DREAM DOCTOR©

Research Report

Research Report

Continuous Cycler Assisted Peritoneal Dialysis Machine for Children

Student name: Eva McSweeney
Student Number: C00003607
Submission Date: 27th January 2006

Table of contents

List of figures

1.0 Introduction

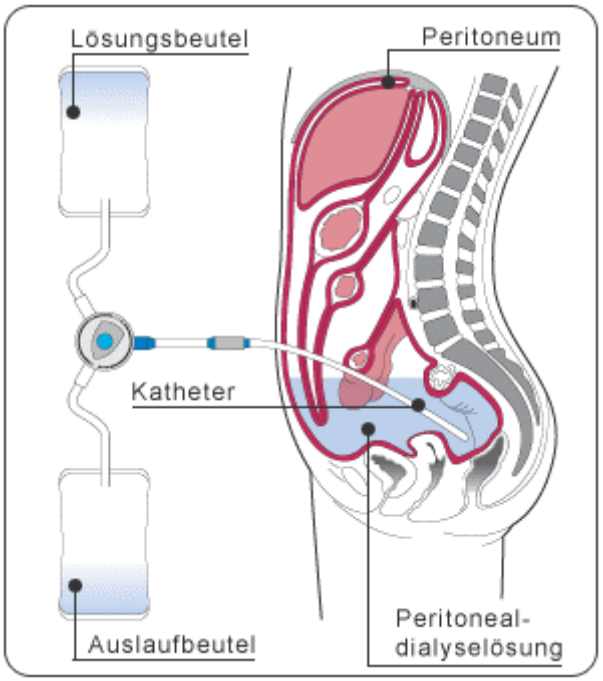
Chronic kidney failure is a condition that affects more than 1,300,000 individuals worldwide. There has been a 33% increase in kidney patients on dialysis treatment in Ireland over the past three years, according to new statistics from the Irish Kidney Association. With this rise in dialysis patients a gap has been identified in the market for a continuous cycler assisted peritoneal dialysis machine aimed specifically at children.

Dialysis treatment is distressing for all patients but most especially children who may not understand the need for the dialysis or the process that is taking place. I propose to design a new machine that enables the child to undergo dialysis at night time while asleep. The new product will be much easier to set up and use, the child should also understand what is going on during the process and can track their treatment with a game like interface. The machine will promote a sleep environment.

Sustainability is a major issue to be considered, the fluid bags should be eliminated and replaced by reusable packs. The machine will be less medical looking so that the child wont be embarrassed of it.

Basic principles of peritoneal dialysis:

The blood is cleaned using the body's natural peritoneal membrane. The fluid flows into the membrane and is held for a specified time, the toxins in the blood are drawn into the liquid, it is then drained using gravity and disposed of as waste.



2.0 The research plan

Title: Continuous cycler-assisted peritoneal dialysis machine for children

Hypothesis: it is possible to develop a continuous cycler-assisted peritoneal machine aimed specifically at children; it should enhance the overall user experience.

Information search:
Baxter Health Care
Fresenius Medical Care
Pinewood Healthcare/ Gambro, Clonmel
South Eastern Health Board, Lacken, Kilkenny.

User research:
Irish Kidney Association
European Dialysis & Transplant Nurses Association
European Renal Care Association

2.1 Implementation of research methodologies

Interviews and user visits:

Marian Tallis, Kilkenny
CCPD user – home visit
13th December

Aileen Russell, Pei Surgical
Clinical Services Manager – telephone interview
13th December

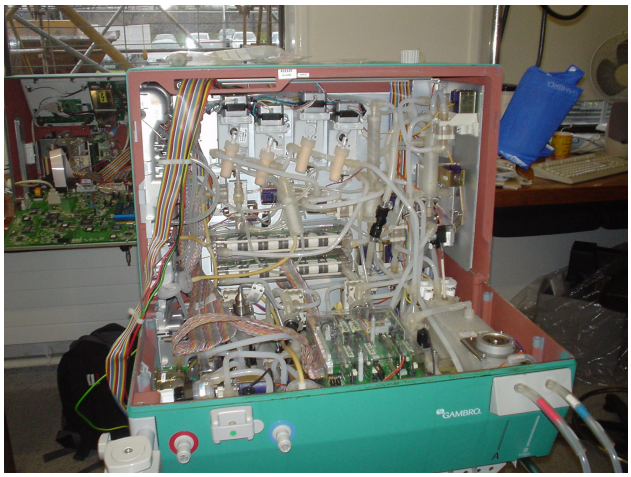
Paul Lowe, Beaumont Hospital
Senior dialysis technician – hospital visit
9th January

Peter Thomas, Beaumont Hospital
Dialysis technician – hospital visit
9th January

Catharine Corcoran, Beaumont Hospital
Dialysis nurse – hospital visit
9th January

Bernie Clancy, Our Lady's Hospital Crumlin
Dialysis head ward nurse – hospital visit
9th January

Marian Tallis's CCPD machine



Haemodialysis machines from Beaumont Hospital

2.2 The contact list

Aileen Roussell,
Clinical Services Manager,
Pei Surgical,
Kilkenny.
rousella@pei.ie
086 8373012

Irish Kidney Association
1890 456 556
Deborah,
Donor House,
Block 43A,
Parkwest,
Dublin 12
01 6689788

Fiona Murphy, Lecturer at Trinity College Dublin.
Fiona.Murphy@tcd.ie

Gary McManneman,
Senior Biomedical Engineer,
Mayo General Hospital.

Dara Purcell,
South Eastern Health Board,
Lacken, Dublin Rd.,
Kilkenny.
purcelld@sehb.ie

Paul Lowe,
Senior Technician,
Beaumont Hospital,
Dublin.
paullowe@beaumont.ie
01 8092512

Temple Street Children's Hospital,
info@cuh.ie

Baxter Healthcare,
Renal_customer_services_uk@baxter.com
Pat Meehan
Business Manager
01 2065531
Gay Grant

Pinewood Healthcare,
Brian Dowling,
Ballymacabry,
Clonmel,
Co. Tipperary.
01 4569123

Bernie Clancy,
Dialysis ward manager
Bernie.Clancy@olhc.ie
01 4096974

3.0 The user

The parent
The child's parent will be the one doing the initial exchanges and teaching the children how to do it themselves. They will have to fully understand the process and how to identify and solve problems if they occur.

The child
The child is the main user as it is they undergoing the dialysis process. They must fully understand what is happening and what to do if something goes wrong. They must be thought about the importance of hygiene.

Pediatrician
A pediatrician is a doctor who treats children. The child's pediatrician is likely to be the first to recognize a kidney problem, either during a routine physical exam or while treating an ailment.

Nephrologist
A nephrologist is a doctor who treats kidney diseases and kidney failure. The nephrologist may prescribe treatments to slow disease progression and will determine when referral to a transplant centre or to a dialysis clinic is appropriate.

DialysisNurse
A nurse with special training will make sure all procedures are followed carefully. The dialysis nurse will train the user so they feel comfortable doing the exchanges at home.

3.1 Product environment

The product is mainly used in the bedroom, it needs to be near a power outlet and access to the bathroom and adequate draining is necessary. The machine should also be easily portable, as trips to the hospital with the machine will occur quite regularly. The machine should not restrict the child's or the family's social life and should be able to be brought away on holidays.

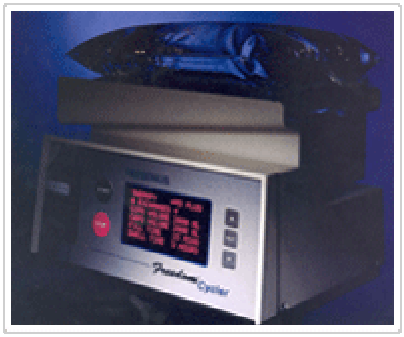
The product should be at the same level as the child, so will either need a bedside table of adequate size or its own stand. Space can be quite limited in children's bedrooms. The machine should be stable and not easily knocked over.

The machine should blend in with the child's environment and not attract too much attention to itself, however it should be clear that it is not a toy and is not to be fiddled with.

Key considerations

- Needs to be near a power outlet
- Access to drainage necessary
- Should be portable
- Needs to be at the same level as the child
- Needs a stand
- Should not look like a toy
- Should be approachable

3.2 Existing and related products



Freedom Cycler
Fresenius Medical Care
http://www.fmcna.com

- **Purpose:** APD
- **Size:** Weight 30.4 lbs.; Height 11"; Length 15.5"; Depth 16"
- **Benefits:** Includes heater tray and valve system for filling and draining
- **Special Features:** Primarily used for paediatric treatments

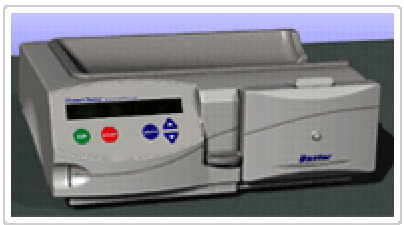
90/2 Cycler
Fresenius Medical Care
http://www.fmcna.com

- **Purpose:** APD
- **Size:** Weight 51.2 lbs.; Height 12"; Length 16.5"; Depth 16"
- **Benefits:** Includes two pumps: a main pump for pumping solution to the gravity bag and a waste pump to pump to waste
- **Special Features:** Easy-to-use five-valve system

Freedom Cycler PD+
Fresenius Medical Care
http://www.fmcna.com

- **Purpose:** APD
- **Size:** Weight 25.0 lbs.; Height 7.5"; Length 15"; Depth 12.8"
- **Benefits:** Smaller, more portable, and easy to set up
- **Special Features:** Only cycler with a "pause" option for peritoneal dialysis

HomeChoice PRO™
Baxter Healthcare
http://www.baxter.com/



- **Purpose:** CCPD/APD
- **Size:** Weight 26.8 lbs.; Height 7"; Length/Width 19.5" x 15.7"
- **Benefits:** Automated dialysis overnight, easy to use, and accurate recording
- **Special Features:** Transfer therapy data

from home to dialysis centre and vice versa

HomeChoice™
Baxter Healthcare
http://www.baxter.com/

- **Purpose:** CCPD/APD
- **Size:** Weight 26.8 lbs.; Height 7"; Length/Width 19.5" x 15.7"
- **Benefits:** Easy trouble shooting without interrupting treatment and easy programming
- **Special Features:** *Smart Dwell* – calculates the maximum dwell time for each session to eliminate fill and drain time

Quantum™
Baxter Healthcare
http://www.baxter.com/

- **Purpose:** CAPD
- **Size:** Weight 25 lbs.; Height 53” (unfolded), 8.5” (folded)
- **Benefits:** Automatically delivers one PD exchange while patient sleeps
- **Special Features:** Better solute clearance without increasing patient's therapy load

Selectra

For CAPD patients, SELECTRA offers the advantages of a single set up per day, readily available warm solution, and the flexibility to tailor treatment to suit individual lifestyle.

SELECTRA is also an ideal machine for manual PD. Treat peritonitis with ease. Simple to operate yet saves valuable time spent on manual PD treatment. Intensive care and non-renal nurses will especially benefit from this unique machine.

Weighs only 11 Kg

Packs easily into a portable suitcase with enough supplies for weekend travel

Selectra Carrying Case
(H 550 x W 400 x D 200) mm

4.0 The process

4.1 The kidneys

The kidneys are a pair of fist-sized organs located in the small of the back behind the peritoneum. The kidney is composed of two regions, the renal cortex and medulla. The cortex is where the renal corpuscles reside, proximal tubules, and distal tubules are found. The medulla is home to the loop of Henle, vasa recta, and collecting tubules. Urine from the various collecting ducts drains into the renal pelvis, ureter, and bladder.

Major functions

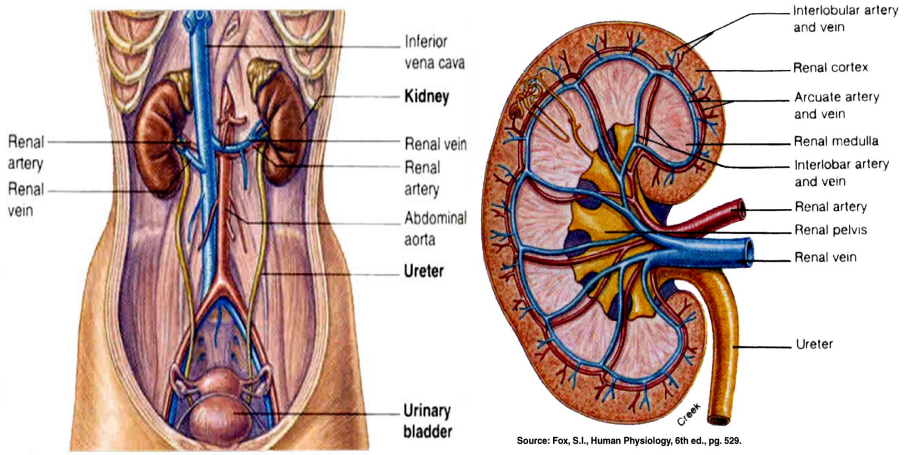
The kidneys are often thought of as the body's filters, removing toxins and metabolic waste products from the body. The kidneys certainly perform this task; however they have a few more responsibilities, without which we would not be able to survive.

As part of the body's waste-removal system, healthy kidneys work primarily to clean the blood of wastes produced through food intake and metabolic function. Every hour of every day, blood travels from the heart to the kidneys for a "cleansing" process. Millions of tiny filters in the kidneys remove unwanted waste and extra fluid from the body. This unwanted waste and extra fluid is excreted through the kidneys in the form of urine. Healthy kidneys also keep body chemicals, or "electrolytes," in balance. They also produce a hormone to regulate blood pressure, and another hormone to help bone marrow produce red blood cells to carry oxygen through the body. Kidney failure, when kidney function operates below 20 percent of normal function, is initially noticed when the body does not produce urine normally.

It is estimated that more than 1.2 million people worldwide suffer from end-stage renal disease (ESRD), a number that is growing at a rate of approximately six-to-seven percent annually. Additionally, the National Kidney Foundation (NKF) predicts that the number of kidney failure patients in the U.S. will double in the next ten years. This growth is influenced in part by diseases associated with the aging population such as diabetes and high blood pressure, two leading causes of ESRD. Current treatment options for ESRD include peritoneal dialysis (PD), hemodialysis (HD) and kidney transplantation. Worldwide, more than one million people suffering from chronic kidney failure are treated with some form of dialysis. However, approximately three million people with kidney failure currently go undiagnosed or untreated, particularly in developing countries.

Chronic kidney failure occurs when the kidneys are slowly damaged - this damage is over the long term and is not reversible. Most people with chronic kidney failure will require treatment to replace the function of their own kidneys.

Acute kidney failure occurs when the kidneys suddenly stop working. This may occur after surgery or due to an injury. It can also occur due to the use of certain drugs. People with acute kidney failure may regain their kidney function depending on the cause of the damage



4.2 Dialysis

Dialysis is a medical process through which a person's blood is cleansed of the toxins the kidneys normally would flush out. It is generally used when a person's kidneys no longer function properly. This can be a result of congenital kidney disease, long-term diabetes, high blood pressure or other conditions.

Dialysis may be either temporary or permanent, depending on the person. If a dialysis patient is waiting on a kidney transplant, the procedure may be temporary. However, if the patient is not a good transplant candidate, or a transplant would not alleviate the condition, dialysis may be a life-long routine.

There are two main kinds of dialysis used: peritoneal and hemodialysis. Peritoneal dialysis can be done in the home, by the patient, either alone or with a helper. Peritoneal dialysis uses the body's peritoneal membrane, inside the abdomen, to infuse a glucose-based solution into the abdominal cavity. The solution remains in the abdomen for about two hours, and is then drained out.

A surgeon must place a tube with a titanium plug inside the patient's abdomen for this procedure. The patient must also be trained to perform the procedure. Absolute attention to sterile procedures is required, or peritonitis could result. This is especially dangerous in patients whose immune systems may already be compromised or suppressed.

Hemodialysis is probably the procedure that most people are familiar with. This procedure is performed at a hospital or dialysis center. The patient is hooked up, via a tube in the veins, to a machine that circulates his blood through a machine, through semi-permeable filters that take out the toxins in the blood. The procedure usually takes three to four hours.

While dialysis may be a life-saving procedure, it is not perfect. Patients must follow a specialized diet that is higher in protein and lower in phosphorus and potassium, since these minerals tend to build up quickly in the blood. They must also limit their fluid intake, since dialysis only removes so much water from the patient's body. Infection

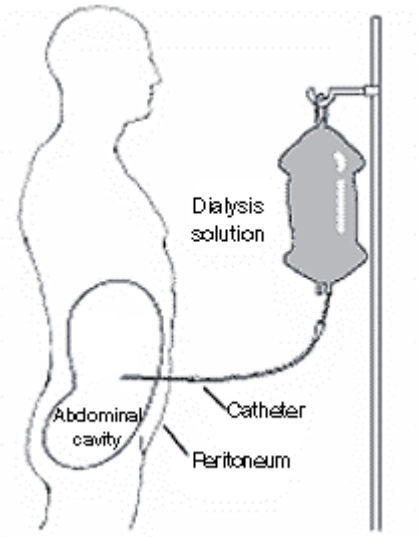
is also an ever-present spectre, since a permanent access point must be created in the body for either dialysis procedure.

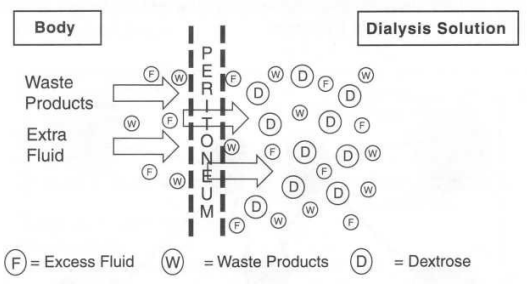
There are stories of people who have survived many years on dialysis, but the long-term outlook is not good without a transplant. Researchers are working to improve dialysis procedures and survival rates. Most doctors will tell a patient that the best treatment is to prevent kidney damage.

With peritoneal dialysis (PD), you have some choices in treating advanced and permanent kidney failure. Since the 1980s, PD has become a practical and widespread treatment for kidney failure. Since you don't have to schedule dialysis sessions at a centre, PD gives you more control. You can give yourself treatments at home, at work, or on trips. But this independence makes it especially important that you work closely with your health care team: your nephrologist, dialysis nurse, dialysis technician, dietician, and social worker. But the most important members of your health care team are you and your family. By learning about your treatment, you can work with your health care team to give yourself the best possible results, and you can lead a full, active life.

How Peritoneal Dialysis Works

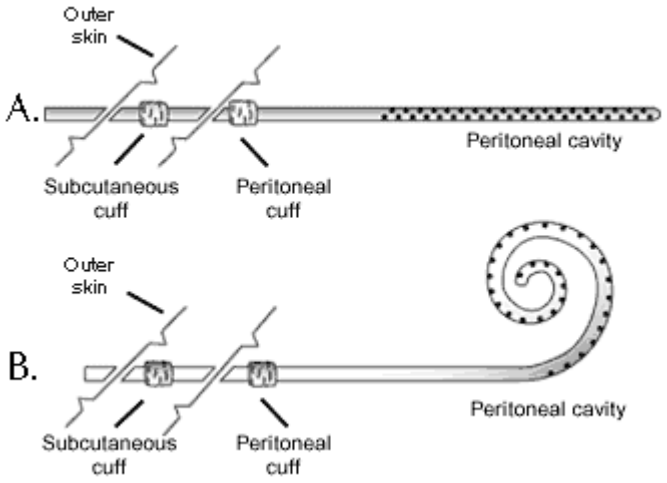
In PD, a soft tube called a catheter is used to fill your abdomen with a cleansing liquid called dialysis solution. The walls of your abdominal cavity are lined with a membrane called the peritoneum, which allows waste products and extra fluid to pass from your blood into the dialysis solution. The solution contains a sugar called dextrose that will pull wastes and extra fluid into the abdominal cavity. These wastes and fluid then leave your body when the dialysis solution is drained. The used solution, containing wastes and extra fluid, is then thrown away. The process of draining and filling is called an exchange and takes about 30 to 40 minutes. The period the dialysis solution is in your abdomen is called the dwell time. A typical schedule calls for four exchanges a day, each with a dwell time of 4 to 6 hours. Different types of PD have different schedules of daily exchanges.





The most common form of PD, continuous ambulatory peritoneal dialysis (CAPD), doesn't require a machine. As the word ambulatory suggests, you can walk around with the dialysis solution in your abdomen. Other forms of PD require a machine called a cycler to fill and drain your abdomen, usually while you sleep. The different types of cycler-assisted PD are sometimes called automated peritoneal dialysis, or APD.

The catheter is the tube that carries the dialysis solution into and out of your abdomen. After getting a local anesthetic to minimize any pain, the doctor will make a small cut, often below and a little to the side of the navel and then guide the catheter through the slit into the peritoneal cavity. As soon as the catheter is in place, they can start to receive solution through it, although they probably won't begin a full schedule of exchanges for 2 to 3 weeks. This break-in period lets you build up scar tissue that will hold the catheter in place.
The standard catheter for PD is made of soft tubing for comfort. It has Dacron cuffs that merge with your scar tissue to keep it in place. (Dacron is a polyester fabric.) The end of the tubing that is inside your abdomen has many holes to allow the free flow of solution in and out.



Two double-cuff Tenckhoff peritoneal catheters

Types of PD

Continuous Ambulatory Peritoneal Dialysis (CAPD)

If you choose CAPD, you'll drain a fresh bag of dialysis solution into your abdomen. After 4 to 6 or more hours of dwell time, you'll drain the solution, which now contains wastes, into the bag. You then repeat the cycle with a fresh bag of solution. You don't need a machine for CAPD; all you need is gravity to fill and empty your abdomen. Your doctor will prescribe the number of exchanges you'll need, typically three or four exchanges during the day and one evening exchange with a long overnight dwell time while you sleep.

Continuous Cycler-Assisted Peritoneal Dialysis (CCPD)

CCPD uses an automated cycler to perform three to five exchanges during the night while you sleep. In the morning, you begin one exchange with a dwell time that lasts the entire day.

Nocturnal Intermittent Peritoneal Dialysis (NIPD)

NIPD is like CCPD, only the number of overnight exchanges is greater (six or more), and you don't perform an exchange during the day. NIPD is usually reserved for patients whose peritoneum is able to transport waste products very rapidly or for patients who still have substantial remaining kidney function.

Preventing Problems

Infection is the most common problem for people on PD. Improved catheter designs protect against the spread of bacteria, but peritonitis is still a common problem that sometimes makes continuing PD impossible.

- Store supplies in a cool, clean, dry place.
- Inspect each bag of solution for signs of contamination before you use it.
- Find a clean, dry, well-lit space to perform your exchanges.
- Wear sterile gloves to perform exchanges.
- Wash your hands every time you need to handle your catheter.
- Clean the exit site with antiseptic every day.
- Wear a surgical mask when performing exchanges if you have a cold.

Indications of problems

- Fever
- Nausea or vomiting
- Redness or pain around the catheter
- Unusual colour or cloudiness in used dialysis solution
- A catheter cuff that has been pushed out

Equipment and Supplies for PD

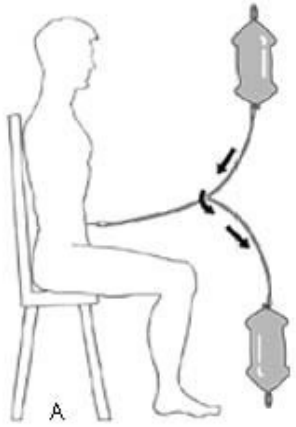
Transfer Set

A transfer set is tubing that connects the bag of dialysis solution to the catheter. Two types of transfer sets are available.

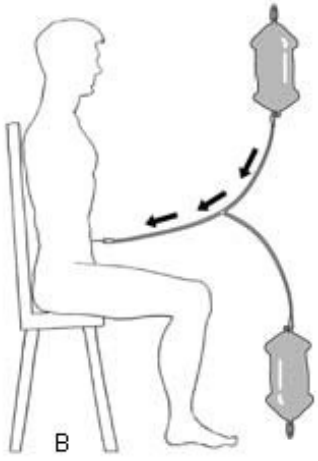
- A **straight transfer** set is a straight piece of tubing that stays connected to your catheter. To begin each exchange, you connect the free end to a fresh bag of solution and hang the bag higher than the catheter, usually attaching it to a special stand, so that gravity pulls the solution into your abdomen. While the solution is in your abdomen, you can roll up the bag and wear it under your clothes. When you've finished your dwell time, you take the bag out and place

it near the floor so that gravity pushes the used solution down into the bag. When the bag is full, you disconnect it from the straight transfer set and connect a fresh bag of solution to start the next exchange.

- A **Y-set** is a Y-shaped piece of tubing that can be disconnected between exchanges. To start, you connect the base of the Y to your catheter. You then connect one branch of the Y to a fresh bag of solution and the other to an empty bag. To flush away any bacteria that might be in the transfer set, you close off the base of the Y and drain a small amount of solution from the full bag into the empty one. Then you close the branch that leads to the empty bag and let the solution flow into your abdomen. Once the bag has emptied, you can disconnect the Y-set from your catheter so you won't need to conceal a bag or extra tubing under your clothes. When it's time to empty the used solution, you reconnect the catheter to the Y-set and drain the solution into an empty bag to discard. Then you connect a fresh bag and begin the process again.



Flush-before-fill strategy used with Y transfer sets. (A) A small volume of fresh dialysis solution is drained directly into the drainage container (either before or just after drainage of the abdomen). This acts to wash away any bacteria that may have been introduced in the limb of the Y leading to the new bag at the time of connection.



(B) Fresh solution is introduced through the rinsed connector.
The Y-set is filled with disinfectant when not in use. This disinfectant is flushed out with the used dialysis solution. These procedures make the Y-set more effective at protecting against peritonitis. A Y-set can be reused for several months.

Dialysis Solution

Dialysis solution comes in 1.5-, 2-, 2.5-, or 3-litre bags. Using a larger bag can increase the dialysis dose, but only within the limit of the amount your abdomen can hold. The solution contains a sugar called dextrose, which pulls extra fluid from your blood.

Step-by-step description of peritoneal dialysis (a CAPD exchange)

The supplies and materials needed for an exchange are gathered in one clean location. Notable amongst these is a bag of dialysis fluid (also called dialysis solution), a solution comprised of a known amount of a glucose dissolved in water. The strength of this solution determines the osmotic gradient, and therefore the amount of water that diffuses out of the bloodstream. Common strengths of glucose are 0.5%, 1.5%, 2.5% and 4.25%. 1.5% is approximately fluid-neutral; it neither adds nor removes fluid and is used for patients who are primarily concerned with waste removal rather than fluid regulation. Higher concentrations lead to greater water removal.

Electrolytes are also present in the fluid to maintain proper body levels. Patients weigh themselves, and measure temperature and blood pressure daily to determine whether the body is retaining fluid and, thus, what strength of fluid to use. Dialysis fluid typically comes premixed in a disposable bag-and-tube apparatus; no additional equipment is needed. The apparatus consists of two bags, one empty and one with the fluid, connected via flexible tubing to a Y-shaped fitting. The bag is heated to body temperature, to avoid causing cramping. Dry heat is used; common methods include microwaves, heating pads and solar radiation (often using the dashboard of a car, for instance while travelling).

The patient, who performs the entire procedure themselves, dons a disposable surgical mask, scrubs their hands using antibacterial soap, and tucks a clean towel into the waistband of their pants to protect their clothing. The bag of dialysis fluid is removed from the protective packaging, and is hung from an IV stand or other elevated location, such as a coat hook. The tubing attached to the bag of fluid is uncoiled, and the second (empty) bag is placed on the floor. The Y-shaped connector is attached to the catheter tip; a protective cap must be removed from both of these before the connection is made, and the two portions of the connector are not permitted to touch anything, to avoid possible contamination.

Once connected to the system, the patient clamps the tubing connected to the full bag of dialysis fluid and then releases the twist valve located in the tip of their catheter; this permits fluid to flow into or out of the peritoneal cavity. Because the full bag of fluid is clamped off but the empty bag is not, the effluent (used dialysis fluid) from within the peritoneum can drain out of the catheter and into the lower, waste bag.

Emptying the abdomen of fluid takes approximately fifteen minutes, and the patient is free to perform tasks such as reading, watching television and browsing the internet. When the abdomen has drained, the lower, drain, bag is clamped off. The twist valve in the catheter is also closed. The clamp is then removed from the upper tubing, permitting dialysis fluid to drain out. The clamp to the drain bag is briefly opened and some fluid is drained directly from the upper bag into the lower bag. This clears the line of air and other impurities. The drain line is then clamped off and the twist valve on the catheter end is opened. This permits fluid to enter the peritoneum. Filling the abdomen with fresh fluid takes about fifteen minutes, and the patient enjoys the same freedoms as while draining.

Once the entire bag of fluid (an amount varying primarily based on body size, ranging from 1500 to 3000 mL) has been introduced to the abdomen, the patient then cleans their hands again (typically using an antiseptic alcohol-based cleanser) and puts the surgical mask on. The Y-connector is detached from the catheter tip and a protective cap is placed on the end of the catheter.

The effluent is inspected after a dialysis exchange is complete; a cloudy effluent indicates probable peritoneal infection. The effluent is drained into a toilet, and the various dialysis supplies are discarded with normal garbage.

Advantages of peritoneal dialysis

- Continuous dialysis **-** peritoneal dialysis keeps pace with the bodies own natural processes by cleansing the blood continuously rather than intermittently, as in haemodialysis. Due to the continuous nature of peritoneal dialysis, a steady blood chemistry is achieved and maintained, therefore minimising the need for dietary restrictions. Generally, continuous dialysis results in an improved feeling of well being.
- Self care dialysis - no helper required.
- Home based dialysis
- Simple to learn & perform **-** short training period. (1~2 weeks)
- Minimal dietary restrictions - due to continuous nature of dialysis.
- No needle punctures required - the dialysis access for peritoneal dialysis is the peritoneal catheter.
- No blood access problems
- Ease of travel **-** freedom to move around between dialysis exchanges
- Minimal cardiovascular stress
- No blood loss
- Flexible schedule - minimal travelling, not fitting in with hospital schedules.
- Blood pressure control
- In centre training
- Less stress on body - due to continuous nature of dialysis

Disadvantages of peritoneal dialysis

- Peritonitis - inflammation of the peritoneal membrane usually caused by bacterial infection. Peritonitis is the major disadvantage associated with peritoneal dialysis, but using a combination of disconnects delivery systems and good hygiene, the incidence is now much lower than in the past.
- Protein loss - valuable body protein escapes through the peritoneal membrane into the peritoneal solution. These proteins are easily replaced by increasing protein intake (meats, fish, dairy products, etc) in your diet.
- Potential for elevated blood lipid (fat) & triglyceride levels - elevated levels of lipids and triglycerides in the blood may lead to a narrowing of blood vessels. Regular exercise and lipid lowering medications reduces this complication.
- Peritoneal catheter - permanent access for dialysis.
- Daily dialysis schedules
- Possible weight gain - the glucose content of the dialysis solution results in a higher intake of kilojoules / calories.
- Storage space needed for supplies (the corner of a room or wardrobe)

Peritonitis

Peritonitis is an infection of the peritoneal membrane. It is the major complication of peritoneal dialysis. The introduction of germs into the peritoneal cavity causes peritonitis.
Peritonitis can become a life-threatening situation if left untreated. Therefore, every precaution should be taken to ensure that it does not develop.
Peritonitis occurs when there has been a breakdown in the exchange procedure and peritoneal dialysis associated techniques.

Signs and symptoms

- Cloudy dialysis solution.
- General abdominal tenderness, which can be severe and can occur quickly.
- Nausea and/or vomiting, diarrhoea. Rise in temperature.
- General feeling of being unwell.

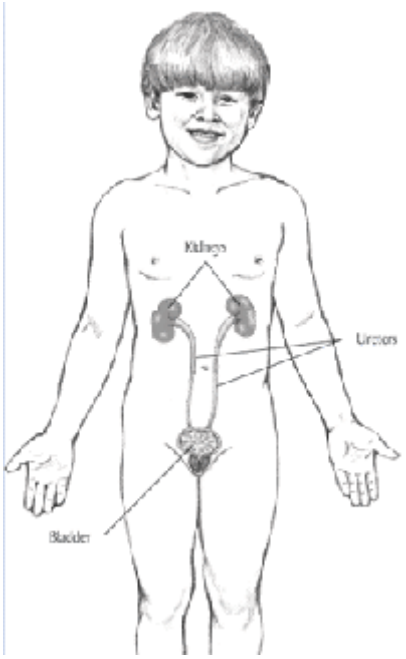
Problems Specific to Children

Everyone who has kidney failure, adults and children alike will experience medical complications, which may include extreme fatigue, inability to concentrate, weak bones, nerve damage, depression, and sleep problems. Additional problems for children can include effects on their growth and development. Children may fall behind on the growth chart and in school.

The isolation people feel because of kidney failure is especially a problem in children and adolescents because of the importance of making friends and fitting in at this age. Finding the best treatment for a child takes on special significance to ensure that the child with kidney failure can become an active, productive, well-adjusted adult.

Treatment Choices for Kidney Failure in Children

Children usually have a range of treatment options for kidney failure. In most cases, the goal is to have a successful transplant that allows the child to lead the most normal life possible. But viable kidneys are not always readily available, and not all children can have a transplant. Many children begin with dialysis to stay healthy until a suitable kidney becomes available. Sometimes, a transplant itself may stop working, and the child may need to return to dialysis.



Peritoneal dialysis for children

Peritoneal dialysis is often the preferred treatment for children. With effective dialysis, good phosphate-calciurn-PTH control and the use of growth hormone the children on both Peritoneal and Haemodialysis have an equal opportunity for growth. The choice between PD and HD is purely based on the individual needs, the environmental and social aspects of the individual's lifestyle, the treating centre's preference, availability of the service and the physical condition of the patient.

Most children are able to use a cycler machine overnight, leaving their daytime hours free.
The volume of dialysis solution generally depends on the weight of the child, i.e. 50mls of dialysis solution per kilogram of body weight.

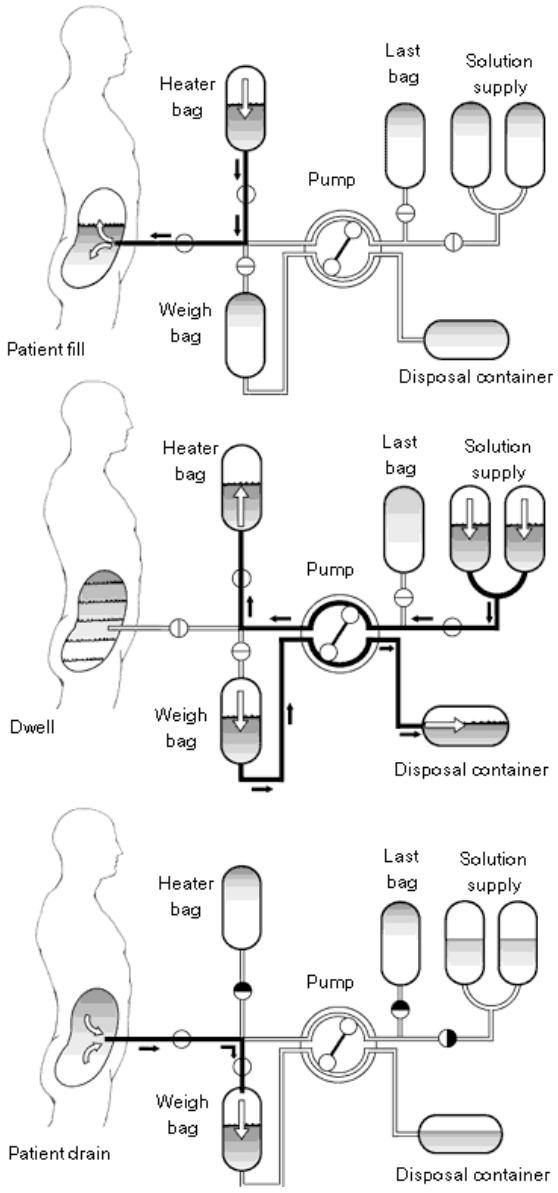
Infants may only require 0.5 litre (50Omls), while teenagers may need 1.5-2 litres of dialysis solution. Children on peritoneal dialysis are able to enjoy a relatively uninterrupted and active lifestyle, participating in varied sports.

5.0 Technology

The CCPD machine uses a number of different technologies including:

- **Pump.** The pump sends the solution from the storage bags to the heater bag before it enters the body and then sends it from the weigh bag to the disposal container after it's been used. The pump doesn't fill and drain your abdomen; gravity performs that job more safely.
- **Solution storage.** At the beginning of the session, you connect bags of dialysis solution to tubing that feeds the cycler. Most systems include a separate tube for the last bag because this solution may have higher dextrose content so that it can work for a daylong dwell time.
- **Heater bag.** Before the solution enters your abdomen, a measured dose is warmed to body temperature. Once the solution is the right temperature and the previous exchange has been drained, a clamp is released to allow the warmed solution to flow into your abdomen.
- **Weigh bag.** The cycler's timer releases a clamp to let the used dialysis solution drain from your abdomen into a weigh bag that measures and records how much solution has been removed. Some systems compare the amount of solution inserted with the amount drained and display the net difference between the two volumes. This lets you know whether the treatment is removing enough fluid from your body.
- **Disposal container.** After the used solution is weighed, it's pumped to a disposal container that you can throw away in the morning.

- **Alarms.** Sensors will trigger an alarm and shut off the machine if there's a problem with inflow or outflow

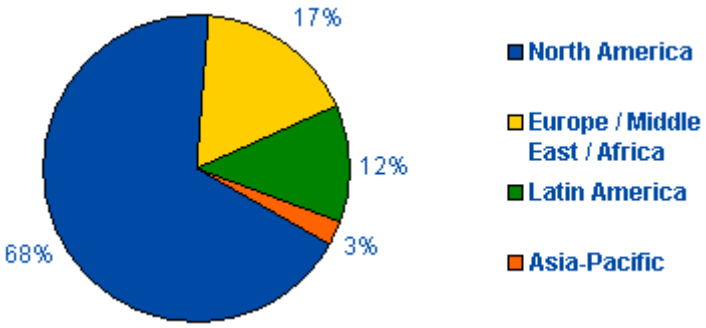


6.0 Manufacturing

The machines are usually made from an injection-moulded polymer. The polymer must be strong and hardwearing but also light. They are usually batch produced. The materials need to promote the strictest hygiene; all gaps that can gather dirt must be eliminated. A superior finish is therefore a major requirement. The manufacturing should be suitable in relation to the most efficient production arrangement and the product lifecycle. As sustainability is our main focus in designing this machine, all efforts must be made to ensure the product is easily assembled and disassembled.

7.0 Business environment

Patients by Region (as of September 30, 2005)



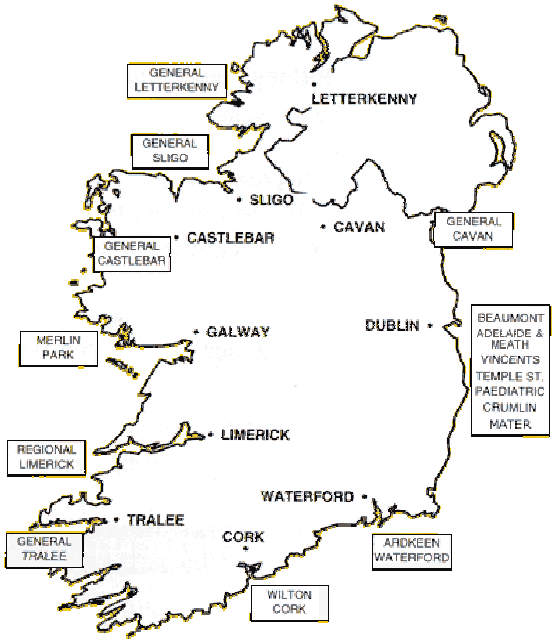
Chronic kidney failure is a condition that affects more than 1,300,000 individuals worldwide. There has been a 33% increase in kidney patients on dialysis treatment in Ireland over the past three years, according to new statistics from the Irish Kidney Association (IKA).

The numbers on dialysis have increased from 911 in February 2002 to 1,210 in December 2004, according to the IKA. This is an increase of 33% or an additional nine patients going on dialysis each month. Between 2003 and 2004, a 16% increase was recorded in the number of patients on dialysis.

A total of 250 patients were on dialysis at the national renal treatment centre at Beaumont Hospital as of December 31 last, according to the statistics. The next highest figure was at Tallaght Hospital in Dublin, which had 154 patients on dialysis.

The new Beacon private clinic in South County Dublin had 47 patients on dialysis at the end of last year. The IKA has said that if the Government implemented a structured national living kidney transplantation programme, more patients could come off dialysis and avail of transplants. The Association says the number of kidney transplants has remained largely static in recent years.
The market is expanding and as the economy grows the need for private and more personal healthcare will rise. There is no CCPD machine aimed specifically at children. An opportunity exists to manufacture home-based dialysis products for children. The machines will be sold in Europe with Germany, France, Italy, England and Ireland being the main focus of sales. The product will be marketed under the existing healthcare company Baxter, however a new sub division will be created aiming its products specifically at the home environment. The new division will be called Baxter Homehealth. The machines will be sold to health boards and heavily promoted using the new easier functions and elimination of the complex line system.

8.0 Future trends



The future of dialysis

In 5-10 years, the baby boomer generation will enter the age of organ degeneration and diseases. Based upon a population growth rate of 7% and an end of 2000 worldwide population of 1,060,000, it is estimated that by 2010, the worldwide dialysis population will double. There will be a blaring need for new therapies, considering the cost of treatment and stagnant quality of life. Unfortunately, most premature ideas will, for scientists and doctors, divert some of the attention and the government resources to developing new treatments for dialysis. There is a growing awareness of tissue engineering, cloning, stem cell research now. This is the perfect time for new ideas to blossom into tangible research endeavours as dialysis treatments did during the Korean War.

On the medical side, the dialysis researchers continue to refine the machinery and the procedures and to debate what constitutes the ideal treatment. On the economic side, policy makers continue to debate how we can meet the growing demand for dialysis patients. Looking back from the Roman baths, to the early work on membranes, to the introduction of the early dialysers over the objections of people who could not understand its potential, dialysis is a triumph of dedication and technology that makes life possible for countless people who cannot battle a dying kidney alone.

9.0 Social environment

The dialysis process is extremely unsociable. Many patients have long and frequent hospital visits. Many patients feel tired and unwell while receiving dialysis treatments and are limited in the activities they can partake in. The machines in the patients home are bulky and medical looking in children this can be a major issue, as other children do not understand what it is. Dialysis takes up a huge amount of time from the child's life daily. The new product should be less intrusive on the patient's life; it should blend into the child's environment and not attract too much attention to itself or the process it is performing

10.0 Conclusions

- Dialysis is on the rise in Ireland and northern Europe
- Home care is an expanding medical market
- There is no existing CCPD machine aimed at children
- CCPD is the best form of dialysis for children
- Hygiene is the major factor in CCPD and all efforts should be made to eliminate the change of infection
- Waste is a major issue with the fluid bags
- The set up of the machine is long and laborious
- Children need to understand the process

11.0 Design brief

Hypothesis:

'It is possible to re-design a home peritoneal dialysis machine aimed specifically at children'

Project background:

The number of cases of dialysis in Ireland has increased by 33% in the last three years. The numbers on dialysis have increased from 911 in February 2002 to 1,210 in December 2004, according to the IKA. Similar statistics can be seen across Northern Europe. A gap has been identified in the market for a dialysis machine aimed specifically at children who use peritoneal dialysis in the home.

Brief:

With this in mind design a continuous cycler-assisted peritoneal dialysis machine.
Factors to be considered:

- The product is aimed at children
- The product is to be used in the home environment.
- The target market is Northern Europe, with the key countries being France, Italy, Germany, Great Britain and Ireland.
- There is potential for a dominant branding presence as competition has a poor branding strategy.
- The product should have aesthetic appeal.
- If possible it should be easily transportable.
- The complicated line set should be eliminated and the product should be simpler to set up and use.

Phase 1

Concept Development:

Product Architecture & Space Envelope
Ergonomics & Anthropometrics
Production & Assembly
Product form & Style

DELIVERABLES:

Boards predecessors, corporate identity, competitors, lifestyle, semantics, benchmarking boards.

Report Research report
Ergonomics & Anthropometrics of product
Product functions & user interaction

Product Architecture Proposal
Production & Assembly
Materials & Processes
Form development

Initial Form Study Presentation
Presentation of final concept renderings
Display of Models

Phase 2

Final Form & Design Proposal & Final Presentation:

Product Development
Final Product Range with regard to aesthetics, detailing, branding, final colouring, packaging, information graphics etc.
External Detailing focusing on branding, user info. safety instructions etc.
Foam Sketch Model to convey form
PowerPoint Presentation of product features, System elements, range interaction (how products relate to generator/ each other), materials and processes, leaflets detailing product range, marketing plan.

DELIVERABLES:

Report Concept Development Report
Outline development of final concepts
Detailing key features / functions / user interface / user interaction
Internal components & external controls
Branding / styling / packaging

PowerPoint Presentation of Final Product Proposals

Final concept presentation of rendering & models
Branding & colour / texture specs.
Marketing and promotional plan
Supporting multi-media

12.0 Appendices

http://www.davita.com/

http://www.chemistry.wustl.edu/~edudev/LabTutorials/Dialysis/Kidneys.html

http://en.wikipedia.org/wiki/Dialysis

http://www.kdf.org.sg/

http://www.nlm.nih.gov/medlineplus/ency/article/003421.htm

http://www.globaldialysis.com/

http://www.ispd.org/

http://www.fda.gov/fdac/features/1998/198_dial.html

http://www.dialysisfinder.com/

Irish Kidney Association

Kidney School Magazine