

## Outline of the Basic ESRD Survey Process

### **Task 1 – Presurvey Preparation onsite:**

- To select facilities to survey, use: Mission and Priority Document (MPD), Outcomes List; Dialysis Facility Reports (DFRs); complaints/concerns/FDA alerts; time since last survey; Network suggestions
- 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 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
  - Make notes (on paper or in STAR) of 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 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 proceed w/entrance conference (Task 4) while team member(s) go to Task 3

### **Task 3 – Tour & Observations of Care:**

Proceed with the tour as soon as possible. Record your findings under the applicable sections of STAR. Tour & observations are ongoing through the survey.

**3a-Environmental tour:** Tour areas: Note that this is an initial tour; 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 area:
  - **Note:** There should be no “dummy drip chambers” in the patient treatment area. Using these to set up dialysis machines for patient use is hazardous to patient safety. If observed in the patient treatment area, it should be considered as an immediate & serious threat to patient health & safety (V403).
  - **General:** sufficient space between patient chairs (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 (V413)
  - **Staffing:** adequate for patient load (V757); RN present (V759); machine alarms set (V403)/responded to (V757)
  - **Isolation room/area:** if in use for hepatitis B+ (HBV+) pts (V128-129); dedicated supplies (V130); staff caring for HBV+ pts only caring for HBV+ & HBV immune pts (V131)
  - **Dialysis treatment records/dialysis prescriptions:** Rx administered as prescribed, check treatment records/orders for blood flow rate, dialysate, dialyzer type, etc. match to machine settings (V541, 543, 544); treatment sheets show machine alarms/safety checks, pH/conductivity (V403, 250); reprocessed dialyzer germicide presence/absence (V350,

351); patient/dialyzer ID'd by 2 persons, documented (V348); patient monitored during treatment (V543)

- Medication preparation & storage area: away from patient station (V117); single dose vials = single use (V118); predrawn syringes labeled w/patient name, contents (V715); multidose vials labeled when opened (V143)
- Water treatment area: restricted access (V184); general condition of equipment (V182, 401, 403); 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, 232, 401, 403); individual jugs clean (V243)
- Supply storage: sufficient, non-expired supplies on-site (V401, 403); correct temperature control for germicides (V319)
- Laboratory area: provide or make available (V675-676)
- Reuse room: overall condition of equipment (V316); storage & aesthetic appearance of reprocessed dialyzers (V321, 343); no noticeable germicide odors (V318)
- Infectious waste storage: restricted access (V121)
- Home training area: sufficient space; restricted access 4 exchanges (V404); h/w sink (V114)

### **3b-Observation of hemodialysis patient care:**

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 between patients & between dirty & clean tasks (V113); patients wear gloves to hold sites (V113)
- PPE appropriate to task worn, i.e., gowns, gloves, eye/nose/mouth protection (V115)
- Items taken to station disinfected, dedicated, or discarded (V116)
- Cleaning/disinfecting machines/chairs/equipment between patients (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)
- No dried blood spills; all blood spills cleaned immediately (V122)

#### Patient care:

- Patients evaluated pre & post treatment; patients & machines monitored per policy during treatment; unstable = more frequent monitoring (V504, 543, 550-551, 715)
- Observe pre & post dialysis access care, e.g., proper skin prep prior to cannulation, aseptic technique used for CVC use & dressing changes (V142, 147, 550-551)

#### Dialysis machine & dialyzer use:

- Dialysis machines: prepared per manufacturer's DFU (V403); safety checks performed, i.e. alarms tested, dialysate pH/conductivity w/independent method (V403, 250)
- Reprocessed dialyzers: all preprocessed b4 1<sup>st</sup> use (V336); label w/patient name b4 1<sup>st</sup> use (V328); sufficient germicide contact time (V349); meet aesthetic requirements (V347); tested for germicide presence (V350, 351); primed per manufacturer's DFU (V352), & tested for germicide residual (V353)

**Note:** Watch carefully. It is easy to miss testing of germicide presence/residual. Be sure testing methods are sufficiently sensitive, & appropriate test strips are used.

- Reprocessed dialyzers ID by 2 persons prior to treatment initiation (V348)
- Non-reuse dialyzers primed per manufacturer's DFU (V715)

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**3c-Emergency equipment & preparation:** Use STAR menu for emergency equipment in the Tour & Observation of Care menu

- Review emergency equipment for function (i.e., AED or defibrillator, Ambu-bag, oxygen, airways, suction) & medications available & ready for use (V413)
- Ask Staff about emergency preparedness; the use of resuscitation equipment & procedures (V409, 411); fire/emergency evacuation procedures (V409)
- Emergency evacuation supplies present & in date (V408)
- Evacuation routes clearly ID'd & unobstructed; fire extinguishers present (V417)

### **Task 4 – Entrance Conference w/administrative personnel:**

- The Team Leader should use STAR to record facility specific information
- Review the purpose of visit, the survey process, & anticipated time schedule
- Review data report w/responsible staff: discuss issues noted during presurvey in data reports
- Provide form CMS-3427 for completion
- Request facility specific information-refer to entrance conference questions in STAR or entrance conference worksheet
- Request reference materials needed for survey; provide Reference Materials List
- Request patient-specific information for selecting a patient sample; this may include (from worksheet):

Current patient census separated into modalities, w/admission dates; Any home patient expected to visit the facility during survey; Current HD patient listing by shifts w/any isolated patients ID'd (seating chart); Aggregate list of individual patients' labs (Kt/V, 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 for individual patients as reported to the ESRD Network/CROWNWeb; Pediatric patients <18; Residents of Long Term Care facilities; Any involuntary discharges since last survey; Deaths last 12 months.

### **Task 5 – Patient Sample Selection:** Using the information requested above:

- Select 10% of patient population for the patient sample; select at least 5 if census <50; maximum of 15 if census >150; You will review the medical record of each sampled patient (Task 11); Attempt to interview as many of the sampled patients as possible (Task 10)  
Note: Other patients may be interviewed or records reviewed as indicated-add them to the patient list as supplement to the 10% sample.
- 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” (low Hgb, poor Kt/V, elevated PTH, etc. for 3 months), infections, repeated “dialysis-related” hospitalizations, patients w/CVCs >90 days, pediatric patients, residents of SNFs, involuntarily dc patients (if (equal to or ) ≥1, include at least 1 in patient. sample)
- Consider including patients identified w/concerns during tour & observations of care
- Create a patient list; Enter the sampled patients into STAR Patient Sample Selection

### **Task 6 – Water Treatment & Dialysate Preparation:**

Use STAR &/or the CfC “Water & dialysate quality” 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. 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/labels (V187); alarms in treatment area (V186); distribution\_system w/continuous flow (V211)
- **Required water treatment components:**
  - Carbon adsorption: 2 tanks w/sample port b/t & minimum 10 min EBCT (V192, 195)
  - Reverse Osmosis: continuously monitored, alarms in treatment area, >90% rejection rate (V199, 200)
  - DI: if no RO or as polish: resistivity monitoring/alarms (V202); auto divert-to-drain (V203); followed by UF filter (V204); log shows resistivity √ twice daily (V202)
- **Standard water treatment components/set up & monitored per RD52/CfCs:** sediment filter (V188); cartridge filters (V189); softeners (V190, V191); 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, 270-273)

### **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 prior to disinfection, from various sample sites (V213, 254); w/in AAMI limits, actions taken if elevated (V178, 255)
- **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)
- **Daily logs:** review 3-6 months: daily monitoring recorded of equipment function: 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); batches verified/tested/logged (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)
- **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 into the dialyzer, “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

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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); 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, 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** B4 1<sup>st</sup> use (V328); measurement of original total cell volume (V336)
  - **Transporting** to reuse room; clean & sanitary, reprocessing initiated timely or refrigerated; facility ID'd max refrig time (V331)
  - AAMI water in use for all reprocessing (V314)
  - **Pre-rinse:** water pressures monitored (V332); if header cleaning=w/stream of AAMI water, reassemble wet w/germicide (V334)
  - **Testing:** Leak/blood path integrity (V337); total cell volume (V336)
  - **Filling w/germicide:** germicide potency sufficient (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 w/in limits (V318)
- **Cultures/LALS:** review 6-12 months of water cultures done in reuse room-w/in limits (V178, 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 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

- Review P & P at user ESRD facility for transportation & clinical use of dialyzers (V306)
- Observe that transporting used & reprocessed dialyzers is done per AAMI (V331)

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

### Task 8 – Machine Operation/Maintenance: Use STAR menu for review

- **Interview the personnel responsible for maintenance & repair of dialysis machines:** determine schedule for PM; method used to alert bio-med of machine breakdown; machines awaiting repair pulled from service; machine tested for function prior to use (V403)
- **Review PM & repair logs** for a sample of dialysis machines (25% or a minimum of 5) for previous 12-18 months; expect manufacturer's instructions for PM intervals to be followed, electrical leakage tested per DFU (V403)
- **Review machine/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 w/equipment & afford patient privacy (V404, 406); 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 w/home training nurse(s):** refer to STAR staff interview or worksheet for interview w/home training nurse. See Task 11 for medical record reviews for home patients.

### Task 10 – Patient Interviews:

Use STAR patient interview menu or patient interview guide for treatment modality

- Interview as many of the sampled patients as possible & other patients as indicated; for ½ the interviews (around 2-4), ask all the questions; for remaining interviews, focus 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 for the treatment modality. Review the records of all sampled patients; for ½ the sample (3-7) a comprehensive review of all areas to eval PA/POC is required. For remaining records, focus review to concentrate on the care concerns/sampling rationale specific for 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. Review for:

- **PA/POC:** completed by all required IDT in all care areas(V501,541); Frequency of initial (V516, 557) & reassessments met (V517,519,520,558)
- **For evaluation of ongoing monitoring & evidence outcome goals not met were addressed:** Review:
- **Laboratory values** for 3-4 months: compare c MAT/ patient-specific goals for dialysis adequacy (V544), anemia (V547), nutrition (V545);CKD/MBD management (V546) achieved; or actions taken to revise the plan of care (V559)
- **Physician's orders:** dialysis prescription, meds, other treatments specific to meet patient needs
- **IDT progress notes:** involvement of all IDT team members to evaluate the patient & address pertinent issues (V501, 541); P/S/rehab/TP status evaluated & addressed (V510-515, 552-555); dialysis access placed & monitored (V511,550-551); treatment seen by medical practitioner at least monthly & periodically during dialysis (V560)
- **Dialysis treatment records:** Review 10-15 for HD treatments; 8-12 wks of home dialysis flow sheets for PD patients: look for compliance w/dialysis prescriptions (V541, 543, 544), medication & treatment orders (V543, 544, 545, 546, 547), safety checks for machines & reprocessed dialyzers (V403, 250, 348, 349, 350, 353); BP/fluid monitoring & control(V543); pre & post-treatment assessments & monitoring during dialysis for in-center HD patients (V543, 715)
- **Pt education:** emergency preparedness (V412); treatment options/modalities (V458);Pts' rights/AD/rules/ grievance (V451-467);transfer/DC policies (V468); dialysis management, infection control; vascular access (V562); home dialysis training content(V585)

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### **Task 12 – Personnel Interviews:**

Refer to the STAR section for staff interviews or worksheets for interviews w/the reuse technician, water treatment personnel, home training nurse, social worker & dietitian.

- Interviews w/medical director, social worker, dietitian, nurse manager, & administrator should be guided by issues identified during the survey to clarify & gather more information & to determine if there is sufficient staff available to meet patient needs (V758)
- 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 QAPI/Governance Review; data entered during presurvey activities will appear at these screens.

**13a-QAPI documentation/interview:** See Measures Assessment Tool for expected targets Review incident logs, trending data, minutes/QAPI records demonstrating analysis, interventions, impact & ongoing monitoring where necessary over the last 12 months; interview the responsible person about the QAPI program. Areas for which data must be *continuously* monitored include:

- Dialysis process & 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)
- Comparison of facility outcomes of quality indicators with Dialysis Facility /Report data on facilities in the state, Network, & U.S. to develop improvement strategies (V628)
- 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 identification (V634)
- Dialyzer reuse (V635)
- Patient satisfaction & grievances (V636)
- Infection control & vaccinations (V637)

**Note:** Look for involvement of IDT members (V626); look for review of trends, identification of problems, analysis for root cause/multiple causes, development of improvement plans using community standards, implementation of plans monitoring for improvement; improvement made/sustained (V638); prioritization for those areas which affect patient safety (V639, 640). Look for special guidance if the facility is involved with a Patient Safety Organization (PSO).

**13b-Emergency preparedness review:** To assess the facility's emergency preparedness, use the information gathered from patient/staff interviews & review for the following required procedures: (V408)

- Fire: emergency blood return & disconnect from HD; evacuation, reporting & responding to a fire; training capable in-center or home HD patients or their care partners in manual blood return and emergency disconnect; identification of in-center patients who require assistance

- Power failure: training staff and capable in-center and home HD patients or their care partners in manual blood return & disconnect from HD; 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 but not limited to cardiac arrest, air embolus, adverse drug reactions, suspected pyrogen reactions, accidental germicide infusion, profound hyper/hypotension, significant blood loss
- Documentation: staff training initially & at least annually (V409); patient education program (V412); annual re-evaluation of procedures (V415); annual contact w/local disaster management agency, collaboration w/Network, suppliers, utility companies (for facility and home patients as appropriate), State survey agencies and other dialysis facilities (V416)

### **Task 14 – Personnel Record Review:**

Refer to the STAR section for Personnel Record Review or use worksheet.

- 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 technicians.
- Include files of staff identified via concerns during survey
- Review files for: licensure (V681); minimum qualifications/training/competencies (V682-693, 696, 307-309, 260, 410); certification (V695); health screenings (V126, 127, V310); emergency/disaster training (V409)
- Review PCT certification program (V693-695)

### **Task 15 – Decision Making:**

- Use STAR pre exit checklist. Review Form CMS-3427 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 w/the survey team (if applicable) to determine what to cite & the level of citation, & whether further interviews, record reviews or observations are indicated; 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:** 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.