

ESRD Core Survey Process Triggers

Environmental "Flash" Tour:

In-center dialysis patient treatment area

- Dummy drip chambers present (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 observable 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:

- 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/day (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:

- Stored reprocessed dialyzers aesthetically unacceptable (V343); not protected from unauthorized access (V321); not stored w/n germicide temp range (V335)
- Reprocessing room or equipment in observable disrepair (V318, 403)
- Dirty dialyzers kept at room temperature >2 hrs. (V331)
- Dialyzer refrigerator temperature not monitored (V331)

Home dialysis training area:

- 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)

Extending the tour to other areas:

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

Observations of Hemodialysis Care and Infection Control Practices:

Observations of direct staff delivering care

- 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/conductivity per manufacturer DFU or staff unaware of acceptable parameters (V250)
- Not performing reprocessed dialyzer germicide tests (V350, 351, 353) or patient/dialyzer identification by 2 people (V348) when patient is at the station
- Not priming reprocessed or dry pack dialyzers per DFU (V352, 403)
- Not assessing patients before & after tx or monitoring during tx per facility policy (V504, 543, 550, 551, 715)
- Medications not prepared in a clean area away from the dialysis stations (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)

Isolation practices:

- 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)

Verification of dialysis treatment prescription delivery:

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

Water Treatment and Dialysate Review:

Chlorine removal/carbon system

- Absence of 2 or more carbon tanks with sample port between (V192), insufficient carbon EBCT-*verified by interview or record review* (V195)
- Observed total chlorine test result >0.1mg/L; test done incorrectly or with incorrect reagents/equip (V196)
- Staff unaware of correct testing, max level of 0.1mg/L total chlorine & breakthrough procedures (V260)

Reverse osmosis system

- Absence of RO % rejection & product water TDS or conductivity monitor & alarm audible in patient tx area; Readings not recorded daily (V199, 200)

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DI, if present (If part of back-up plan, items below must be included in plan)

- Absence of functional resistivity monitor/alarm, visible & audible in patient treatment area or not monitored 2x/day (V202, 203)
- Absence of a functional automatic divert-to-drain or 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)
- No ultrafilter post DI (V204)

Interviews

- 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)

Log reviews

- 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)
- Microbiological results exceeding action/maximum levels & no documentation of appropriate actions taken (V178, 180)
- Practice audits of staff not conducted at least annually (V260)

Dialyzer Reprocessing/Reuse Review:

- 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)
- Dialyzers stored for extended periods (V345)
- 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)
- Reprocessing equip not maintained/repared per DFU &/or not documented (V316,317)
- QA audits listed not done or incomplete (V362-368)
- Noticeable strong germicide odors or patient/staff complaints (V318)
- Serious adverse events related to dialyzer reprocessing/reuse without documentation of appropriate actions taken to prevent future similar events (V355-357, 635)

Dialysis Equipment Maintenance:

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

Home Dialysis Training and Support Review:

- Home training nurse(s) lack knowledge of training or monitoring patients/caregivers
- 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 Care

Patient Interviews:

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:

- Absence of a functional IDT process that monitors, recognizes & addresses barriers to attainment of identified outcome goals in clinical & psychosocial areas
- Patient or caregiver interviews indicate lack of functional patient education program & patients' rights concerns
- 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:

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

Personnel Record Review:

- Personnel lack required qualifications, 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 and Performance Improvement (QAPI) review:

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)