OPTIONS FOR KIDNEY REPLACEMENT THERAPY: DIALYSIS

Illinois Health Facilities & Services Review Board
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DISCUSSION GOALS

- End Stage Renal Disease (ESRD) Statistics
- Review basics of dialysis modalities
 - peritoneal dialysis (PD)
 - hemodialysis (HD)
- Choice of dialysis modality
- o in-center (IHD) versus home hemodialysis (HHD)
 - Brief overview of processes of each and how they are similar or different
 - Pros and cons

DIALYSIS IN THE U.S.: STATISTICS

- Among 124,675 new End-Stage Renal
 Disease patients in 2016:
 - 87.3% began hemodialysis
 - 98% of those used in-center hemodialysis
 - 2% of those used in-home hemodialysis
 - 9.7% began peritoneal dialysis

CRUDE AND STANDARDIZED INCIDENCE RATES OF ESRD AND ANNUAL NO. OF ESRD INCIDENT CASES, OVERALL AND BY MODALITY AND ESRD NETWORK IN THE U.S., 2016

		Total ESRD			Hemodi	Hemodialysis		Peritoneal dialysis		Transplant	
Network	States* in Network	No. of ** cases	Crude incidence rate (per million/yr)	Standardized incidence rate (per million/yr)	No. of cases	% of network	No. of cases	% of network	No. of cases	% of network	
14	TX	11,433	409	442	10,234	89.5	910	8.0	262	2.3	
18	S. CA	9,465	384	409	8,330	88.0	948	10.0	179	1.9	
13	AR, LA, OK	5,113	439	387	4,481	87.6	540	10.6	89	1.7	
9	IN, KY, OH	9,245	407	382	8,145	88.1	865	9.4	196	2.1	
10	IL	5,297	412	382	4,496	84.9	616	11.6	154	2.9	
8	AL, MS, TN	6,940	478	381	5,944	85.6	884	12.7	108	1.6	
3	NJ, PR, VI	5,310	420	378	3,393	90.1	253	6.7	119	3.2	
12	IA, KS, MO, NE	4,693	333	346	3,953	84.2	601	12.8	139	3.0	
17	N. CA, HI, GU, AS, MP	6,318	369	345	5,083	83.9	830	13.7	138	2.3	
6	NC, SC, GA	11,093	435	339	9,659	87.1	1,214	10.9	213	1.9	
2	NY	7,600	382	335	6,945	91.4	388	5.1	261	3.4	
4	DE, PA	5,285	384	335	4,663	88.2	451	8.5	153	2.9	
11	MI, MN, ND, SD, WI	7,625	333	334	6,610	86.7	650	8.5	330	4.3	
5	MD, DC, VA, WV	6,986	410	333	6,135	87.8	626	9.0	218	3.1	
7	FL	8,342	403	318	7,458	89.4	732	8.8	141	1.7	
15	AZ, CO, NV, NM, UT	6,015	282	297	5,145	85.5	649	10.8	215	3.6	
16	AK, ID, MT, OR, WA	3,664	245	259	3,088	84.3	465	12.7	111	3.0	
1	CT, MA, ME, NH, RI, VT	3,980	269	254	3,463	87.0	343	8.6	167	4.2	
	All networks	124,675	388	361	107,225	87.5	11,965	9.8	3,193	2.6	

Data Source: Reference Table A.10 and special analyses, USRDS ESRD Database. *Standardized to the age-sex-race distribution of the 2011 U.S. population. Listed from highest to lowest standardized rate per million/year. The special analyses exclude U.S. territories, unknown age, sex, network, and unknown/other races. ** Includes 50 states, Washington, D.C. (DC), Puerto Rico (PR), Guam (GU), American Samoa (AS), U.S. Virgin Islands (VI), and the Northern Mariana Islands (MP). Northern and Southern California (CA) are split into Networks 17 and 18. Abbreviations: ESRD, end-stage renal disease; yr, year.

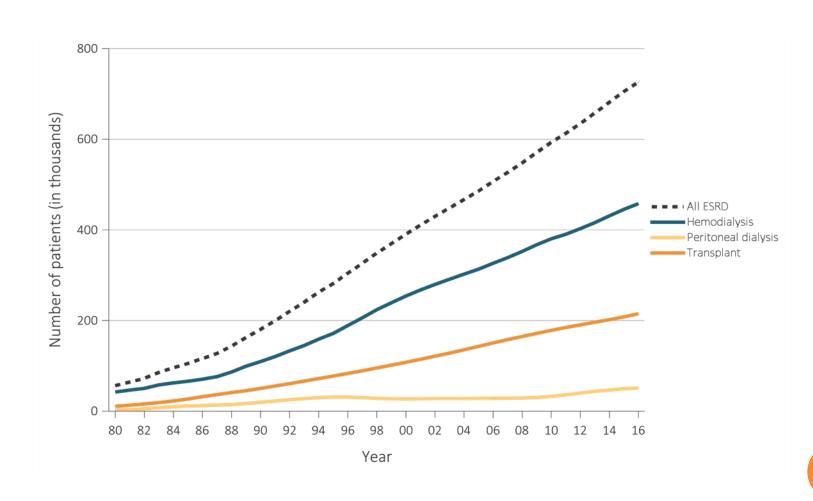
DIALYSIS IN THE U.S.: STATISTICS

- 726,331 prevalent cases of ESRD (2 million world wide)
 - ~0.2% of the population
 - ~1.6% of the Medicare population
- Number of cases continued to increase annually by 20,000 cases
- In 2016, 63.1% of all prevalent ESRD patients were receiving HD therapy
 - Among HD cases, 98.0% used in-center HD
 - 2.0% used home HD
- 7.0% were treated with home PD
- 29.6% had a functioning kidney transplant

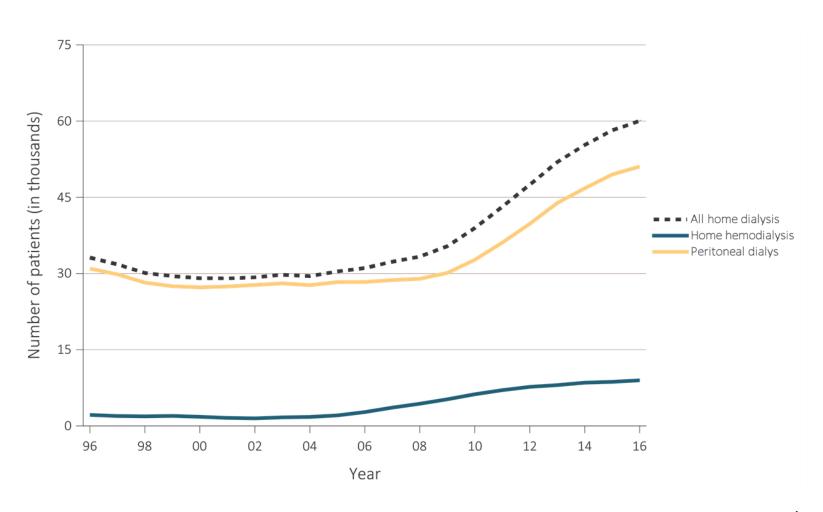
PREVALENCE OF ESRD (PER MILLION) AND ANNUAL NUMBER OF ESRD PREVALENT CASES, OVERALL AND BY MODALITY AND ESRD NETWORK IN THE U.S., 2016

		Total ESRD		Hemodialysis		Peritoneal dialysis		Transplant		
			Crude	Chandandina d						
		No. of	prevalence (per	Standardized prevalence	No. of	% of	No. of	% of	No. of	% of
Network	States in network*	cases**	million)	(per million)	cases	network	cases	network	cases	network
3	NJ, PR, VI	28,864	3,141	2,870	13,398	63.7	1,005	4.8	6,572	31.2
18	S. CA	60,362	2,446	2,618	40,597	67.3	4,737	7.8	14,895	24.7
14	TX	65,415	2,321	2,490	45,145	69.0	4,237	6.5	15,837	24.2
10	IL	31,906	2,473	2,293	19,367	60.7	2,274	7.1	10,176	31.9
17	N. CA, HI, GU, AS, MP	39,881	2,417	2,270	23,726	61.2	3,349	8.6	11,541	29.8
11	MI, MN, ND, SD, WI	46,573	2,025	2,094	25,869	55.6	2,682	5.8	17,860	38.4
9	IN, KY, OH	48,366	2,120	2,060	30,458	63.0	3,747	7.7	13,965	28.9
12	IA, KS, MO, NE	26,282	1,860	2,025	14,553	55.4	2,241	8.5	9,403	35.8
4	DE, PA	30,504	2,212	2,010	18,529	60.7	1,929	6.3	9,946	32.6
13	AR, LA, OK	26,851	2,300	1,981	18,078	67.3	2,289	8.5	6,359	23.7
2	NY	45,334	2,258	1,966	29,576	65.2	1,655	3.7	14,008	30.9
8	AL, MS, TN	37,446	2,568	1,948	25,368	67.7	3,063	8.2	8,908	23.8
15	AZ, CO, NV, NM, UT,WY	37,416	1,746	1,877	21,892	58.5	2,800	7.5	12,623	33.7
5	MD, DC, VA, WV	41,439	2,430	1,867	26,224	63.3	2,591	6.3	12,485	30.1
6	NC, SC, GA	64,220	2,501	1,814	43,859	68.3	5,334	8.3	14,849	23.1
7	FL	43,988	2,102	1,738	28,314	64.4	3,170	7.2	12,337	28.1
16	AK, ID, MT, OR, WA	23,081	1,532	1,694	12,555	54.4	1,998	8.7	8,442	36.6
1	CT, MA, ME, NH, RI, VT	24,583	1,653	1,640	13,379	54.4	1,451	5.9	9,648	39.2
All networ	k	726,331	2,274	2,138	450,887	63.2	50,552	7.1	209,854	29.4

TRENDS IN THE NUMBER OF ESRD PREVALENT CASES BY MODALITY IN THE U.S., 1980-2016



TRENDS IN THE NUMBER OF PREVALENT ESRD CASES USING HOME DIALYSIS BY TYPE OF THERAPY IN THE U.S., 1996-2016



WHAT IS DIALYSIS?

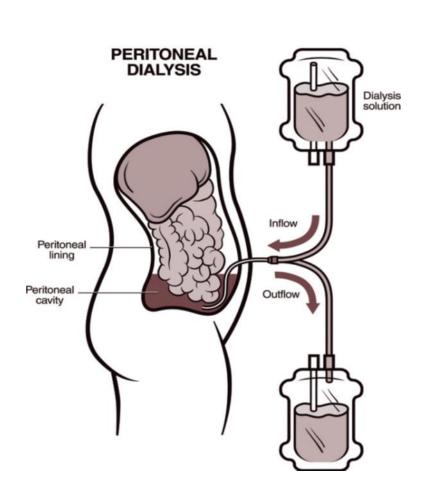
- A form of kidney replacement therapy
- A life saving treatment that removes wastes and extra fluid from a person's blood
- Types of Dialysis:
 - Peritoneal Dialysis (PD)
 - Hemodialysis (HD)

PERITONEAL DIALYSIS

- Takes place in the home
- Usually done every day, either several times throughout the day [continuous ambulatory peritoneal dialysis or CAPD] or overnight [automated peritoneal dialysis or APD]
- Patient and nephrologist can determine a prescription that meets patient's needs and lifestyle

DIALYSIS MODALITY: PERITONEAL DIALYSIS

- A home dialysis modality
- Utilizes soft plastic tube (catheter) inserted in peritoneum by surgery
- Inside lining of the patient's peritoneal cavity is used as a natural filter
- Patient uses dialysis fluid to cleanse blood
- "Dwell time" allows dialysis fluid to remove waste
- Used fluid drains into bag and is thrown away



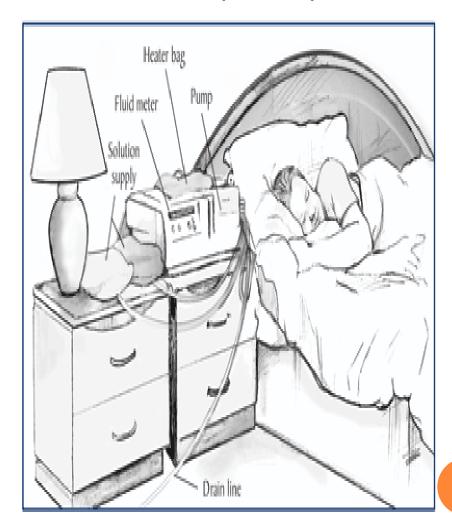
HOME DIALYSIS MODALITY: CONTINUOUS AMBULATORY PERITONEAL DIALYSIS (CAPD)

- Patient manually fills dialysis fluid via catheter into the peritoneum
- Dialysis fluid dwells in the peritoneum for several hours
- Patient manually drains dialysis fluid with waste
- Patient does exchanges 3 or 4 times a day



HOME DIALYSIS MODALITY: AUTOMATED PERITONEAL DIALYSIS (APD)

- Patient connects to the cycler machine at home before bedtime
- Machine automatically cycles exchanges while the patient sleeps
- Lasts 8 to 10 hours
- Patient self disconnects and starts his/her daily routine



PROS: PERITONEAL DIALYSIS

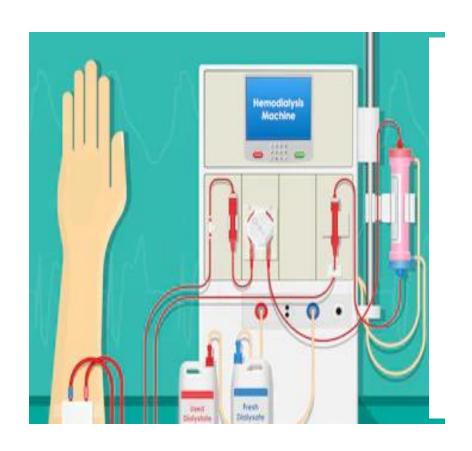
- Performed in the comfort of one's own home
- Tailored according to an individual's daily schedule
- Bloodless
- For many individuals, better quality of life (work, travel, leisure activities)
- Decreased travel costs
- Patients have a better understanding and selfmonitoring of their health
- May be better in the setting of certain conditions such as heart failure, liver failure, or other conditions with low blood pressure which make tolerating hemodialysis more difficult
- Fewer food and fluid restrictions
- May help to preserve residual kidney function

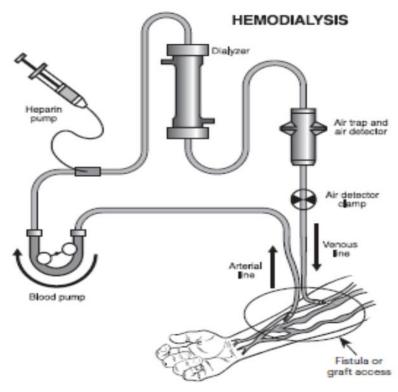
CONS: PERITONEAL DIALYSIS

- Need to be domiciled
- In most instances, must do every day
- Thin tube (catheter) must stay in the abdominal cavity
- Risk for infection of the peritoneum (peritonitis)
- Rarely, over time, peritoneum can become scarred.
- In some individuals, protein levels may decline
- Some individuals may gain weight
- Increased risk of developing hernia

DIALYSIS MODALITY: HEMODIALYSIS

 hemodialysis machine and special filter used to remove wastes from blood

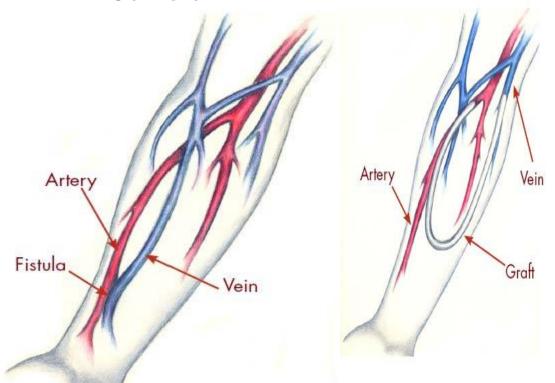


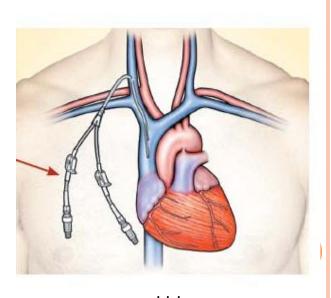


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DIALYSIS MODALITY: HEMODIALYSIS

- Uses one of the following common accesses:
 - AV fistula
 - AV graft
 - Catheter

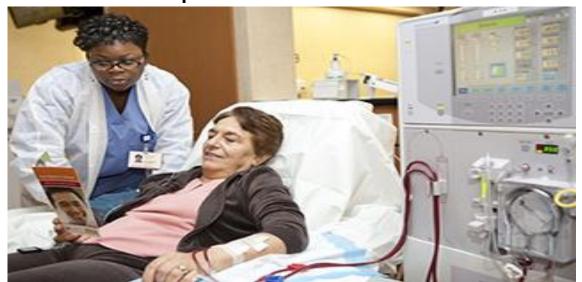




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HEMODIALYSIS: IN-CENTER

- Takes place in a hospital or traditional dialysis center setting
- Usually done three times per week, for about four hours (or more) at a time
- Depending on several factors, nephrologist may prescribe more frequent treatment



PROS: IN-CENTER HEMODIALYSIS

- No equipment in house
- Monitored by hemodialysis trained technicians and nurses
- HD Centers may be located in or near a medical center or hospital
- Have 4 days of the week free of dialysis

CONS: IN-CENTER HEMODIALYSIS

- Have to go to a clinic minimum 3 days a week, rain or shine
- Tiring
- Transportation costs
- Time consuming
- If travel is anticipated, must plan in advance, and there may be additional charges
- Frequently diet and fluid restriction is recommended
- Common side effect is low blood pressure which may be followed by nausea, dizziness

HOME DIALYSIS MODALITY: HOME HEMODIALYSIS

- Works the same as in-center hemodialysis
- May use a smaller machine and filter used to clean wastes from blood



HOME DIALYSIS MODALITY: HOME HEMODIALYSIS

- Takes place in a home setting
- Usually done 3-6 times per week
- Depending on several factors, physician may prescribe more or less frequent treatment

HOME HEMODIALYSIS: A BRIEF HISTORY

- Started in U.S. in 1964
- In 1973, Medicare started to cover the cost of dialysis; 40% of patients received HD at home
 - Thereafter more HD centers opened
- Since 2008, CMS requires kidney replacement therapy Options Education to include home dialysis modalities PD and HD.

IN-HOME HEMODIALYSIS: SCHEDULES

- Conventional home hemodialysis (HHD)
 - Similar schedule to in-center HD
- Short daily HHD
 - HD 5 to 7 x week
 - Treatment duration is 2 to 3 hours
- Nocturnal HHD
 - Longer, slower treatments while sleeping
 - 6 nights or every other night, per MD prescription

PROS: HOME HEMODIALYSIS

- Similar to the advantages of PD
- More flexibility in schedule
- Done in the comfort and privacy of your home
- More autonomy (you do it yourself)
- Save on transportation costs
- May have more freedom with diet (especially if prescribed more frequently than 3 times a week)

HOME HEMODIALYSIS

- Generally offers more hemodialysis per week than in-center HD. Thus there are benefits:
 - Less medication to control high blood pressure and anemia
 - Less medication to control high phosphorous
 - Improved blood pressure control, nerve damage, and symptoms of restless legs syndrome
 - Feel better during HD and less fatigued after HD
 - Less restrictions on food and fluid intake
 - More energy for daily activities
 - Better sleep quality
 - Fewer and shorter hospital stays
 - Live longer

Cons: In-Home Hemodialysis

- Must be able to insert and remove needles in fistula or graft
- Space in home for HD machine, supplies, HD chair
- Overcome fears of cleaning and maintaining HD machine
- May need to modify plumbing and wiring at home
- May observe an increase in electric, gas, and water bills
- Learning how to do HD at home may be overwhelming
 - Training takes 6 weeks or longer (3-5 hours training sessions per week)
- Most programs require a care partner to learn/monitor treatments
 - Fatiguing for care partner
- Travel may be harder
- No social interaction with other patients during treatment

HOME HEMODIALYSIS TRAINING

- Begins once access is ready to use
- Typically 6 weeks or longer (some may be shorter)
- Set up dialysis machine and equipment at home
- Insert and remove needles
- Determine home much fluid to remove from blood during treatment
- Monitor blood pressure, heart rate during treatments and weights
- Maintain and disinfect dialysis machine
- Maintain and disinfect water system
- Monitor and troubleshoot medical and equipment problems
- Order and store supplies

HOME HEMODIALYSIS: ROLE OF THE CARE PARTNER

Most programs require a care partner who trains with patient and stays with patient during treatments

- Inserts and removes needles
- Administers medications
- Monitors blood pressure and heart rate
- Calls for help if needed
- Care partner may experience stress, burnout, sleep loss may occur
 - In-center HD for care partner respite
- Can hire a technician or nurse
 - Medicare does not pay for this
 - Medicare Part B will pay for visits by trained hospital or dialysis care centers to check on equipment, help in emergency, or assess home dialysis process

REASONS FOR LOW HOME HEMODIALYSIS USE

- Rapid increase in no. of Hemodialysis Centers, including for-profit centers
- Increasing number of elderly or ill patients with ESRD
- Concern that patients should not dialyze without direct supervision
- Sub-optimal options education
- Sub-optimal training of home modalities in nephrology training programs
- Patient self-care treatment concerns
- Loss of social aspects with in-center HD

- Medicare does not cover fistula surgery or other services to prepare for dialysis before Medicare coverage begins unless
 - Patient is already on Medicare due to age or disability in which case fistula placement will be covered
- Medicare coverage can begin the 1st month of maintenance dialysis if a patient meets both of these conditions:
 - Patient participates in a home dialysis training program offered by a Medicare-approved training facility during the 1st 3 months of the regular course of dialysis
 - Physician anticipates patient will complete home training to do own treatments

- If patient is eligible for Medicare because of ESRD, coverage does not start until the 4th month of dialysis [aka "waiting period"]
 - Thus alternate health insurance will be the sole payer for the 1st 3 months of dialysis
- The 1st 3 months is followed by a "coordination period" of 30 months duration when non-Medicare insurance pays for treatment
- Medicare may pay some of the costs ["coordination of benefits"] during which alternate insurer pays first and Medicare pays second
- After the 1st 30 months, Medicare will pay 1st for all Medicare-covered services. Alternate health insurance may pay for services not covered by Medicare.

Service or Supply	Not covered
Paid dialysis aides to help with HHD	X
Any lost pay to patient or care giver during home training	X
A place to stay during treatment	X
Blood products for home dialysis unless part of a doctor's service	X

- Medicare Part B covers training for home dialysis only by a facility certified for dialysis training
- Training sessions occur at the same time a patient gets dialysis treatment and are limited to a maximum number of sessions
- Medicare makes a single payment per dialysis treatment to the dialysis facility for all dialysisrelated services, including equipment and supplies
- Dialysis facility is responsible for providing all home related equipment and supplies

- Medicare pays for 80% of the cost of home HD and training
- Alternate payment sources:
 - Private insurance
 - Medicare supplement insurance
 - Some managed care organizations
 - Medicaid
 - Veterans Administration
 - Indian Health Service (IHS)
- If home plumbing or wiring changes are needed, alternate insurance may cover
- Monthly, electric, gas, and water bills may increase

Service or supply	Covered by Medicare Part A	Covered by Medicare Part B
Inpatient dialysis treatments	X	
Outpatient dialysis treatments in a Medicare approved facility		X
Outpatient MD services		X
Home dialysis training		X
Home dialysis equipment and supplies*		X
Certain home support services**		X
Most drugs for home and incenter dialysis		X
Lab tests		X

^{*}machine, water treatment system, basic recliner, alcohol, wipes, sterile drapes, rubber gloves, scissors

^{**}visits by trained hospital or dialysis facility workers to check on home dialysis, to help in emergencies when needed, andto check on dialysis equipment and water supply

DIALYSIS COST ASSISTANCE

- Patients may face high out-of-pocket costs
- Dialysis social worker is critical to educate patients on dialysis costs and financial assistance options
- Mortgage bill assistance [https://www.illinoishardesthit.org/]
- Electric bill assistance [www.comed.com/MyAccount/CustomerSupport/Pages/ResidentialHardship.aspx]
- Specific state assistance programs [<u>www.dhs.state.il.us/page.aspx?item=29719</u>]
 - Food stamps and cash assistance
- American Kidney Fund. [<u>www.kidneyfund.org/financial-assistance/</u>]
 - Health Insurance Premium Program. Pays premiums for Medicare, Medigap, commercial or COBRA health coverage. Must use Medicaid or state kidney programs first. Monthly income <\$600, savings <\$7,000
 - <u>Safety Net Program</u>. Small grants to help pay for transportation, medication co-pays, nutrition supplements, emergency assistance. Savings <\$1,000
 - Donated Medication Program
 - Medicare Part D for Prescription Bone Medications
- Medicare recommendations to save on medications:
 - State pharmaceutical assistance programs [www.medicare.gov]
 - Prescription cost defrayal [<u>www.ssa.gov/benefits/medicare/prescriptionhelp/</u>]
 - Partnership for Prescription Assistance [www.pparx.org]
 - NeedyMeds [www.needymeds.org]
 - RxAssist [www.rxassist.org]

ADDITIONAL RESOURCES

- National Kidney Foundation of Illinois:
 - http://www.nkfi.org/education/dialysis
- U.S. National Kidney and Urologic Diseases Information Clearinghouse
 - https://www.niddk.nih.gov/health-information/kidneydisease
- American Association of Kidney Patients www.aakp.org
- Medicare
 - www.medicare.gov

THANK YOU.