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## The requirements of antimicrobial catheter lock solutions:

## What should they do and what can they do?

Catheter lock solutions are instilled into central venous access systems to have certain effects in this location. These access systems can be either dialysis catheters, Hickman- type lines or port-a-cath systems. The latter are used mainly in parenteral nutrition and for the administration of medication in oncology patients. These access systems are approved as medical devices and are CE marked. The central venous access is inserted in the subclavian, jugular or femoral veins.

The use of Antimicrobial Lock Solutions have been recommended in the "Hygiene Guideline complementing the German Dialysis Standard" and in the Position statement of European Renal Best Practice (ERBP)". Pure heparin solutions containing no antimicrobial agent do not meet this criterion. Antibiotics are associated with the development of resistancy which is a major drawback. Highly concentrated citrate solutions and taurolidine-citrate solutions are therefore conceivably useful in this application.

Highly concentrated citrate solutions (30% and 46.7%) cause major adverse effects such as cardiac arrests and embolisms that are a significant risk for the patient. **TauroLock™** as an antimicrobial lock solution has proven useful in dialysis, oncology and parenteral nutrition for many years and has meanwhile become established in the prevention of catheter-related infections.

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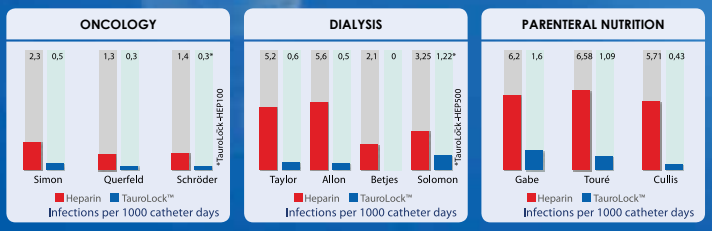


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**TauroLock™ is safe:** The concentration of 4% citrate in TauroLock™ is safe and efficient - according to the recommendation of the FDA (ref.: FDA Warning Letter, April 2000). No hypocalcaemic effects are observed in contrast to highly concentrated citrate solutions (30% resp. 46,7%) e.g. arrhythmia, cardiac arrest*, emboli**, tingling fingers and metallic taste***. TauroLock™ is biocompatible and non toxic. In contrast to highly concentrated citrate there is no protein precipitation if using TauroLock™****.


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# With a little help from my friends: developing an assisted automated peritoneal dialysis program in Western Australia

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## Abstract

**Background**

Nurse-assisted automated peritoneal dialysis (AAPD) offers a model of care that has been successfully used in frail dialysis populations internationally. AAPD offers cost savings over hospitalisation on peritoneal dialysis (PD) or in-centre haemodialysis (HD).

**Method**

A pilot AAPD model of care was developed in Western Australia (WA). Patient evaluation was measured utilising a perceptions of dialysis survey, clinical events, hospitalisation and peritonitis rates, Charlson Comorbidity Index (CCI), KDQoL-SF 36 and a survey. Staff opinions and perceived competency were measured by an online survey. Economic analysis was undertaken.

**Results**

A successful collaborative model was developed. 40 staff were trained and competency significantly improved during program delivery ($p<0.0001$). 15 patients with an average CCI score of 8.7 used the service for 18 periods of care over 18 months (mean 33 days SD 47). Two non-renal cause deaths and two episodes of peritonitis occurred. Patient opinions were extremely positive. Cost savings were estimated at $620,000.

**Conclusion**

In WA, an AAPD pilot program has been successfully developed and delivered. A sustainable model has overcome initial hurdles. Staff have gained new skills and delivered effective care, demonstrated by high patient acceptance. The program was cost-effective compared to staying in hospital or transferring to HD.

## Keywords

**Automated peritoneal dialysis, assisted peritoneal dialysis, staff education, quality of life.**

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## Background

In recent years, there has been mounting evidence to suggest the use of home dialysis therapy is both beneficial to patients with end-stage kidney disease (ESKD) and cost-effective for the health care system when compared to traditional in-centre haemodialysis (HD) (George Institute, 2010). In Australia, 30% of people on dialysis treatments self-care at home, with 20% using peritoneal dialysis (PD) and 65% of these using automated peritoneal dialysis (APD) (ANZDATA, 2015). Country, policy and model of care influence dialysis modality prevalence and compared to some international practice Australia has opportunities to improve PD rates (Fortnum *et al.*, 2012).

PD confers lifestyle advantages including; more time at home, reduced travel to/from the dialysis unit and more flexibility in dialysis regimes; as well as health advantages including better dialysis tolerance, improved health outcomes, reduced exposure to hospital pathogens and better quality of life, particularly for elderly patients. (Brown, 2011; Jager *et al.*, 2004). However, independent PD utilisation is on the decline in many regions around the world for many reasons, including an ageing and frail dialysis population (Oliver & Quinn, 2009). In Australia, 41% of incident and 49% of prevalent patients using PD are now over 65 years of age (ANZDATA, 2015).

Reported disease burden of ESKD patients includes vascular disease, reduced vision, deafness, poor mobility, often related to arthritis, and increasingly dementia and cognitive impairment (70% of those over 55) (Dimkovic *et al.*, 2009). One study found that 25% of PD patients had visual impairment and 20% had severe mobility impairment. (Oliver & Quinn, 2009). Assisted automated peritoneal dialysis (AAPD) has been demonstrated to overcome physical, cognitive, psychological or social barriers to enable patients to have PD, and can be long-term or short-term (Oliver & Quinn, 2009).

Australia clearly has an ageing population and planning is recommended to manage the growing health burden (Productivity Commission, 2013). Assisted PD is not new in Australia. Seventy per cent of PD patients already receive some assistance with their dialysis, from friends or family (Fortnum *et al.*, 2015). However, the authors are only aware of two limited services in Australia for non-family AAPD: one a pilot study in Victoria delivered by the community nursing service and another service by Baxter Health Care in South Australia a number of years ago (unpublished).

Providing non-family AAPD involves identifying and training an employee to perform dialysis-related tasks. Public system nurses, private nurses, nursing aids and assistants have all been employed and trained successfully overseas (Brown & Wilkie, 2016; Oliver & Quinn, 2009; Povlsen & Ivarsen, 2007). The tasks may include setting up the cycler, connecting the patient to a cycler, patient assessment, disconnecting from a cycler, or performing continuous ambulatory peritoneal dialysis (CAPD) exchanges (Dimkovic *et al.*, 2009; Lyasere *et al.*, 2016).

Internationally, AAPD is highly successful (Brown & Vardhan, 2011; Li, 2008; Lyasere *et al.*, 2016; Querido *et al.*, 2015). In France, where AAPD programs have existed for many decades, registry data has demonstrated that 56% of patients >70 years old were considered unable to independently perform PD, with assistance successfully provided by visiting nursing staff in 86% of cases (Lobbedez *et al.*, 2006; Verger *et al.*, 2006). In Toronto, the AAPD program has increased the proportion of patients considered eligible for PD and has proven cost-effective, being highly valued by patients and staff (Oliver & Quinn, 2009). Although AAPD programs cost money, the cost differential between PD and HD is more than the cost expended (Franco *et al.*, 2012; Health Policy Analysis Pty Ltd, 2009; Laplante *et al.*,2015).

There are many indications for AAPD. It can act as a bridge therapy when either an intervening illness makes it temporarily difficult to continue on PD, or someone is waiting to train for PD (Povlsen & Ivarsen, 2007). In those that develop permanent barriers to self-care dialysis, the provision of assistance can avert PD technique failure and a forced switch to in-centre HD (Brown & Wilkie, 2016).

AAPD can also provide respite for family-assisted APD to help carers maintain employment and decrease burnout (Brown & Wilkie, 2016; Brown & Vardhan, 2011; Povlsen & Ivarsen, 2007). AAPD also provides reassurance to elderly persons and their families, alleviating the concern about family burden (Tong *et al.*, 2013). For new patients, AAPD can be used as a form of ongoing training or mentoring that allows patients to gain confidence performing PD-related tasks in a supervised setting, where some patients eventually graduate to self-care PD (Oliver & Quinn, 2009).

Given all of the data there appears to be an opportunity for the development of ongoing AAPD programs in Australia. Notably, in 2014, 16% of Australian patients discontinued PD because of personal reasons, including inability to self-care (ANZDATA, 2015). Anecdotally in WA, lengthy hospitalisations or transfers to HD were occurring related to the inability of a patient or family to manage AAPD due to acute illness (often physical injury or surgery), chronic deterioration in health, carer burnout and a delay in time to training.

AAPD has to fit into the service provision model. WA home dialysis services are corporatised, with partnership care divided between the hospital (inpatient service only) and the external provider, Fresenius Medical Care (FMC — outpatient service, including training and ongoing follow-up and management). There was no provision for AAPD or respite care.

In 2014, it was identified that the Home Link nursing service at Sir Charles Gairdner Hospital (SCGH) offered an opportunity to develop a pilot, metropolitan-based AAPD program, modelled on a program at Manchester Royal Infirmary (Brown & Vardhan, 2011). The Home Link nursing service has an objective to shorten length of stay in hospital (LoS), meaning that AAPD for previously hospitalised or about to be admitted patients fit under the service criteria. Of note, nursing home patients are excluded from the Home Link program.

## Aim

This project sought to develop a sustainable AAPD model and also to assess current patients' attitudes towards home dialysis, determine whether providing AAPD is cost-effective and measure the characteristics of the users and their quality of life. The aim was to run a one-year prospective research project as a pilot.

This paper focuses on the model development, nurse training and some clinical research results.

## Method

The development of the AAPD program was a joint project between the external provider FMC, SCGH PD unit staff, Home Link, a lead nephrologist and the renal ward. As with all new programs, hospital permissions were sought. Funding was obtained through a State Health Research Advisory Grant (SHRAC).

To determine potential uptake of AAPD, a 28-question (multiple-choice format) paper-based perceptions of dialysis survey was offered to any current PD or HD patients at SCGH. Clinical evaluation of the AAPD service included a KDQoL-SF36, Charlson Comorbidity Index scores (CCI), clinical outcome measures and a structured phone survey of participant opinions (AAPD participants).

Costings were calculated using a cost-minimisation analysis approach. Home Link nurses could opt in to complete an online survey focused on their education and experience.

Other stakeholders underwent semi-structured interviews to determine strengths and weaknesses of the program and to allow future development of both the program and business plans.

The research component was ethics-approved (HREC reference 2014-149) and patients consented to take part. It was intended to have a control group of those who were eligible but did not consent to AAPD, but every eligible patient consented. Prism version 6.0b statistical software was used to perform frequency, means and chi-square tests. Qualitative responses were thematically analysed.

## Results

### Development of the AAPD program

The key areas were: 1. Development of pathways and roles; 2. Staff training; 3. Policies and protocols 4. Research and evaluation.

### 1. Development of pathways and roles

Communication is central to any patient management process and the wide group of WA stakeholders meant the pathways and roles were critical. Alterations to contracts between the hospital and FMC were undertaken. Two key pathways were developed: one for patients already on APD and the second for those who were pre-training. Basic training and on-call for new patients was provided by the SCGH ward or PD staff. For those already on APD, this responsibility stayed with FMC.

### 2. Staff training

To provide continuous cover the decision was made to train all Home Link staff. They had previously received some theoretical training to facilitate administration of intra-peritoneal antibiotics. The training was conducted by FMC with a focus on practical machine skills because Home Link staffing time constraints limited the sessions to two hours. Following a demonstration, staff were supervised to perform skills but did not have competencies completed. They were provided with step-by-step guides and Home Link facilitated a pairing or mentoring system to support initial home visits until staff and their mentor determined they were competent.

### 3. Policies, protocols and governance

Standard APD procedures were adapted for the program and key forms including a referral form were developed. It was determined that to be cost-effective the nurses could only visit once a day and this visit would involve patients' assessment, machine strip-down and machine set-up. This led to one key change to policy — increasing the time delay allowed from set-up to connection, giving a wider range of visit times. The once-a-day policy also meant the patient or carer had to be able to perform the connection and disconnection. This was also considered a risk management mitigation policy ensuring patients could disconnect in the case of alarms or an emergency in the home.

Patient criteria also included a working PD catheter, willingness to consent, reasonable house condition and a phone. Categories of patients included pre-training requiring immediate dialysis and any short-term need for existing patients who would otherwise be hospitalised. Referrals could be made by all stakeholders and went via the lead nephrologist, who consented patients into the service and research.

Governance and support for the new patients was hospital-led, whereas for respite patients FMC managed their ongoing PD-related care.

## 4. Research and evaluation

### Perceptions of dialysis survey

Fifty-three PD patients responded to the perceptions of dialysis survey and 60% indicated they would be willing to have AAPD by a paid external person as a permanent treatment choice. In a further question, 92% of responding PD patients would be willing to have a nurse manage their PD rather than transfer to HD if they were temporarily unable to remain independent (Fortnum & Chakera, 2017).

### Participants

In 2015, 98 WA patients were using APD with 41 new patients trained in total. Forty-seven per cent of these were from SCGH. During 17 months of the pilot study, 18 referrals for 15 individual patients occurred and 594 episodes of AAPD care were delivered. Table 1 shows the demographics. The key reasons for use of the service were acute injury/surgery, pre-training, reduced capacity to manage PD post-hospitalisation and requested carer respite (Table 1). Two patients also received intraperitoneal drugs for existing peritonitis during their respite.

### Clinical data and outcomes

The average patient had a high CCI of 8.7 (Table 1). The average score of those who have since died was 12.2, compared to 6.9 in those still alive. QoL scores were particularly low in physical health (27.5), mental health (35.2) and burden of kidney disease (25.0) domains (Table 1). KDQoL total scores did not correlate with CCI scores.

Seventy-eight per cent of patients resumed or started independent PD. Two respite patients deceased from myocardial infarction whilst on AAPD. Their age-adjusted CCI scores were 14 (metastatic cancer) and 7. One respite patient (CCI 16) contracted a gram-negative peritonitis and transferred to HD with a subsequent death due to metastatic cancer. Another respite patient with a previous six episodes of peritonitis in 11 months (history of dyscopia, depression and on

*Table 1*

| | Number (%) or mean (SD) | Range | Benchmark data |
|---|---|---|---|
| Male | 11 (64%) | | 60% (ANZDATA) |
| Age (years) | 68.9 (SD 9.0) | 49–83 | 65 years (ANZDATA) |
| CCI (age-adjusted) | 8.7 (SD 3.7) | 3–16 | 4.3–7 (Lobbedez *et al*.) |
| KDQol-SF 36 | | | |
| Physical function — SF 12 | 27.5 (SD 5.3) | 19–36 | 33 (Lyasere *et al.*) |
| Mental function — SF 12 | 35.2 (SD 9.9) | 22–60 | 49 (Lyasere *et al.*) |
| Symptom/problem list | 64.4 (SD 13.2) | 31–85 | |
| Effects of kidney disease | 49.6 (SD 18.9) | 12–72 | |
| Burden of kidney disease | 25.0 (SD 28.0) | 6–93 | |
| PD data | | | |
| Time on PD (weeks and respite only) | 101 (SD 48) | 22–150 | 63% of patients on PD at two years (ANZDATA) |
| Time spent on AAPD (days) | 33 (SD 47) | 1–143 | |
| Kt/V (closest date if not done during AAPD) | 2.17 (SD 0.31) | 1.56–2.64 | Target 1.7 (ISPD) |
| Reason for referral | | | |
| Pre-dialysis | 5 (28%) | | |
| Acute injury/illness (self-care) | 5 (28%) | | |
| Respite (carer) | 3 (17%) | | |
| Post-hospital (self-care) | 5 (28%) | | |
| Outcomes (total 21 patient months) | | | |
| Death | 2 (11%) | | |
| Started training | 5 (28%) | | |
| Transfer to HD | 2 (11%) | | |
| Resumed usual PD | 9 (50%) | | |
| Peritonitis rate | 1 in 11 months | | 1 in 18 (WA — ANZDATA) |

intermittent HD) contracted peritonitis and transferred to HD. There were no other episodes of hospitalisation.

Home Link nurses managed 14 documented health issues that were non-renal, with five resolved by the GP, five by liaison with the hospital and three sent to emergency departments. There were four renal issues with collaborative resolution and 48 prescription queries with resolution managed by Home Link via FMC for established patients and via the hospital for new patients. Ten technical problems with dialysis were managed by Home Link staff in collaboration with FMC, but five did result in the patient missing a night of dialysis.

Ten patients (66%) answered the phone follow-up survey to determine quality and acceptability of AAPD delivered by Home Link. One had used the service twice. Ninety-one per cent rated the service as extremely important, 73% as excellent and 27% as very good. One hundred per cent thought it should continue and would recommend the service. Respite periods of care ran more smoothly and rated higher than pre-training. Recommendations for change were minor and actionable.

## Home Link nurses survey

Sixteen of 40 nurses responded (40%) to the survey: 10 registered nurses, five clinical nurses and one other. Twenty-five per cent of nurses had less than 10 years' experience and 44% had over 20 years' experience. Eighty-seven per cent had none or little experience of PD.

Training included theoretical (68.8% attended group theory) and practical components (100%) — either simulated or in the home. Following initial group education sessions, 81% felt "just adequately" or "inadequately" skilled. However, they were provided with step-by-step guides and Home Link facilitated a pairing or mentoring system to support initial home visits, until staff and their mentor determined they were competent.

The mean average for care sessions delivered was 15 sessions (range 0 to over 20). In February 2017, 50% of staff felt "reasonably confident", with 43.8% "completely confident" in care delivery. Delivering more than five sessions correlated strongly with current higher competence level $p<0.0001$. The skills that nurses felt most competent in were patient assessment (80%), seeking support (80%), setting up the machine (66.7%) and dismantling the machine (60%). One hundred per cent of staff felt that training refreshers should be held annually.

Satisfaction with delivering the service was high:

- 71.4% enjoyed delivering the AAPD care.
- 100% felt the skills were valuable to have learned "all" or "most of the time".
- 78.6% felt it was a positive service for the patients "always" and the remainder for "most of the time".

Practical aspects of the program were also evaluated and overall were positive:

- The referral form met needs "always" for 14.3% of respondents and "most of the time" for 64.3%.
- Policies and procedure met needs "always" for 35.7% and "mostly" for 57.1%.
- Clinical support was adequate "always" for 50% and "mostly" for 57.1%.
- Supplies were available "always" for 50% and "mostly" for 50%.

All respondents thought it should be continued with expanded criteria including a long-term service and a broader catchment area. Additional general comments included "Life in hospital and with patients is never routine and one box does not fit all". "Logistics of becoming an outpatient after being an inpatient are often complex."

The final evaluation related to nursing care delivery assessed the support phone calls. FMC collected this data. Sixty-three phone calls (one per 10 visits) were documented with a mean time of 5.3 minutes (range 1–15 minutes). Forty per cent were for prescription enquiries, 34% for clinical PD issues and 20% for technical set up and support. There was an even split between calls being made during hours compared to out of hours.

## Costing

In summary, the program delivery was found to be cost-neutral for WA health, with Home Link being able to deliver the service for $274 per visit, and then reclaim this cost from the Commonwealth government (total claim of $162,756). To calculate the cost differential, patients were allocated to either staying in hospital or transferring to centre-based HD, based on their history and preferences and for the time they needed to use the AAPD service. The costs were compared to being on AAPD.

It was calculated that 518 bed days and the equivalent to 11 weeks of centre-based dialysis were saved. Five hundred and ninety-four AAPD days were incurred. All dialysis, transport and overhead costs were included for each treatment option. Initial calculations estimate that by having the option of AAPD, rather than staying in hospital or transferring to HD, substantial savings were realised for WA Health (and the health system as a whole). This is as expected, given the cost differential between inpatient and outpatient care and home therapies versus in-centre HD.

## Discussion

The patient cohort included existing patients with acute injury, surgery, hospital deconditioning, carers being unavailable and new patients requiring urgent dialysis but on a waiting list to train. It strongly represented the anticipated cohort and those in programs overseas, although AAPD for the pre-training period was only found in one study (Povlsen & Ivarsen, 2007).

The goal of the WA program meant that the participants were dependent (requiring hospital bed days). Seventy per cent of the cohort was frail and unable to self-care for their PD due to either acute injury or hospital deconditioning. The CCI score average was 8.7. Comparable overseas cohorts scored 7.0 for assisted PD compared to 4.3 for self-care PD (Lobbedez *et al.*, 2006) and 6.8 for an AAPD cohort (Brown & Vardhan, 2011).

There are clinical differences in group KDQoL-SF36 scores in the literature but one similar study on AAPD patients recorded mean physical scores of 33 and mental scores of 49. They found comparable mental scores for HD patients, although AAPD patients had lower physical functioning than the HD population (Lyasere *et al.*, 2016). These physical and mental scores reflect those found on the WA pilot program. Future data on frail HD patients for benchmarking would be useful.

## Outcomes

One measure of AAPD program outcome benchmarking is peritonitis rates. Of note, due to both staffing constraints and safety concerns for emergency situations, WA participants had to self-connect, which rarely occurs in other programs and this limits outcome comparison. The programs detailed in the literature mention peritonitis rates, for example in Brazil it was 1 per 37 patient months (Franco *et al.*, 2012). As with our pilot, the small cohort and variable models in most programs makes it difficult to calculate reliable data or benchmark but there are no indications that peritonitis is a barrier for AAPD, particularly as there is little choice in therapy for most of this cohort.

It is also an important question as to whether morbidity or mortality are better on HD or AAPD. The WA study could not generate the control group because no one was rejected from program participation and sent to HD. Looking at international data, frailty has been identified to be the only real predictor for poor dialysis outcomes ($p<0.0001$) but no difference was found between matched groups of HD and AAPD patients (Brown & Wilkie, 2016; Lyasere *et al.*, 2016). Brown and Vardhan (2011) reported similar mortality, hospitalisation and QoL scores for HD and PD patients in an elderly UK cohort. Brown and Vardhan (2011) reported high but acceptable hospitalisation rates in their frail population — mean time on AAPD 29–745 days — (15 out of 24 patients hospitalised, with 13 of these patients in hospital 1–2 months).

## Staff factors

Staff PD training will always be a "time and cost" versus "required knowledge" debate, particularly where large staff numbers are needed. The training time of two hours was relatively short for nurses unskilled in APD and this probably was reflected in their low self-reported post-training competence. For comparison, Povlsen and Ivarsen (2007) reported that their program delivers 2.5 hours of theory and 2.5 hours of practice to health care assistants prior to providing AAPD, benchmarking positively with international PD outcomes. The French program operates on a half-day training program, but the UK program provided three days of training by an external provider (Lobbedez *et al.*, 2006; Povlsen & Ivarsen, 2007).

Staff support is also a critical factor to improve outcomes (Povlsen *et al.*, 2007). The WA nurses operated a mentor support program and valued the support offered. This pilot also found that continuous exposure to delivery of care is key to long-term competency.

## Models of care

There are multiple models to deliver AAPD. The models of care internationally depend on resources, varied health care models and funding models (Dimkovic *et al.*, 2009). All published overseas models offer AAPD as an ongoing replacement therapy choice, not just an acute service (Brown & Wilkie, 2016). Consistencies throughout programs include on-call support, patient assessment and the desire to reduce hospitalisation and burden to HD units.

Some programs offer two visits a day and include disconnection and connection for APD, but still report cost-savings over HD (Lobbedez *et al.*, 2006). Most programs discuss an aim for independence and minimised visits if possible in the long-term, again to control costs. One program offered a dialysis free day per week on a Sunday (Brown & Wilkie, 2016; Lyasere *et al.*, 2016). The WA program used only registered nurses, whereas many overseas programs use specifically employed nursing assistants to control costs (Dimkovic *et al.*, 2009).

Both public and private nurses have been used, some already skilled but many not (Lobbedez *et al.*, 2006). WA chose to deliver AAPD, whereas some countries prefer to support CAPD, which can remove the machine complexities. With CAPD to minimise staff time, the French program encourages some patient involvement to drain using non-disconnect systems or flash systems (Brown & Wilkie, 2016; Lobbedez *et al.*, 2006).

## Sustainability

Sustainability relies on funding, staff skills and referrals. The funding source for Home Link nurses became sustainable by accessing a national health activity-based funding payment, the standard Tier 2 clinic non-admitted service funding ($275). Although AAPD has additional costs compared to standard APD the total cost is considerably less than in-centre HD at SCGH.

The staff skills are being maintained with a "train the trainer" mentor approach. Occasional retraining days are planned or new training days if there are significant numbers of new staff. Step-by-step procedures have also been developed. The success of the program is being advertised and expanded criteria for those using the program are being evaluated.

## Conclusion

If AAPD can be offered as a cost-neutral or cost-saving service for dialysis patients compared to centre-based HD, then our pilot study and those of other countries suggest it is a viable model, meeting both the demands of health care systems and being positively accepted by patients and their families. It is important that data are collected and benchmarked to ensure a quality service.

A WA pilot of AAPD has been successful and continues to operate. A sustainable model has been developed, overcoming initial hurdles. Staff have gained new skills and delivered effective care, demonstrated by a high patient acceptance. The program was cost-effective compared to staying in hospital or transferring to HD.

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