfecting stations: machines/chairs/equipment between patients; extreme caution used if pt still in chair (V122)
- Meds prepared & administered w/aseptic technique (V143); single dose vials = single use (V118); qualified staff admin meds (V681)
- Infectious waste/sharps properly handled & disposed (V121, 142)
- No dried blood anywhere; all blood spills cleaned immediately (V122)

Patient care:

- Patients evaluated pre & post tx; patients & machines monitored per policy during tx; unstable = more frequent monitoring (V504, 543, 550, 551, 715); transducer protectors changed when wetted (V120)
- Pre & post dialysis access care: proper skin prep, glove change; aseptic technique used for CVC use & dressing changes (V113, 142, 147, 550, 551)

Dialysis machine & dialyzer use:

- **Dialysis machines:** prepared per manufacturer's DFU, alarms tested,(V403); dialysate pH/conductivity w/independent method (V250)
- **Reprocessed dialyzers:** labeled w/pt name (V328); sufficient germicide contact time (V349); meet aesthetic requirements (V347); tested 4 germicide presence (V350, 351);

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primed per manufacturer's DFU (V352), tested 4 germicide residual (V353); sufficiently sensitive tests used (V346); pt/dialyzer ID by 2 persons prior to tx initiation (V348)

- Non-reuse dialyzers primed per manufacturer's DFU (V403)

3c-Emergency equipment & preparation:

- Review emergency equipment for function: AED or defibrillator, Ambu-bag, oxygen, suction & medications available & ready for use (V413)
- Ask staff about emergency preparedness; the use of resuscitation equipment & procedures (V409, 411); emergency/fire evacuation procedures (V409); Pt education (V412)
- Emergency evacuation supplies present & in date (V408)
- Evacuation routes ID'd & unobstructed; functional portable extinguishers present (V408)

Task 4 – Entrance Conference w/administrative personnel:

- STAR should be used by the Team Leader to record facility specific information
- Review the purpose of visit, the survey process & anticipated time schedule
- Review DFR: discuss issues noted during presurvey
- Provide form CMS-3427, Personnel File Review & PCT Certification worksheets for completion
- Request facility specific information: in STAR refer to Entrance Conference menu or use Entrance Conference Questions Worksheet
- Provide Reference Materials List to guide facility in collecting patient specific information needed for selecting a patient sample & materials needed for survey

Task 5 – Patient Sample Selection: Using the patient specific information provided:

- Select 10% of patient population for the patient sample; a minimum of 5 if census <50, maximum of 15 if census >150. Review the medical record of each sampled patient (Task 11); most of the sampled patients should also be interviewed (Task 10); other patients may be observed, interviewed or records reviewed as indicated; add them to the Patient Roster as supplement to the 10% sample.
- Select patients to include all modalities provided (in-center HD, nocturnal 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 patients with negative trends in labs (e.g. low Hgb, poor Kt/V), infections, repeated "dialysis-related" hospitalizations, patients w/CVCs >90 days, pediatric patients, residents of SNFs, involuntarily dc patients (if ≥ 1 , include at least 1 in sample)
- Consider including patients identified w/concerns during Tour & Observations of Care; closed pt records may be included if there are concerns re those patients
- In STAR, enter the sampled patients to create a Patient List; if not using STAR, maintain a Patient Roster

Task 6 – Water Treatment & Dialysate Preparation:

Use STAR or the Optional Worksheet-Interview/Observation: Water/Dialysate Technician to guide your survey of the water treatment & dialysate preparation systems.

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

Talk to the person doing the work to assess level of knowledge. Walk through water treatment components while interviewing staff (V696).

• Required water treatment components:

- Carbon adsorption: 2 tanks w/sample port b/t & minimum 10 min EBCT (V192, 195) &
- Continuous H₂O quality monitor w/alarm in tx area (V200, 202, 203) &
- Reverse Osmosis (RO) or Deionization (DI):
 - RO: TDS/conductivity monitored, >90% rejection rate (V200)
 - DI: if no RO or as polish: resistivity monitoring/alarm (V202); auto divert-to-drain required 2 prevent pt injury/death (V203); followed by UF filter (V204); resistivity $\sqrt{}$ twice daily & logged (V202)
- All H₂O tx components set up & monitored as required: sediment filter (V188); cartridge filters (V189); softeners (V190, 191); ultraviolet irradiator (V214, 215); UF filter (V207); holding tank (V208, 209)
- System construction: no metals (except stainless steel) post H₂O tx (V212); schematic/labels (V187); alarms in treatment area (V186, 200,203)
- Observe water testing for chlorine/chloramine: 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, 270-273)

6b-Review of water treatment logs

- Chlorine/chloramine testing: review 3-6 months: tests recorded prior to each shift or q 4 hrs(V196); actions taken if maximum levels exceeded (V197, 270-273)
- Microbial surveillance: review 6-12 months: monthly samples from required sites for cultures & LAL prior to disinfection (V213, 254); results w/in AAMI limits or actions taken (V178, 255); results logged & trended (V213)
- Daily logs: review 3-6 months: daily monitoring recorded of equipment function: softeners/hardness @ end of day (V191); RO/DI parameters (V199, 202)
- Chemical analysis: review 12 months: required at least annually; frequency may vary by equipment in use & seasonal changes (V177, 201, 206)

6c-Review of dialysate preparation & delivery

Determine what systems are used for mixing & delivery of acid & bicarbonate concentrates; dialysate proportioning ratios match (V248)

- Batches mixed on site: try to observe mixing & transfer: mixing per manufacturer DFU (V226); batches verified/tested/logged (V229); bicarb not over mixed (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)
- Individual jugs: acid concentrate w/added electrolytes ("spiked") clearly labeled (V236); policy addresses which staff may "spike" (V235); bicarb jugs rinsed daily (V243) & disinfected weekly (V244)
- Log review:3- 6 mo of: acid & bicarb mixing/transfer (V229); bicarb disinfection (V239)

Task 7 – Reuse:

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

Use STAR menu for Reuse &/or the Reuse Technician Observation/interview Worksheet to conduct & record the reuse survey; talk to person doing the reprocessing to evaluate knowledge & training (V308, 309).

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

- Reuse room clean, sanitary (V318); chemicals stored properly (V319); no noticeable germicide vapors (V318)
- PPE appropriate to task available & used (V320)
- Inspect reprocessed/stored dialyzers for aesthetics (V343); dialyzer labels intact, complete, legible, do not obscure manufacturer label (V327, 329); similar names alert (V330); storage time w/in facility policy & germicide manufacturer DFU (V345)
- Observe complete reprocessing procedures for at least 2-3 dialyzers
 - Labeling before 1st use (V328); preprocessed to measure original total cell volume (V336)
 - Transporting: clean & sanitary, reprocessing initiated w/in 2 hrs or refrigerated; facility sets max refrig time (V331)
 - AAMI water in use for all reprocessing (V314)
 - Pre-rinse: water pressures monitored (V332); if header cleaning=only w/stream of AAMI water, reassemble wet w/germicide (V334)
 - Testing: leak/blood path integrity (V337); total cell volume (TCV) (V336)
 - Filling w/germicide: germicide potency sufficient (V341); caps disinfected (V340)
 - Exterior surface cleaned w/germicide solution (V342)
 - Inspect for aesthetics, leaks, cracks, clots, caps intact (V343)
 - 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: several patient specific records: complete, legible, accessible (V326)
- Microbial surveillance: review 6-12 months of water cultures & LALs done in reuse room w/in limits (V178, 314); sample sites as required (V314)
- Germicide air vapor levels: review last 2 (V318)
- PMs/repairs: of reprocessing equipment: per DFU or at least semiannual (V316)
- QA: required practice audits done (V362-368); if problems ID'd reviewed in QAPI (V635)

7c-Centralized reprocessing: *on-site review of tasks 7a & 7b are required at the centralized reprocessing location. Task 3b is conducted at the user facility.*

Observe systems at user facility for storage and transfer of dialyzers (V306, 331, 345)

- Centralized reuse audits and complaints reported to user facility (V635)

Note: Any deficient practices at the centralized reprocessing location affect all user facilities; Condition-level findings at the centralized location must be cited for all user facilities.

Task 8 – Machine Operation/Preventative Maintenance (PM):

 Use STAR menu for review

- Interview the personnel responsible for maintenance & repair of dialysis machines: determine: schedule for PM, method to alert resp staff of machine breakdown; verify: machines awaiting repair pulled from service & tested 4 function prior to return 4 use (V403); dialysate proportioning ratios match supplies on site (V248)
- Review PM & repair logs for a sample of dialysis machines (25% or a minimum of 5) for previous 12-18 months; PM intervals & electrical leakage tested per DFU (V403)
- Microbial surveillance: Review dialysate culture & LAL 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 (V403)

Task 9 – Home Training & Support Review: *Note: All CfCs apply to home programs. Specific certification for home training & support & a qualified RN are required.*

9a-Observation of home training area: sufficient space for training w/equip & affords pt privacy (V404, 406); basic emerg supplies or method for summoning immediate help (V413); training materials: on site, geared for pt understanding (V453) cover required topics (V585)

9b-Interview w/home training nurse(s): in STAR, use Home Training Nurse Interview or use the Optional Worksheet-Interview: PD (or Home Hemodialysis) Training Nurse

9c-Review of home equipment/H2O & dialysate quality: requirements vary according to equip in use; must follow DFU 4 maintenance (V403); review: H2O chemical analysis (V594); chlorine/chloramine tests; CFU & LAL of H2O/dialysate quarterly (V595)

Task 10 – Patient Interviews:

In STAR use Patient Interview menus or use optional worksheets for interviews with patients based on treatment modality.

- Interview as many sampled patients as possible & other patients as indicated; for ½ the interviews, ask all questions; for remaining interviews, focus questions on areas of concern
- Patients may be interviewed by phone if they prefer

Task 11 – Medical Record Review:

In STAR use Medical Record Review or use Medical Record Review Worksheets for the treatment modality. Review the records of all sampled patients; for ½ the sample a comprehensive review is required. For remaining records, focus review on the reason 4 sampling that patient & issues ID'd in other records or during the survey. Refer to the **Measures Assessment Tool (MAT)** for current practice standards/POC goals.

Record review should demonstrate care is monitored & outliers are recognized & addressed. **Review:**

- Laboratory values for 3-4 months: compare w/MAT/patient-specific goals achieved, or actions taken to revise the plan of care for: dialysis adequacy (V544), anemia (V547, 548, 549), nutrition (V545); CKD/MBD management (V546)
- Physician's orders: dialysis Rx, meds, other txs specific to meet patient needs
- Dialysis treatment records: Review 10-15 for HD; 8-12 wks of PD flow sheets. Look for compliance w/dialysis Rx (V541, 543, 544), med = tx orders (V543, 544, 545, 546, 547), safety checks for machines (V250, 403) & reprocessed dialyzers (V348, 349, 350, 353); BP control, fluid monitoring (V543); For in-center HD patients pre & post-tx assessments & monitoring during dialysis (V503, 504, 543, 715)
- IDT progress notes: evidence of ongoing monitoring of care areas, actions for POC revisions when goals not met
- PA/POC: completed by all required IDT in all care areas (V501-562); choose tag specific 2 problems ID'd; Refer to laminate Correlation Grid & Timelines for Patient Assessment/Plan of Care
- Patient education: emergency preparedness (V412); tx options/modalities (V458); Patients' rights/AD/rules/grievance (V451-467); transfer/DC policies (V468); dialysis management, infection control; vascular access (V562); home dialysis training content (V585) & demonstration of comprehension (V586)

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Task 12 – Personnel Interviews:

In STAR use section for Staff Interviews or use available optional worksheets for interviews with the water/dialysate technician, reuse technician, home training nurse(s), social worker & dietitian. Interviews w/other staff (e.g. RN, PCT, Admin.) should be conducted as indicated.

- All interviews should be guided by issues ID'd during the survey to clarify & gather more info & to determine if there is sufficient staff available to meet pt needs (V758)
- Interview w/the Medical Director is required if there are poor clinical outcomes, findings pertinent to the Medical Director's role, or potential Condition level findings

Task 13 – Personnel Record Review:

In STAR use section for Personnel Record Review or use the Optional Worksheet-Personnel File Review. Also refer to Optional Worksheet-Verification PCT Certification.

- 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/dialysate technicians
- Include files of staff identified via concerns during survey
- Review PCT certification information (i.e. PCTs are certified as required) (V693-695)

Task 14 – QAPI/Governance:

In STAR use section for QAPI/Governance Review where data entered during other survey tasks will appear. Use the Measures Assessment Tool (MAT) & QAPI Document Chart as guides. *Note: this task should be conducted toward the end of the survey to review the facility QAPI process, compare w/survey findings, and to evaluate the effectiveness of facility actions to reduce injuries and improve outcomes.*

14a-QAPI documentation/interview:

- Review QAPI materials (i.e. incident logs, trending data, minutes/QAPI records) 4 the last 6-12 months: involvement of IDT members (V626); review of trends, identification of problems, analysis for root cause/multiple causes, development of improvement plans using community standards, implementation of plans for monitoring improvement; improvements made/sustained (V638); prioritization for those areas which affect patient safety (V639, 640)
- Interview the responsible person about the QAPI process. Include questions about any concerns ID'd during the survey.
- Review of materials and interview with the responsible person should demonstrate ongoing monitoring, analysis, interventions & sustained improvement where needed
- Determine if facility compared outcomes on DFR with other facilities in the state, Network, and U.S. and developed improvement strategies where indicated (V628)
- Areas for which data must be *continuously* monitored include:
 - Dialysis process and facility operations (water/dialysate quality, physical environment, equipment maintenance/repair, staffing/staff qualifications, medical staff appts, Network relationship, modality choice) (V626)
 - Health outcomes-morbidity & survival (V627)
 - Health outcomes-physical & mental functioning (V627)
 - Dialysis adequacy-HD & PD (V629)
 - Nutritional status-HD & PD (V630)
 - Mineral metabolism/CKD MBD-HD & PD (V631)
 - Anemia management-HD & PD (V632)

- Vascular access/PD access (V633)
- Medical injuries & errors identified and trended (V634)
- Dialyzer reuse (V635)
- Patient satisfaction & grievances (V636)
- Infection control & vaccinations (V637)

14b-Emergency preparedness review: *Note: Facility emergency prep is reviewed during other survey tasks (e.g. tour, staff/pt interviews, med rec review, personnel file reviews). This task is intended for verification of facility preparedness for on-site and off-site emergencies for in-center and home patients.*

The following areas should be in the emergency plan, ensuring restoration of pt treatment or safe transfer (V408):

- Fire: emergency blood return & disconnect from HD; evacuation, reporting & responding to a fire, ID of in-center patients who require assistance; training capable pts in manual blood return, disconnect & evacuation;
- Power failure: Manual blood return & disconnect from HD; training capable pts in procedures; emergency phone communication & lighting
- Water supply interruption/equipment failure: plan for providing dialysis in the event the H2O supply is interrupted or contaminated (V182); HVAC system failure
- Natural disasters that may be anticipated in the geographical area: must address specific physical aspects of facility, not general corporate procedures; annual contact w/local disaster mgt agency; collaboration w/Network, suppliers, utility companies (for in-center & home pts), State survey agencies and other dialysis facilities (V416)

Task 15 – Decision Making:

- Review Form CMS-3427 for accuracy & completeness
- In STAR complete Pre Exit Checklist, then the "Review All Findings"; in Review All Findings, uncheck potential tags to choose best tags.
- If STAR is not available, review findings, determine deficient practices you have sufficient evidence to cite. Discuss the findings w/the survey team (if applicable) to determine what to cite & the level of citation & whether further interviews, record reviews or observations are indicated or additional copies of documents are needed
- Contact your state agency if indicated
- **If at any time during the survey, practices are identified which present serious hazard(s) to patient health & safety, consider review of Appendix Q for determination of an Immediate Jeopardy situation & contact State survey agency & CMS RO**

Task 16 – Exit Conference: In STAR use the Exit Conference menu

- Verbally present findings in order of severity; do not provide specific V-tags
- Follow relevant SOM & State procedures
- 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 requirements for a dated signature on the first page, one date of correction for each V-tag & the potential for a revisit