Management of HD Centers in the USA

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Types of dialysis organizations in USA

- Large Dialysis Organizations (LDO's) 71%
 - Fresenius and DaVita
- Small Dialysis Organizations (SDO's) 10%
 - Own ~5 to 500 dialysis centers
- Independent 13%
 - (physician or businessman owner)
- Hospital based 10%

Figure 1. The 10 largest U.S. dialysis providers in 2015

Dialysis Provider	# Patients	In-Ctr. Conv. HD	In-Ctr. Noc HD	Home HD	PD	Units	Patient growth 5/15 (vs. 5/14)	% growth 5/15 (5/14)
1. Fresenius Medical Care N.A.	178,337	158,664	2,192	2,569	14,912	2,312	6,331 (7,445)	3.7% (4.5%)
2. DaVita Kidney Care	174,300	151,300	1,400	3,100	18,500	2,173	8,000 (9,000)	4.8% (5.7%)
3. U.S. Renal Care	16,050	14,285		260	1,505	274	1,663 (540)	11.5% (208%)
4. Dialysis Clinic Inc.	14,800	12,992	7.5	209	1,599	233	338 (221)	2.34% (3.8%)
5. American Renal Associates	12,250	11,020	100	110	1,020	184	1,490 (1,300)	13.8% (13.7%)
6. DSI Renal	7,436	6,593	18	123	702	100	780 (116)	11.7% (1.8%)
7. Satellite Healthcare	6,541	5,036	136	167	1,202	75	326 (678)	5.2% (12.1%)
8. Renal Ventures Management	2,387	2,037		6	344	38	71 (40)	3.0% (1.78%)
9. Atlantic Dialysis Management	2,149	2,102	n/a	14	33	13	n/a	n/a
10. Centers for Dialysis Care	1,544	1,644				15	(10) (42)	0% (2.5%)
* Excludes 101 in-center hemodialysis	patients, 48	PD patients, a	and 31 HHD	patients in	three clini	cs where (CDC owns less than	50%
2015 totals [growth: 5% (6%)	415,794	365,673	3,846	6,558	39,817	5,417		
2014 totals	396,019	348,212	3,285	6,098	38,424	5,161		

All dialysis organizations have similar management approaches - WHY?

- ~ 80% of all ESRD patients in the US
 (636,000 including transplant) have their
 treatment and most other heath care paid
 by Centers for Medicare & Medicaid
 Services (CMS)
- 2. CMS monitors each center rigorously
 - Must submit data on regular basis clinical and financial
 - Inspect centers annually

Why are management styles similar in all USA HD centers?

- 3. Availability of clinical care guidelines:
 - Kidney Disease Improving Global Outcomes (KDIGO)
 - Kidney Disease Outcome Quality Initiatives(KDOQI)

Why are management styles similar in all USA HD centers?

- CMS requires specific staff to do certain defined jobs – i.e. Chief Executive Officer, Medical Director, Nurse Manager, Social Worker and Dietician
- 5. Companies like Fresenius are constantly developing new management methods that improve quality and/or efficiencies. These methods soon become known and implemented by other center owners.

Components of management methods

Quality Assessment and Process Improvement (QAPI)

and

Other Important Functions of the Hemodialysis Center

QAPI starts with a Multidisciplinary Team

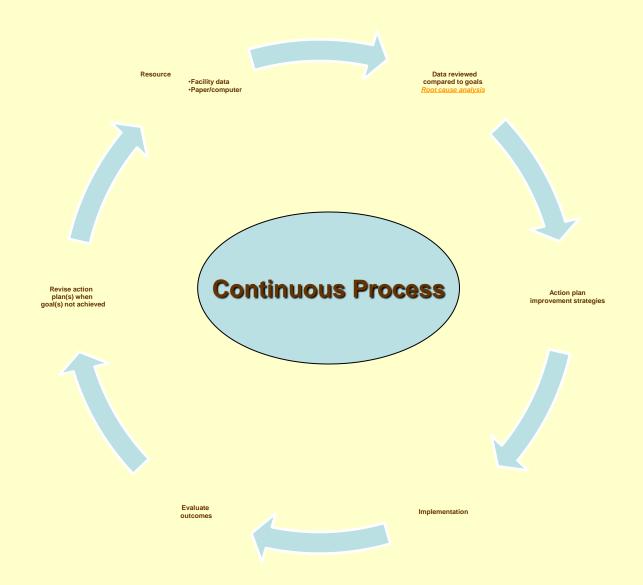
- Who is a member? Medical Director is chairman of committee and members are nurse manager, dietician, social worker
- When do they meet? Mandatory monthly meetings
- What is the purpose?
 - Review pre defined quality indicators for each patient – Need Data
 - Create an action plan for individual patient outliers – Need Goal Standards

Multidisciplinary team - continued

- Examine for each quality indicator a trended graph for period of time* for each patient
- Examine for each quality indicator a trended graph for period of time* for the dialysis center in aggregate
- Develop a basis for comparing dialysis centers within your system of centers or with industry standards

^{*}Six month period of time

Quality Assessment and Performance Improvement (QAPI)



Kt/V as example

- Start with center's data list of patient's Kt/V for the month of August – either computer generated or paper list
- Review the Kt/V for each patient and compare it to goal. *Goal for Kt/V by CMS is a spKt/V of ≥ 1.2.

- 3. Look at each patient that does not have a Kt/V of ≥ 1.2 and discuss with team and discuss why goal is not being achieved?
- 4. Develop a written plan to investigate what the failure of goal achievement may be due to and who is responsible for each action item required

Example of Kt/V goal failure reasons

- Patient # 1 has a central venous catheter
 - ✓ Action Plan: Doctor must get surgery for fistula creation scheduled
- Patient #2 asks for treatment to be shortened every time
 - ✓ Action Plan: Social worker/doctor/nurse must educate patient on why it is important to stay on the machine the full treatment time.

- Patient #3 is not eating properly
 - **√Action Plan:**

Dietician/doctor/nurse/social worker must speak/examine patient in detail

- Patient #4 has fistula but only gets a blood flow of only 250 ml
 - ✓Action Plan: Doctor must have patency of the fistula checked

Implementation of action plan

Execute the specific action item(s) with each individual patient after the multidisciplinary team meeting (doctor, nurse, social worker, dietician)

- Tests/procedures must be ordered as determined
- Dialysis/medication orders may require changes
- Prepare to report back to committee

Evaluate outcomes

Prepare for the next QAPI meeting - the multidisciplinary team member (doctor, nurse, social worker, dietician) should organize their report on the status of each patient's detail(s) that they are responsible for and chart these results in the medical record.

Evaluate outcomes

IF the goal is not being resolved – the action plan should be revised. For example Patient #2 still demands to come off machine early.

Revise action plan — schedule family meeting with patient to discuss why this might be happening (maybe as simple as family member wants to pick up patient too early from treatment) and does not understanding the importance of staying on full time.

Next month's multidisciplinary meeting – key to the QAPI process

- Start with center's data list of patient's Kt/V for the month of September – either computer generated or paper list
- 2. Review the Kt/V for each patient and compare it to goal.
 - * Goal for Kt/V by CMS is a Kt/V of ≥ 1.2.
- 3. First look at patients that had a low Kt/V last month did they improve? Did others fall below goal?

The QAPI cycle repeats itself each month.

Next month's multidisciplinary meeting – key to the QAPI process

- Question: did each of the 4 patients improve their specific problem and if not WHY?
- Patient #1 Agreed to have fistula surgery and it is scheduled for October.
- Patient #2 Another family member will pick up patient after treatment so patient can stay on for entire treatment
- Patient #3 Diagnosed cancer of the stomach
- Patient #4 Fistula had stenosis and it is scheduled to be repaired in October.

VERY IMPORTANT POINTS

Must:

- look at trend of <u>each</u> data point for clinical quality indicators – do the same for operational and business data points.
 - √Compare year by year
 - ✓ Create a bar/line graph to illustrate month to month easy to do on Excel
 - ✓ Should be done for both individual patients and the HD center as aggregate

Changes occurring very slowly over time are very hard to recognize when you are following MANY patients.

Key factors for effective QAPI process

Must:

- generate either by computer or hand written log precise list of patient outcomes for each month for each quality indicator
- have goals for each indicator that are evidence based
- have 100% attendance at monthly meetings by ALL team members – doctors are an essential team member.

Key factors for effective QAPI process

Must:

- have precise system to track:
 - ✓ who (doctor, nurse, dietician, social worker)
 spoke to the patient during the month
 - ✓ exactly what action each team member was going to do
 - ✓ was the action item done
 - ✓ if not done why not and what will happen next

- 1. Adequacy monthly
 - HD spKt/V ≥1.2 3 times/week treatments *
 - PD weekly standard Kt/V_{urea}≥1.7 (dialysis + residual renal function)
- 2. Volume status euvolemic & normotensive

*High flux dialyzers highly recommended.

- 3. Nutritional status † within set target range monthly
 - albumin ≥ 4.0g/dL BCG method
 - % body weight
 - % usual weight
 - % standard weight
 - BMI
 - estimated % body fat

- 4. Mineral metabolism & renal bone disease
 - calcium and phosphorus † within set target range monthly
 - Calcium >8.4 mg/dL and <10.2 mg/dL
 - Phosphorus 3.5 5.5 mg/dL
 - Intact PTH 150-300 pg/mL (16.5-33.0 pmol/L)

5. Vascular access

- ↓ to <10% cuffed catheters after 90 days on HD
- ↑ to ≥65% AV fistulas for dialysis
- ↓ to <0.25/pt/yr (graft) or <0.50/pt/yr (fistula) thrombosis episodes
- to <1% (fistula) or <10% graft infections per use-life of access
- †%with fistula >3yrs and graft >2 yrs access patency

- 6. Anemia management
 - Patients taking ESA
 - † % with mean hematocrit between 30-36%
 - Transferrin saturation >20%
 - ↑% with hemoglobin between 9 11 g/dL
 - Serum ferritin >200ng/mL
 - Patients not taking ESA
 - >10g/dL

- Medical injuries and medical errors ↓
 frequency by % through prevention –
 must have proof of doing root cause
 analysis
- 8. Patient satisfaction & grievances must report grievances and † as a % number for patients satisfied with care

- 9. Infection control
 - Minimize infections
 - Promote immunizations

10. Vaccinations -↑% of patients vaccinated

11. Patient survival - ↓ mortality and track causes

Required patient assessment by CMS

- 1. Multi disciplinary team comprehensive assessment by each member within 30 days of dialysis initiation.
- 2. Re-assess by 4 months after initiation of dialysis
- 3. Assess HD prescription monthly
- Assess PD prescription initially then every 4 months
- 5. Monitor lab values monthly
- 6. Assess vascular access

Required water and dialysate quality by CMS

- Water quality
 - Max. chloramine ≤0.1 mg/L daily/shift
 - Max. total chlorine ≤0.5 mg/L daily/shift
- Product water
 - Max. bacteria for product water = <2 CFU/mL
 - Max. endotoxin for product water <0.25EU/mL

^{*} Fresenius & RRI standard for endotoxin 0.06 EU/mL

Additional QAPI activity by providers such as Fresenius/RRI

- 1. Diabetic foot checks monthly
- 2. Patients on cardiac drugs
- 3. Patients requesting early termination of HD treatment
- 4. Patients missing HD treatment and not in hospital
- 5. % patients on transplant list
- 6. Hospitalization and cause per admission

Additional QAPI activity by providers such as Fresenius/RRI

- 7. Number of patients with positive blood cultures
- 8. Patients falls in HD center
- 9. Cardiac arrests in HD center
- 10. Line Separation
- 11. Blood lose of >275ml
- 12. Patient testing for hepatitis C antibody, hepatitis B antigen, hepatitis B antibody negative

Additional QAPI activity by providers such as Fresenius/RRI

- 13. Patient immunization for hepatitis B and pneumococcal
- 14. Dialysate LAL test
- 15. Product water LAL test
- 16. Emergency preparedness
- 17. Physical environment regulatory risk assessment

Other topics related to QAPI

Tracking System

- 1. Paper process is OK
 - If HD center is small and/or lack of money
 - Must develop paper form for each indicator for each month
 - Written notes at monthly meetings must be kept precisely for follow up
- 2. Modest computerization
 - Begin one quality indicator at a time and create paper log into Excel or programmed spread sheet
- 3. Highly computerized BEST
 - Interface with as many related computer systems as possible - laboratory, admissions, etc.

Other topics related to QAPI

Competition Between Multiple HD Centers

- 1. Rank centers by each quality indicator each month for achieving goal as either defined by CMS or the center (some centers set higher goals) as a percent
- 2. Aggregate rankings for all quality indicators to illustrate over best quality HD center, second best, down to worst center.
- 3. Distribute rankings within the HD center clinical leadership
- 4. Motivates poor centers to improve 🙂

Overall Rank	Facility Name	Overall	Oct-08	Oct-08	Oct-08	Oct-08	Oct-08	Oct-08	Oct-08	Oct-08	Oct-08	Oct 2008 3- Mns-Avg	Oct-08	Oct-08	Oct-08	Oct-08
			Hgb>13	HGB<10	TSAT>=20 %	eKdrt/V>=1 .2	Early Terminatio ns	No Shows	Fistulae Percent	Total Catheters Percent	Albumin>= 4.0	Mortality	Patients on Transplant List	Calcium<8. 5	Calcium>9. 5	. Phosphoru s<=5.5
1	Queens AKC	9.3	30	5	22	2	1	15	1	2	4	13	10	12	37	18
2	Michigan Dialysis - Livonia	10.8	15	3	26	15	8	11	20	9	15	7	2	38	6	3
3	Atlantic Hemodialysis	12.1	4	29	13	9	11	28	20	15	9	14	7	2	41	6
4	Milford Dialysis Center	13.6	2	4	28	13	4	6	26	26	29	1	5	19	24	23
5	Newport Beach Dialysis Center	13.6	5	8	18	5	9	4	13	32	20	11	28	34	32	13
6	Bayside Dialysis	14.3	13	9	11	4	12	10	3	12	26	15	39	33	16	37
7	Michigan Dialysis - Ann Arbor	14.4	28	5	24	10	32	29	29	13	5	16	1	24	8	21
8	Brookdale Physicians Dialysis Associates	14.6	17	37	9	37	13	19	16	5	6	6	6	17	39	20
9	Carolina Dialysis - Pittsboro	14.6	43	35	2	1	2	7	36	11	42	1	11	25	17	32
10	St. Alban's Dialysis	15.2	37	14	4	33	36	21	2	3	11	8	20	4	43	27
11	South Queens Dialysis Center	15.9	11	10	16	11	26	30	4	4	13	40	22	8	38	30
12	Brooklyn Kidney Center	16.5	22	13	27	27	22	41	17	22	7	5	19	9	36	2
13	Montefiore Dialysis Center IV	16.7	36	16	39	31	33	8	10	7	14	4	12	26	14	31
14	Branford Dialysis Center	16.8	9	36	19	12	7	1	27	34	30	29	21	40	1	10
15	City Dialysis Center	16.9	38	25	5	28	40	34	7	18	16	10	25	30	18	4
16	Upper Manhattan Dialysis Center	17.3	1	17	14	40	15	44	5	10	8	18	15	5	29	34
17	Central Suffolk AKC	17.5	16	11	37	26	31	17	14	23	24	24	14	28	3	9
18	Carolina Dialysis - Siler City	17.8	34	1	1	14	3	26	30	1	2	39	38	42	15	44
19	St. Raphael's Dialysis	18.3	6	18	30	30	23	5	37	38	10	9	3 24	36	22	26
20	Carolina Dialysis - Sanford	18.3	42 26	19 21	3 23	8 18	24 34	35 42	15	6 8	32	26 31	31	16 31	21	42 16
21	Southern Manhattan Dialysis Center Finger Lakes Unit	18.4 18.9	39	2	6	16	16	12	11 19	37	40	43	18	22	23 9	22
23	Harlem Dialysis Center	19.8	23	40	33	7	27	23	34	27	23	30	9	6	40	19
24	Living Center Unit	19.0	41	27	10	23	21	1	6	28	43	32	44	32	25	7
25	Middletown Dialysis Center	20.0	3	39	32	6	18	9	33	20	24	36	16	35	20	43
26	Irving Place Dialysis Center	20.0	10	44	8	25	42	39	20	25	3	21	17	43	2	39
27	Nephro Care West	20.0	25	33	20	3	6	31	35	14	37	41	29	13	33	14
28	Sound Shore Dialysis Center	20.3	29	32	7	34	10	14	12	21	17	42	33	10	42	25
29	WNYAKC - Kenmore *	20.3	32	15		38	37	20	31	36	36	1	13	29	7	10
30	Montefiore Dialysis Center III	20.5	44	7	15	36	19	27	24	16	18	25	8	15	34	41
31	Carolina Dialysis - Carrboro	20.9	19	22	12	21	25	40	32	19	22	20	26	44	13	29
32	Amsterdam Dialysis Center	21.2	20	12	17	17	28	25	38	43	35	16	40	11	10	17
33	Southern Westchester Dialysis Center	21.7	18	31	31	35	14	18	25	17	12	19	35	14	31	40
34	Capital District Dialysis Center	22.4	31	24	36	24	17	16	8	35	33	33	36	7	26	28
35	Clinton Crossing Unit	23.2	27	20	25	41	44	33	9	33	27	34	23	39	5	12
36	Nephro Care Inc.	23.3	21	45	22	34	5	36	42	32	33	12	29	3	35	15
37	Champaign-Urbana Dialysis Center	24.9	24	23	35	22	43	22	20	28	38	38	30	18	28	36
38	WNYAKC - Buffalo	25.2	14	38	43	20	35	13	41	42	39	35	4	37	11	38
39	Albany Dialysis Center	25.8	33	30	38	19	30	24	43	41	41	37	42	27	4	5
40	Albany Regional Dialysis Center	26.0	35	28	42	29	29	32	42	40	34	27	31	19	19	8
41	Yorkville Dialysis Center	26.1	7	34	29	43	38	37	28	31	21	22	34	23	27	35
42	Cobble Hill Nursing Home	27.1	12	42	40	39	20	1	44	44	44	44	43	1	44	10-
43	Strong Memorial Hemo Program	27.4	40	26	34	42	41	38	18	39	19	23	37	41	12	₃ 37
44	Dutchess Dialysis Center	28.8	8	41	41	44	39	43	39	24	28	28	41	21	30	24

In addition to QAPI – how do you know if your HD center is functioning well?

1. Is the HD center properly staffed by type and number of staff?

Type of staff

- Head Nurse
- Registered nurse
- Dietician
- Social worker
- Medical director
- Medical record practitioner
- Equipment technician
- Center clerk/secretary

Number of staff by type

Direct patient care staff*:

- Registered nurse
- Patient care technician
 - ~ 1 direct patient care staff to every 3 to 4 HD patients

*Significant changes since inception of HD

Number of staff by type

Support staff are professional and nonprofessional staff:

- Nurse Manager 1 FTE* if center has a small patient population (~≤30 patients) Nurse Manager may take patient assignment
- Dietician 1 FTE per ~150 patients

FTE = full time equivalent or a person that works 40 hours every week

Number of staff by type - continued

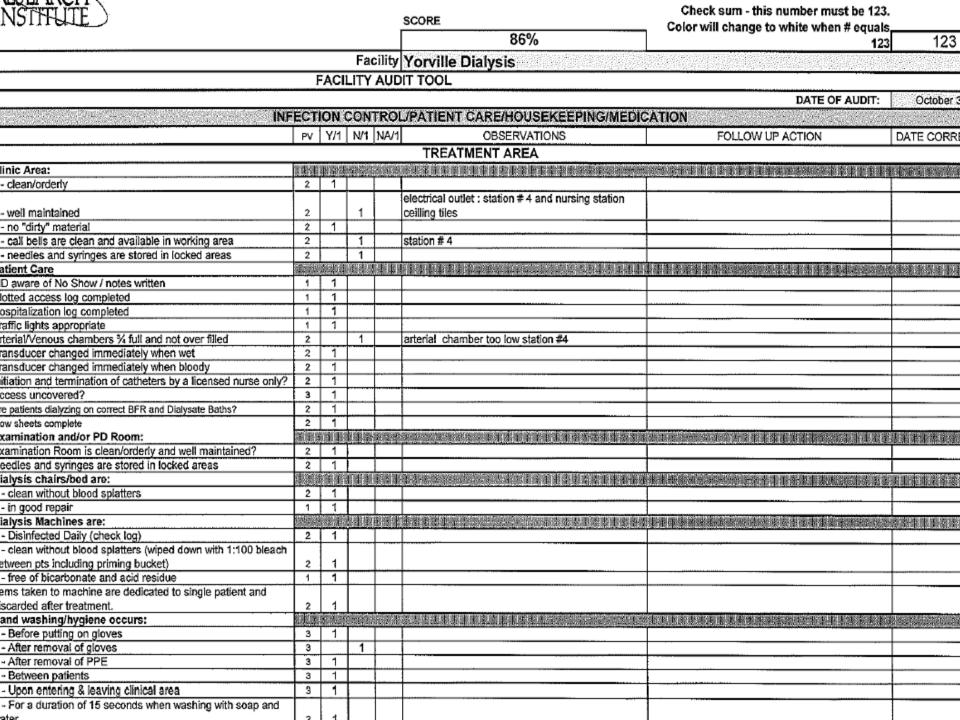
- Social Worker 1 FTE per ~100 patients
- Equipment technician 1 FTE per center unless <~60 patients or contract with equipment manufacturer
- Center clerk/secretary 1 FTE per center
- Medical Director 1 per center (not likely to work full time in center)

- 2. Is the staff properly educated (have license/degree) and/or have properly on the job training?
 - Direct patient staff must pass on the job training program (nurses as well as technicians)
 - Develop and perform annual proficiency auditor for existing staff
 - Provide in-services to review routine topics and introduce new topics
 - Support patient staff must prove necessary education or job experience

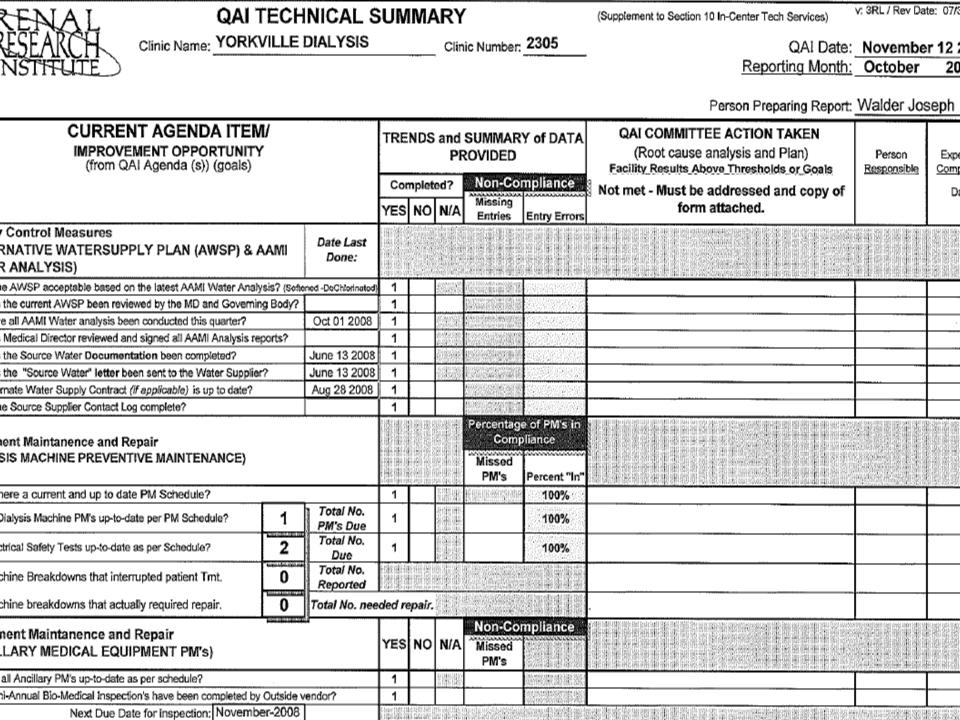
- 3. Is there a high frequency of HD staff turnover (quit)?
 - Monitor monthly by staff type leaving and why?
 - Use root cause analysis to determine why this is happening (expensive to train new staff) and how it can be improved
 - Compare to other HD centers

- 4. Is the patient schedule as efficient as it can be to admit the maximum number of patients available for HD?
 - Stagger (mix in) on each HD station patients with longer dialysis times (4-5 hrs) with shorter times
 - Time between patients should be ~30 minutes

- 5. Is the HD center clean and complies with all infection control requirements?
- Perform monthly audit of the physical environment of the HD center for example:
 - Are all floors clean?
 - Medication refrigerator is at a temperature of 2-8 C?
- Perform monthly audit of infection control for example:
 - Does clinical staff wear gloves when giving care/examining patients?
 - Does clinical staff wash hands between patients



- 6. Is the technical program activities being done correctly?
 - Perform monthly audit of technical program:
 - Are dialysis machines being checked monthly/quarterly per manufacturer's recommendation by internal technician or contract?
 - Are daily/weekly/monthly/annual water treatment and dialysate tests and checks being completed?
 - Who is reviewing these results and how often?



- 7. Is the HD center inventory system effective?
 - Is there a proper storage room?
 - Does it contain the needed supplies dialyzers, blood lines, saline, etc.
 - Is the amount of supplies set so there is not too much (expensive) or too little (expensive)

- 8. Is the cost per treatment (add up total cost for a month and divided by exact treatments done) of expenses that can be controlled in the HD center within acceptable amounts?
 - Direct patient care (put patients on and off the machine) staff for example:
 - ✓ Payroll for nurses and technicians in the month of August is \$200,000 USD
 - √HD treatments done in month of August = 1,700
 - ✓ Cost per treatment = \$117.64 USD
 - √Compare to other HD centers

- Other controllable expenses that should be monitored on a cost per treatment performed each month are:
 - ✓Support staff (head nurse, dietician, social worker, etc.) payroll
 - ✓ Supplies used for the HD treatments
 - √Compare to other HD centers

Summary

Developing systems and audits for all important functions of the HD center's activities, with actual outcome data to examine and trend, will improve the center and encourage staff to continue with the improvement process.

Topics for discussions

- Describe staff in your HD center patient care and support.
- Quality process?
- Dialyzer reuse?
- Duties of your Medical Director?
- Patient treatment time and "coming off" early?
- Perform environmental audits?