**Technology:** Portable home hemodialysis devices

**Manufacturer:** Home Dialysis Plus (HD+), Home Dialysis Plus, Ltd., Portland OR; PHD® Personal Hemodialysis System, Aksys, Ltd., Lincolnshire IL (Other systems that are in use or under development are mentioned, but not assessed in this report).

**Purpose:** Home hemodialysis for the treatment of end stage renal disease (kidney failure).

**Current Regulatory Status:** The HD+ device is still under development and has not yet been considered by regulatory authorities in Canada or the US. The company expects to obtain US regulatory approval late in 2005 (Michael Baker, Home Dialysis Plus, Portland, OR: personal communication, 2004 Dec 14). The Aksys PHD system has not yet received licensing from Health Canada (Kathleen Savage, Health Canada, Ottawa: personal communication, 2004 Dec 3). The PHD system received US Food and Drug Administration approval in 2002.1

**Description:**

The Canadian Institute for Health Information (CIHI) estimates that nearly 16,000 people were receiving dialysis treatment in Canada as of December 2001. During the five years before 2001, the number of Canadians receiving dialysis increased by 20%. About three-quarters of the patients are receiving hemodialysis. Most dialysis treatments in Canada occur in hospitals or in clinics that are affiliated with hospital dialysis programs.2,3

The main treatment options for advanced kidney failure are hemodialysis, peritoneal dialysis or kidney transplantation. In hemodialysis, which is the most commonly used treatment, the blood is slowly filtered through an external dialysis machine that removes waste products and excess salts and fluids before returning the cleansed blood to the body. Hemodialysis may be performed in the home, but most patients travel to dialysis clinics to undergo the procedure three times per week. Each procedure takes several hours.4 In peritoneal dialysis, the filtration takes place in the patient’s body. A catheter is used to fill the abdominal cavity with dialysis solution and the walls of the abdominal cavity (the peritoneum) act as a filter for the waste products, which are then drained from the body. This filling and draining is called an exchange. Different types of peritoneal dialysis are used and each require a different schedule of regular exchanges.

For hemodialysis units that are developed for home use, there have been efforts to decrease the size of the dialysis equipment; prepare the ultrapure dialysate with the use of disposable sorbent cartridges or compact reverse osmosis systems; reduce the water volume required; reduce the preparation and clean-up times; and ensure a simpler operation.

The HD+ unit incorporates a microfilter technology, which is used to minimize the space between fluids and maximize the efficiency of mass transfer in the filter. This technology, which was developed at Oregon State University, allows miniaturization of the dialyzer. With this technology, a dialysis machine can be reduced from the size of a refrigerator to that of a small suitcase.
The Aksys PHD system has simplified the processes that are involved in home dialysis and reduced the preparation and clean-up time, so that a person can save up to 90 minutes per dialysis session (up to seven sessions per week may be needed). Conventional at-home dialysis requires about one and a half hours of effort before and after dialysis. The PHD filters and blood tubing kits are changed monthly, rather than daily. The PHD system uses dry dialysate chemicals, rather than intravenous fluid bags – thus requiring less home storage space for dialysis supplies. The Aksys PHD system is 136 kg, stands 125 cm tall and has a width and depth of 64 cm by 74 cm, respectively.

Several other hemodialysis units have been developed or modified for home use, including the 2008K@home (Fresenius Medical Care North America, Charlotte NC), Formula Domus Home Care System (Bellco Health, N. Amityville NY), AK 95 S (Gambro, Lund, Sweden), Aurora Dialysis System (Baxter Healthcare, Inc., Deerfield IL), NxStage System One (NxStage Medical, Inc., Lawrence MA) and the Allient System (HemoCleanse, Inc., Lafayette IN).

National Quality Care Inc. (Los Angeles CA) is planning a 10-patient, phase I safety study of a “wearable artificial kidney” device, which is intended to provide continuous dialysis treatment at home.


Evidence: Recent interest has focused on the benefits of daily nocturnal home hemodialysis and short daily dialysis. Daily nocturnal home hemodialysis involves more frequent and longer duration hemodialysis. It is performed for eight to 10 hours, six or seven nights a week, while the patient is asleep at home. The proposed advantages of this approach, compared to conventional hemodialysis (performed three times per week, in a clinic) include improved patient well-being (better appetite and diet; less dietary restriction, and fatigue; and shorter recovery time); better hemodynamic stability and blood pressure control; and improved clearance of wastes. Short-term daily dialysis, either at home or a clinic, involves approximately two hours of hemodialysis, six days per week. It offers improved clinical outcomes compared with those of conventional dialysis. The US National Institutes of Health is funding a randomized controlled trial to compare conventional hemodialysis to short daily, and daily nocturnal home hemodialysis. The results of this trial should be available in 2008.

The HD+ device is at the prototype stage, so there are no data on its clinical performance. The company is planning a trial involving 25 patients to support their application for US Food and Drug Administration (FDA) 510(k) premarket approval.
Results of a three-year, quasi-experimental, controlled before-after trial of the Aksys PHD system formed the basis for the US FDA approval. In this study, 23 patients underwent short daily hemodialysis at home, using conventional dialysis machines (a total of 2,822 dialyses), then switched to the PHD system (a total of 1,623 dialyses). Patients using the PHD system had less frequent episodes of adverse events, such as cramps, headache, nausea and hypotensive episodes. The Aksys study reported that seven of the 14 most common problems experienced by patients on hemodialysis were “significantly” less frequent with PHD dialysis. On average, blood pressure dropped 8 mm Hg during PHD dialysis, compared with 17 mm Hg during conventional dialysis. The incidence of a pulse rate of >90 beats per minute occurred in 23% of patients on conventional hemodialysis, compared with 8% of patients during PHD dialysis. Participants in the study had used conventional home dialysis units for an average of about five years, whereas using the PHD system was new to all of them. At the end of the trial, 90% of those in the study preferred the PHD system.

Available Alternative Technologies:

Peritoneal dialysis is also used in the home setting. Alternatives to home dialysis are dialysis treatment at a hospital or dialysis centre; or kidney transplantation (in individuals who are candidates for transplantation when a suitable donor organ is available).

Commentary:

Home hemodialysis was first performed in the 1960s, but the use of this approach in North America has been limited. Several centres in Canada offer nocturnal hemodialysis for a total of about 140 patients.

Recent Canadian studies suggest that short-term daily and nocturnal home hemodialysis are clinically effective and cost-effective compared to conventional in-centre hemodialysis. They also provide further benefits through improved quality of life for patients. Appropriate patient training; and clinical and logistical support from a dialysis centre are essential.

A 2003 UK assessment concluded that expanding home hemodialysis services may be one option for coping with the increasing number of people requiring dialysis. The UK National Institute for Clinical Excellence (NICE) has recommended that “all suitable patients should be offered the choice between home haemodialysis or haemodialysis in a hospital/satellite unit.”

Several improvements in reliability and ease of use have contributed to the appeal of home dialysis equipment. The devices from Aksys and Home Dialysis Plus are developments that indicate the advances expected to become available for routine use.

References:


This summary was prepared by Leigh-Ann Topfer; CCOHTA.

This series highlights medical technologies that are not yet in widespread use in Canada and that may have a significant impact on health care. The contents are based on information from early experience with the technology; however, further evidence may become available in the future. These summaries are not intended to replace professional medical advice. They are compiled as an information service for those involved in planning and providing health care in Canada.

These summaries have not been externally peer reviewed.

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