Dialysis History of Innovation

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What is Innovation?

The introduction of something new

- A device that improves quality, reduces labor, or increases availability (the dialysis machine)
- A method or procedure that saves time, increases safety or reduces cost (dialyzer reuse automation)
- Something that deviates from established doctrine or practice (home dialysis)
- A application of scientific principals to perform a known function in an entirely different manner. (CAPD)

Membrane Innovation

- In order to dialyze at all, there needs to be a semipermeable membrane to separate the blood from the dialyzing fluid
- The development of this membrane occurred indirectly by accident, but innovation took over after that

The first practical membrane

- 1845 Friedrich Schoenbeim spills a combination of nitric and hydrochloric acids and wipes it up with his wife's cotton apron.
- The reaction synthesizes cellulose trinitrate (gun cotton).
- He patents the process and forms his own company making the product which proved to be a fairly safe explosive for construction and mining.
- The material is modified by Alfred Nobel of Sweden into a controlled explosive called dynamite.
- Nobel uses his wealth to create the Nobel Prizes.
- Schoenbeim also created cellulose dinitrate which could be dissolved in ether and then dried to make thin films of the material.

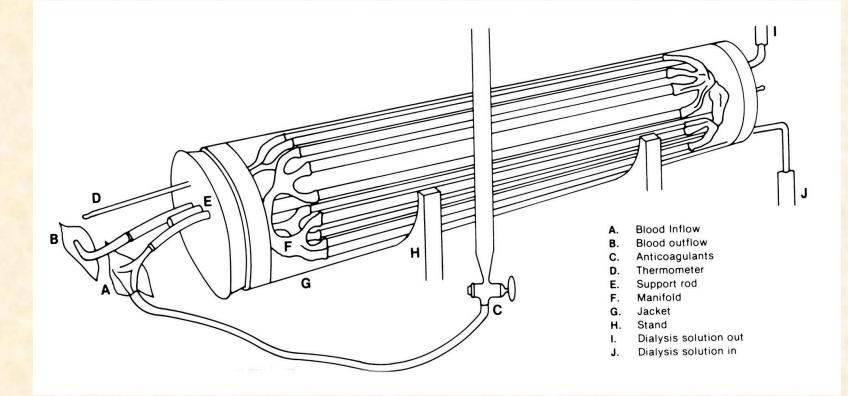
The development of Collodion

- Sheets of cellulose dinitrate were used as surgical dressings and the basis for photographic film until 1935.
- The material was called "collodion" from the Greek word "Kolla" for glue like substance.
- In the laboratory it became known as a good semipermeable membrane and was used by Fick to study diffusion.
- 1913 It was used by Able, Roundtree, and Turner to perform the first in vivo studies of blood. They made the collodion into tubes by dipping glass rods into the collodion solution.
- 1924 Haas dialyzed patients using collodion for two years but none of the patients lived.
- 1929 Collodion was replaces by cellulose acetate when the Visking company in Chicago started making tubes of cellulose acetate for sausage casing.

Abel, Roundtree, and Turner (1912 – 14)

- The Team:
 - John Jacob Abel Pharmacologist
 - Leonard Roundtree MD
 - Bernard B. Turner Biochemist
- The Innovation:
 - First artificial kidney apparatus
 - Able did the chemical analysis
 - Roundtree was the glass blower
 - Turner made the membrane

The First ARTificial Kidney



Equipment Innovation

- Dr. Kolff's rotating drum dialyzer was a crude device. The drum was made of wood and there was no cover.
- Improvement to this system's design to expand it's use to more patients was needed

Kolff, Walter, and Olson (1948)

- The Team:
 - Willem Kolff MD
 - Carl Walter Surgeon (the "wal" in Fenwal)
 - Edward Olson Engineer
- The Innovation:
 - The Kolff Brigham Kidney

Before.....



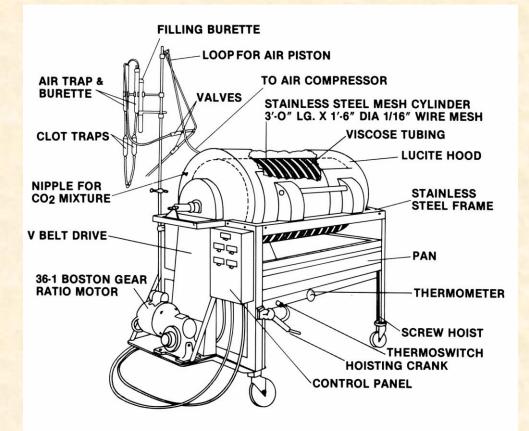
Photo from Global Education Museum – Largo, Florida





Photo from Global Education Museum – Largo, Florida

The Kolff Brigham Kidney



Reducing the Blood Required for Dialysis

- The Kolff- Brigham dialyzer was definitely a better mouse trap than the Kolff rotating drum, but it still needed more blood than the patient could provide in order to operate.
- Two creative MD's, both from Scandinavian countries, designed dialyzers to address the problem.

Nils Alwall Dialyzer - 1946

- Created in Lund, Sweden
- Called a vertical drum
- Required a blood pump
- Positive pressure on blood created UFR
- Alwall built 1st dialysis center – 1950
- Founded Gambro 1964



Fred Kiil Dialyzer - 1960

- Created in Oslo, Norway
- Used cuprophan membrane
- Priming volume = 300 cc
- No blood pump needed if patient had shunt
- Negative pressure on dialysate created UFR
- Scribner used for overnight unattended HD



First mass produced dialyzer and machine

- Even with "modern" dialyzers like the Kill and Alwall design, there was a need to to have a dialyzer that could be used quickly and conveniently.
- In the early 50's, Kolff traveled to Chicago to see if Abbott Laboratories was interested in manufacturing his latest coil dialyzer design.
- Abbott quickly and politely said "no thanks".
- Having some unexpected extra time before his plane back to Cleveland, Kolff took a short cab ride down the street....

1956

- Kolff meets William B. Graham, Chemist and Senior Chairman of Baxter Healthcare.
- Baxter develops the first disposable coil.
- The model number is: U200A
- It comes with arterial and venous blood lines for "only" \$59.00.
- UA 10 = 100 liter batch tank = \$975.00
- UA 11 = Sigmamotor Pump = \$310.00
- Date: October 30, 1956

Genesis of the Artificial Kidney, Pat McBride, Baxter Healthcare, 1987, pg. 43-47

First complete hardware system



Baxter Dialysis Historical Museum - Largo, Florida

The First Shunt

- Even in the 1950's access was still a problem. The number of dialysis treatments per patient was limited to the number of access sites a patient could tolerate.
- The need for a single site that could be utilized multiple times would enable a patient to live longer and increase the possibility of the return of renal function

Scribner, Quinton, Shields, Dillard (March 9th, 1960)

• The Team:

- Belding Scribner MD
- Wayne Quinton Biomed Engineer
- David Dillard Surgeon
- Clyde Shields Patient
- The Innovation:
 - First permanent shunt

The First Cannula

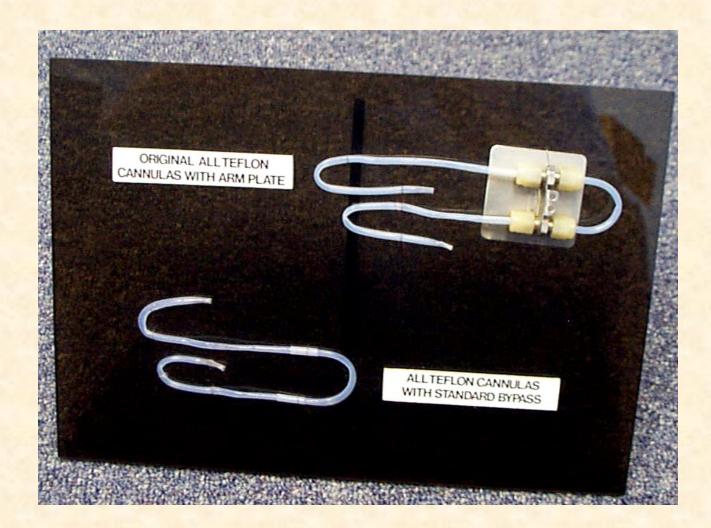


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Clyde Shields

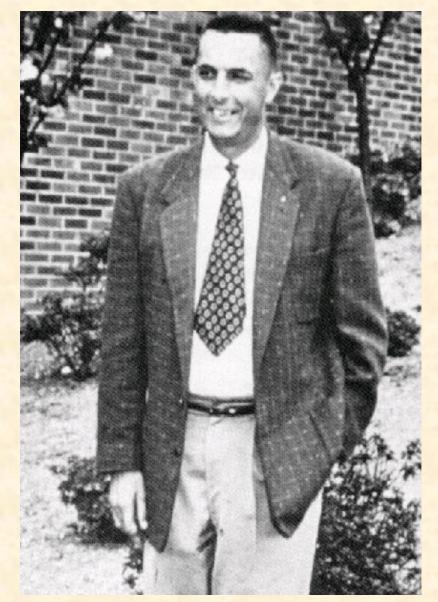


Photo: Genesis of the Artificial Kidney, Pat McBride, Baxter Healthcare, 1987, pg. 50

Quinton, Palmer (1964)

- The Team:
 - Wayne Quinton Biomed Engineer
 - Robert Palmer MD
- The Innovation
 - First silicone catheter for PD

Palmer Catheter

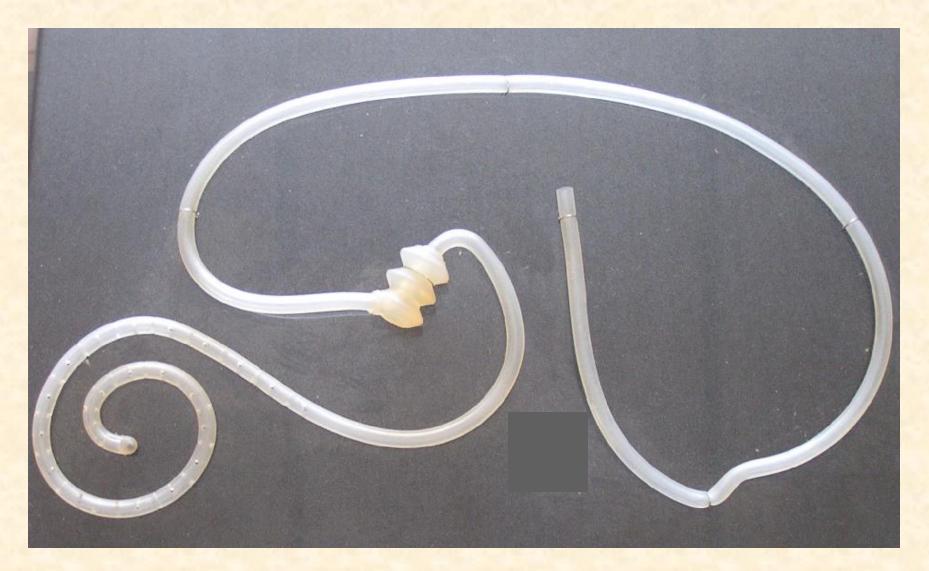


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The individual dialysis machine

- In the early days of dialysis kidney centers used central dialysis systems. One dialysate chemistry for all patients.
- As centers reached capacity new patients had to be turned away.
- The idea that a patient could dialyze themselves was basically unheard of.
- The need was for an automated machine that a patient could use.

Scribner, Babb, Helm (1964)

- The Team:
 - Belding Scribner MD
 - Albert "Les" Babb Chemical Engineer
 - Caroline Helm 1st Patient
- The Innovation:
 - First single patient machine

Albert Leslie Babb



- Univ. of British Columbia 1948
 B.S. Chemical Engineering
- Univ. of Illinois 1951
 PhD Chemical Engineering
- Univ. of Washington 1961-1981 Head of Nuclear Engineering Dept.
- Created 1st Proportioning Dialysis Machine in 1963
- Created 1st Home Dialysis Machine in 1964
- Nominated for Noble Prize in 1977
- Professor Emeritus 1992

The Mini - I

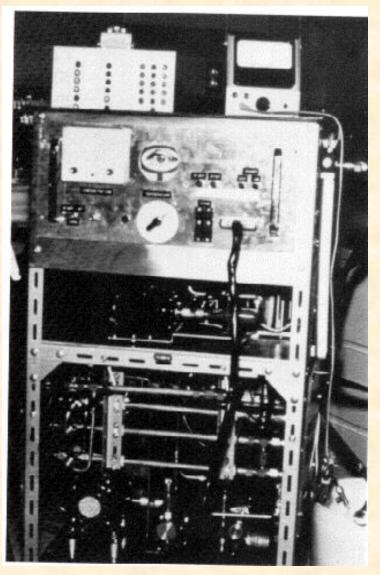


Photo: Genesis of the Artificial Kidney, Pat McBride, Baxter Healthcare, 1987, pg. 77

Caroline Helm and her machine

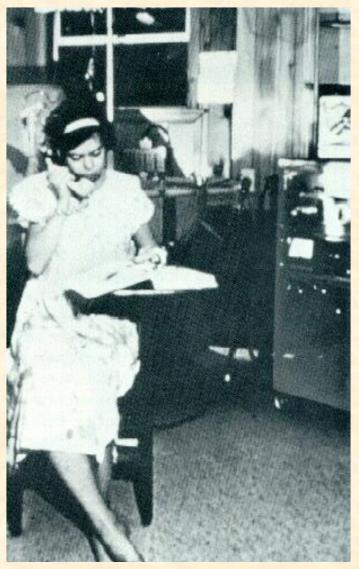


Photo: Genesis of the Artificial Kidney, Pat McBride, Baxter Healthcare, 1987, pg. 62

The 1st Commercial Proportioning HD Machine

•Chronic dialysis creates a large ESRD patient population.

Mass production of equipment/dialyzers becomes a necessity.

•The collaboration of individuals to fill this need are:

- University of Washington
 - Belding Scribner Nephrologist, Head of Nephrology Dept.
 - Albert "Les" Babb Chemical Engineer
- Milton Roy Company
 - Robert T Sheen Chemical Engineer, Cofounder and CEO
 - John Martin Mechanical Engineer

•Albert Babb created the prototype and John Martin refined the device to enable mass production.

•The machine was called the Model A. The Model B and Model C would follow over the next 5 years.

Design and Construction of a Portable, Single Patient, Dialysate Proportioning Machine at the University of Washington 1964-1965, A. L. Babb, ASAIO Journal 1995.

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Milton Roy Model A - 1965

Solid state logic circuit

Electronics – "works in a drawer"

Automated hot water sterilization system (90°C)

> Pre-treatment alarm testing



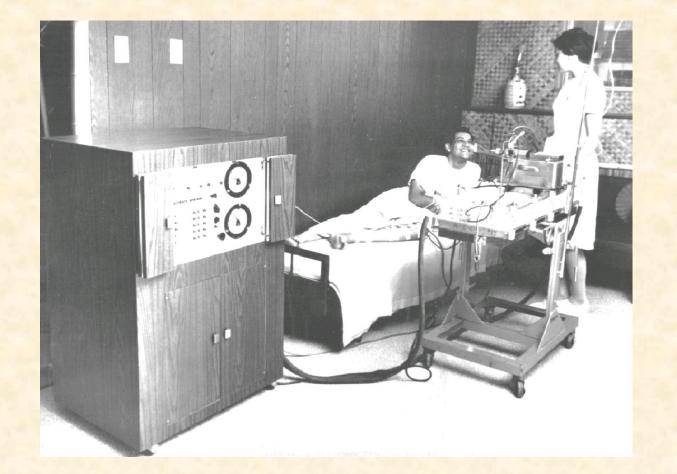
Patient remote control

Wood veneer for that "furniture" look

Acoustic tile to reduce noise

Adjustable Dialysate Prescription

Model A with Patient



Carlos Clar and his wife dialyze at their home in Seattle Washington. (Milton Roy Annual Report – 1965)

Dialysis Machine Evolution

- As good as the Model A was it had drawbacks:
 - Needed 220 V to run
 - Took up a lot of bedroom space
 - Sophisticated electronics
 - Was expensive (\$7200 in 1965)
- What was needed was a "Chevy" to replace the "Cadillac"

Drake, Willock, Smith (1965)

- The team:
 - Richard Drake MD
 - Charles Willock Engineer
 - Robert Smith Business
- The Innovation:
 - DWS Model 4002 Hemodialysis Machine

DWS Model 4002 (1965)



Photo from Global Education Museum – Largo, Florida

HD Equipment Progression

- •1967 Gambro AK 1
- •1969 Drake Willock 4215
- •1970 Milton Roy Model BR
- •1971 Gambro AK 3
- •1972 B Braun HD 103
- •1972 Marquardt REDY
- •1975 Cobe Centry 2
- •1977 Gambro AK 10
- •1978 Extracorporeal SPS 350
- •1980 Cobe Centry 2Rx
- •1981 Cobe Centry 2000
- •1984 B. Braun HD-secura

- •1984 Drake Willock DWS-480
- •1984 Fresenius 2008C
- •1984- Travenol SPS 450
- 1987 Cobe Centrysystem 3
- •1988 Baxter SPS 550
- •1991 Baxter 1550
- •1991 Althin System 1000
- •1992 Fresenius 2008H
- •1995 B. Braun Dialog
- •1996 Gambro AK 95
- •1997 Althin Tina

A New Therapy to Replace HD

- Although peritoneal dialysis had been around a long time (actually before HD) it was never considered to be a therapy for continuous dialysis of a patient.
- The development of CAPD truly fits the quote, "Where there is a will, there's a way."

Moncrief, Popovitch, Pilcher (1975)

- The Team: (1975)
 - Jack Moncrief MD
 - Robert Popovich Biomedical Engineer
 - Peter Pilcher Patient
- The Innovation:
 - Continuous Ambulatory Peritoneal Dialysis

Moncrief and Popovich



Photo: Genesis of the Artificial Kidney, Pat McBride, Baxter Healthcare, 1987, pg. 95





Photo: PD Milestones Poster (5K9314), Pat McBride, Baxter Healthcare Corp.

Baxter CAPD System Innovation Worldwide Results in Improved Patient Safety and Convenience



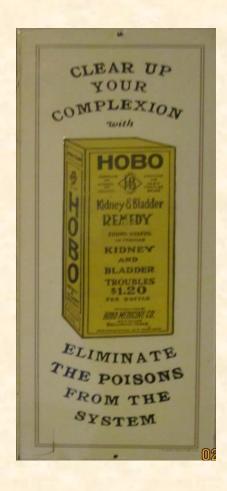
What needs Innovating in Your Facility?

- Simplification of complex procedures.
- Updating of training materials for new employees.
- Reorganization of the storage area to make it more efficient.
- Action items list for when there's an emergency.
- Plan to reduce patient time spent in the waiting room.

Qualities of Innovational People

- Desire to fill a need.
- Knowledge of the subject.
- Don't mind asking for help.
- Possess organizational skills.
- Attitude to learn from experience.
- Discipline to follow through.
- Satisfaction in accomplishment.

Where would we be without Innovation?



References

- History of the treatment of renal failure by dialysis, J. S. Cameron, Oxford Press, copyright 2002, pp.32-43.
- Genesis of the Artificial Kidney, Patrick McBride, Baxter, copyright 1987, pp. 3,50,62.77.
- The Introduction of CAPD, Jack W. Moncrief, Trans Am Soc Artif Intern Organs, Volume XXXIV, 1988, pp.86-87.
- Chronic Hemodialysis in Seattle: 1960-1966, Part I, Belding H. Scribner and Albert L. Babb, DIALYSSIS & TRANSPLANTATION, Volume 11, Number3, March 1982, pp. 223-229
- Laudation Albert Leslie Babb, PhD, PE, Twardowski, Hemodialysis International, Vol. 7, No. 4, 2003, pp.269-276