**THE 5 DIAMOND APPROACH TO DIALYSIS PATIENT SAFETY**

Division of Nephrology
Quality Improvement Initiative
September 30, 2011

**September 1967**
- 2 YQ PMH left nephrectomy for pyelonephritis in poorly functioning kidney
- Presented febrile, unresponsive to ABX with infection of a double right kidney with hydronephrosis
- Surgical exploration was complicated by twisting on pedicle, infarction, and complete loss of function
- PE notable for BP 145/105, prior PD catheter incision in mid-line abdomen, draining nephrectomy incision in right flank, hgb 7.6, Na 126, K 5.8, BUN 120

**October 1967**
- Access – UE AV shunt with poor flow and venous clot after 5 days, venous cannula re-routed with resultant excellent flow
- Access care – Qday pHisoHex wash and dressing change
- Equipment care – Assembled, continuity checked, ethylene oxide gas sterilized, then aired
- Circuit volume 150 ml, whole blood prime volume 100 ml
- Anticoagulation – heparin / protamine solution
- 100 L Dialysate bath solution kept at 37.5°C

**Monitoring**
- Q 30min: Blood pressure, Lee-White clotting times, and blood flow rate
- Q 1hour: BUN (160 → 11) and creatinine measurement at kidney inflow and outflow
- Na (126 → 135) and K (5.4 → 4.5) pre and post treatment
- Weight pre and post treatment (Δ0.3-0.4 kg)

**Introduction to QI Initiative**
- Pediatric ESRD population = 7,216 patients
- Pediatric chronic HD population = 1,248 patients
- In-center HD treatment, 3-4 hours per session, three sessions per week
- The complex procedure is vulnerable to error involving: the procedure, the equipment - dialyzer, dialysate, the dialysis access – AV fistula, AV graft, or indwelling venous catheters, or medications administered during the treatment – heparin, vitamin D, ESA, iron.
- The recognition and reduction of errors in dialysis units are mandated by numerous oversight bodies and increasingly are among the responsibilities of dialysis unit medical directors

**Introduction to QI Initiative**
- Centers for Medicare & Medicaid Services stipulate specific quality indicators in the treatment of dialysis patients regulated by:
  - New York State Department of Health
  - End-Stage Renal Disease Networks (Network 2)
  - United States Renal Data System
  - Association for the Advancement of Medical Instrumentation
  - Centers for Disease Control and Prevention
5 Diamond Approach to Patient Safety

- IPRO End Stage Renal Disease Network of New York announced a program to assist dialysis facilities improve staff and patient awareness of patient safety issues. This program seeks to:
  - Build a patient safety culture in every dialysis unit
  - Promote patient safety values
  - Create awareness of patient safety issues
  - Help dialysis units learn more about specific areas of patient safety

History of Hemodialysis

- Thomas Graham, 1805 – 1869
  - Scotland, 1850
  - Experimental chemist and father of modern dialysis
  - Investigated osmotic forces and fractionation of fluids by dialysis
  - “It may perhaps be allowed to me to apply the convenient term dialysis to the method of separation by the method of diffusion through a system of gelatinous matter.”

- John J. Abel, 1857 - 1938
  - Baltimore, 1912
  - The first professor of pharmacology at Johns Hopkins University School of Medicine
  - Applied the principles described by Graham to remove substances from the blood of a living animal
  - Together with Benjamin Turner and Leonard Rowntree, Abel built the first functioning dialysis machine
1st successful dialysis of a dog

- Circulated blood through celloidin tubing immersed in a saline-dextrose solution wrapped around a rotating drum using hirudin as an anticoagulant. Urea passed into the solution and oxygen passed into the blood in a process Abel called vividdiffusion.


Georg Haas, 1886 - 1971

- Physician, Giessen, Germany 1924
- Unaware of Abel’s work likely due to WWI, independently developed a dialyzer suitable for rabbits and dogs
- In 1925, proposed that the methodology and anticoagulation (hirudin) application had become sufficiently reliable to employ dialysis on humans with uremia

Haas G. Versuch der Blutauswaschung am Lebenden mittel der Diffusion. Klin Wochenschr 1913;4:413-4

First human hemodialysis

- Vascular cannulas inserted into left radial artery and antecubital vein under local anesthesia with no untoward effect from the procedure
- Dialyzing using celloidin tubes and hirudin anticoagulation for 15 minutes
- Calculating that 150 ml of blood had been cleansed
- 2nd patient a uremic boy, dialyzed for 35 minutes


February 18, 1925

January 1928

"There have indeed only been three cleansings on a grand scale up to now – and I know that one swallow still doesn’t make a summer – but despite the limited number of observations, I have already gotten the distinct impression that it is worth the effort to continue along the path taken."

George Haas in a lecture to the Giessen Medical Society, Giessen, Germany.

Willem J. Kolff, 1911 - 2009

- Physician, Kampen, The Netherlands, 1940
- "When I was this young assistant at the University of Groningen my responsibility was for four beds, or rather the patients in four beds. That was all I had to do. And, one of these patients was a young man, 22 years old, who slowly and miserably died from renal failure. He became blind, he vomited, and it was a miserable death. And I, as a very, very young physician, had to tell his mother, in a black dress and a little white cap like the farmers have, that her only son was going to die. I couldn’t do a damn thing about it. So, I began to think, ‘If I could just every day remove as much urea as this boy creates, which is about 20 grams, then the boy could live.’ Well, he died, but I began to work on that."

"I started to work on that..."
Willem J. Kolff, 1911 - 2009

- Began to experiment with cellophane sausage casings, 2.5 cm wide x 30 – 40 m long, wound about a cylindrical drum (initially a beer can), to be perfused with a patient’s blood, through a rotating coupling (copied from a Ford water pump)
- The lower half of the drum is immersed in a stationary tub containing dialysate
- Rotation of the horizontal drum (together with arterial pressure) would propel the blood through the tubing eliminating the need for a blood pump

Early dialysis machines in Kampen

Willem J. Kolff, 1911 - 2009

- I had one patient with chronic renal failure that was in 1943, during the war. And, I dialyzed one-half liter of blood, and had it run through that artificial kidney and gave it back to her. And then waited two days to see if anything terrible would happen. Nothing happened. And so, I then took a little more blood, and so on. By that way, at that time if either an institutional review committee for research on human patients, or the FDA had been breathing down my neck, the artificial kidney would never have been made. Never. My conscience was my only brake. Otherwise, I could do what I wanted. But I had to explain to the patient what I was going to do, and I always did.

March 17, 1943

- Janny Schrijver, 29 yo housemaid with “contracted kidneys and malignant hypertension” presented with terminal uremia, cardiac failure, and BP 245/150
- Initially, fractionated dialysis was performed with increasing aliquots of blood and decreasing symptomatology was noted after each treatment
- In subsequent sessions, continuous dialysis was performed via femoral arterial supply and peripheral venous return followed by radial arterial supply and then various surgical cut down which was complicated by bleeding
- By treatment #12, no further arteriotomies or venesections possible and the patient expired on Day 20 of treatment

March 1943 – July 1944

- Kolff continued to struggle with membrane leaks, hemolysis, blood line disconnections, and hemorrhages
- 15 patients with AKI treated and only 1 survived
- A man with lobar pneumonia given sulfanilamide became anuric
- Following one session of dialysis his BUN fell from 220 to 102 mg/dl
- Definitive therapy came shortly thereafter when the sulfonamide crystals were removed from his ureters and kidney function returned
September 1945
- Sophia Schafstad, 67 YO, National Socialist imprisoned in Kampen, The Netherlands, suffered acute cholecystitis, jaundice, and AKI presumed secondary to sulphonamide therapy.
- Thereafter her BUN rose to 185 (400) mg/dl, she lost consciousness, and was transferred to Kolff’s “Kidney Room.”
- Her initial dialysis session lasted 11 hours during which she regained consciousness. She improved markedly and her diuresis and recovery began within 1 week.
- She died 6 years later from an unrelated illness.
- “It's now been proven that the artificial kidney can save a life, but it's not been proven that it's of any real use to society.” The moral is that we have to treat patients when they need help, even if we don't like them.

George Thorn and John Merrill
- In the years immediately following the war, he shipped free dialysis machines to researchers in England, Canada and the United States.
- In 1947 Kolff traveled to the United States to promote the use of his machine. He gave the blueprints of his latest invention to doctors at the Peter Bent Brigham Hospital and explained the technique he used.
- The doctors included John Merrell, Karl Walter, and George Thorn. The trio made kidney dialysis a standard treatment for kidney problems.
- They also used dialysis to support patients in their pioneering development of kidney transplantation in 1954. Dialysis made the transplanting of kidneys possible by keeping patients alive until their new kidneys started to function.

Kolff–Brigham Kidney
- The Kolff-Brigham kidney passed its practical test under extreme conditions during the Korean War.
- At that time, eight of ten injured soldiers with post-traumatic kidney failure died.
- Major Paul Teschan, a military doctor with the U.S. Army, was familiar with the work at the Peter Bent Brigham Hospital and took one of the machines from the Walter Reed Army Hospital to a MASH (Mobile Army Surgical Hospital) unit in Korea where he used 72 treatments to dialyze 31 patients.
- Under the most extreme conditions, the use of dialysis was able to significantly increase the average survival rate of the severely ill patients and win time for additional medical procedures.

Boston, 1949
- Modifications to the Kolff Rotating Drum to increase the safety and efficiency of the procedure for clinical use.
- Warm dialysate, minimize clotting and hemolysis, reduce pyrogen reaction, minimize leaks, improve blood flow control and fluid exchange, and optimize dialysate composition.

**Paul Teschan**

- 1940s, Lund, Sweden
- Introduced the concept for the Arterio-venous fistula
- In studies with anuric rabbits he created shunts between the carotid artery and jugular vein using siliconised glass tubes joined by narrow glass capillary
- Device rapidly clotted despite repeated heparin administration and was predisposed to local infection

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**Nils Alwall, 1904 - 1986**

- Developed a new system with a vertical stationary drum kidney and circulating dialysate around the membrane
- Into this system negative hydrostatic pressure was applied to achieve controlled ultrafiltration

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**Criticism**

- Careful conservative management was the mode of care of almost all patients with acute renal failure at this time
- Conservative management had become so well understood that in good units, periods of oliguria of up to 2-3 weeks could be managed without dialysis
- The important principles were: strict fluid balance, stringent sodium and potassium restriction, and protein-free high calorie intake to reduce muscle breakdown and urea generation

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**John Peters, 1887 - 1955**

- The value and proper role of the variety of artificial dialyzing procedures remain subjects for investigation, and interestingly demonstrated is the artificial kidney of the Kolff design in competent hands has been a serious hazard to the patient. It has been shown that an artificial kidney is efficient and a use of the artificial kidney in the treatment of kidney disease has been an important addition to the medical bag of tricks. Further it appears that the artificial kidney may well increase the mortality rate in lower nephron nephrosis.

(From John Peters)
Belding Scribner, 1921-2003

- Seattle, Washington, 1960
- Lack of a procedure for repeated vascular access limited dialysis to patients with acute kidney injury
- Unaware that shunting of cannulas was previously attempted and that Teflon had non-stick properties, Scribner hoped to create an external shunt connecting cannulas in the radial artery and forearm vein to enable repeated dialysis treatments

Scribner Shunt

- Two cannulas made of thin-walled Teflon tubing with tapered ends were inserted in the radial artery and cephalic vein, near the wrist, the external ends were connected to a curved Teflon bypass tubing using two SwageLock couplings, which were fixed on a stainless steel arm plate
- When it was time for dialysis, the U-shaped portion could be disconnected and the artery and vein extensions connected to the artificial kidney.
- Thus treatment no longer required new incisions and repetitive trauma to vasculature
- Modifications and improvements in the years following resulted in an all Silastic shunt system, with a single break, a short single Teflon connector and Teflon tips, and the arm plate omitted

March 1960

- Clyde Shields, 39 YO, Boeing machinist with end stage renal disease secondary to chronic glomerulonephritis
- March 9, 1960, Shields uremic, vomiting, and unable to ambulate with a BUN 125 mg/dL, creatinine 20 mg/dL, and hematocrit 22%
- Following 76 hours of dialysis, Shields much improved – no longer vomiting, fully ambulatory, and able to go home
Shortly thereafter, 2 additional patients initiated chronic hemodialysis, Harvey Gentry and Rolin Heming without much thought to the implications of chronic life saving therapy. University Hospital in Seattle Administration placed a moratorium on the acceptance of new patients. It was estimated that dialysis would cost $10,000 – 20,000 per year per patient and research monies would soon prove insufficient.

Scribner and his colleagues worked hard to keep treatment out of the public eye. Immense pressure from physician colleagues to accept more patients. They felt that all segments of society, not just the medical community should share the burden of choice.

1961 – King County Medical Society and the Seattle Area Hospital Council with funding support from the John A. Hartford Foundation later supplemented by a grant from the US Public Health Service established a community based hemodialysis unit in the basement of the Swedish Hospital’s Nurses’ residence hall. Estimates at the time suggested that there would be 5 – 20 ideal candidates for long term dialysis per million population per year. A selection process was thus needed so 2 committees were established:

Medical Advisory Committee made initial screening based on stringent medical criteria:
- A stable, emotionally mature, responsible citizen disabled by symptoms of uremia
- Absence of long-standing hypertension and its permanent complications
- Willingness to cooperate in carrying out the prescribed treatment
- Age 25 – 45 years
- Slow deterioration of renal function (serum creatinine 8-12 mg/dl)
- Six months of residence in the area (WA, AL, D, MT, OR)
- Financial support
- Value to the community
- Potential for rehabilitation
- Psychological and psychiatric compatibility
- Children and young adults who were not potentially self supporting were excluded

The Life or Death Committee:
- Admissions Advisory Committee
- A voluntary and anonymous committee representing a cross-section of the community
- A lawyer, minister, banker, housewife, state government official, labor leader, and surgeon
- Factors governing their decisions included: age and sex of the patient, marital status and number of dependents, income, net worth, emotional stability with particular regard to the patient’s capacity to accept treatment, educational background, nature of occupation, past performance and future potential, and names of people who could serve as references.

Surgeon: how do the rest of you feel about Number 3 – the small businessman with 3 children? I am impressed that his doctor took special pains to mention that this man is active in church work. This is an indication to me of character and moral strength.
- Housewife: Which would certainly help him conform to the demands of the treatment.
- Lawyer: It would also help him to endure a lingering death.
- Minister: Perhaps one man is more active in church work than another because he belongs to a more active church.
Banker: We could rule out the chemist and accountant on economic grounds. Both do have a substantial net worth...

Lawyer: Both these men have made provisions so that their deaths will not force their families to become a burden on society.

State official: But that would seem to be placing a penalty on the very people who perhaps have been most provident...

HR 1


Conclusion QI Initiative

Replacement of renal function book page 30-40

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