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Original Investigation

Procedure-Related Serious Adverse Events Among Home Hemodialysis Patients: A Quality Assurance Perspective

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Background: There has been resurgent interest in home hemodialysis (HD) in recent years because of the reported benefits and its excellent safety record. However, the potential for adverse events, including potentially catastrophic ones, exists when patients are performing HD in their homes without supervision. There is a lack of literature on this important topic.

Study Design: Quality improvement report.

Setting & Participants: We present the experience of 2 adult home HD programs in Canada from 2001 to 2012, including a total of 190 patients and approximately 500 patient-years of treatments.

Quality Improvement Plan: We retrospectively reviewed all life-threatening adverse events occurring in our programs and re-examined our approach to patient training, retraining, and safety monitoring.

Results: We report 1 death and 6 potentially fatal adverse events, yielding a crude rate of 0.060 events/1,000 dialysis treatments. Six of 7 events involved significant blood loss (including 1 exsanguination); 5 of 7 events involved human error with lapses in protocol adherence. Because such events are rare, evaluation of specific intervention strategies will require much longer follow-up.

Limitations: Retrospective identification of cases. A specific quality improvement initiative was not undertaken.

Conclusions: Life-threatening adverse events in home HD are uncommon; however, when one does occur, this should prompt review of home HD–related policies and procedures to make this therapy even safer.

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INDEX WORDS: Adverse event; exsanguination; home hemodialysis; nocturnal hemodialysis; air embolism; hemorrhage.

Editorial, p. 178

Home hemodialysis (HD) has its origin in the earliest era of managing end-stage renal disease with long-term HD therapy, and by the early 1970s, ~40% of dialysis patients in the United States were performing home HD.[1] While home HD fell out of favor over the next 20 years, there has been resurgence in interest in this modality and many dialysis providers are again offering this therapy.[2,3] This is driven predominantly by the excellent outcomes reported for contemporary home nocturnal HD and short daily HD.[4-12]

Home HD generally is considered very safe, with similar low adverse-event rates (<6 adverse events/100 treatments) for home HD and conventional in-center HD.[13,14] This may be because patients are highly selected prior to initiating home therapy and because they initially spend many weeks learning the technical aspects of self-managing the dialysis procedure. In addition, a variety of safety measures are routinely implemented to minimize the risk of blood loss from needle dislodgement, including wetness detectors near the access site and on the floor. However, the potential for catastrophic events, including exsanguination, exists when patients are performing home HD, although literature concerning such complications is lacking.

From 2001 to 2012, there were 7 life-threatening adverse events in approximately 117,000 home HD treatments in the home HD programs in Edmonton and Ottawa, Canada. This results in a crude event rate of 0.060 events/1,000 treatments. Although this rate appears low and home HD is a very safe therapy, there is no published literature for procedure-related life-threatening adverse events in home HD. By reviewing

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our cases, we sought to: (1) benchmark the event rate for serious procedure-related adverse events, (2) determine any patterns to these events, and (3) offer suggestions for quality improvement as warranted.

METHODS

Quality Assurance Review and Patient Consent

For this quality assurance review, we identified all serious procedure-related home HD adverse events resulting in death or having the potential to cause death. Types of events included bleeding into or from the dialysis circuit, bleeding from the vascular access, hemodynamic decompensation from aggressive ultrafiltration or dialysate leaks, air embolism, and hemolysis.

As required by University of Alberta regulations, consent to report the details of the patient's case was obtained from the individual in case 2; this was not possible for cases 1 and 5 because both patients are deceased and an extensive search for the next of kin was unsuccessful. The remaining cases originated from the University of Ottawa where consenting patients for this quality assurance initiative was not required.

Program Description

Our contemporary home HD programs in Edmonton and Ottawa, Canada, started in 2001. Currently, there are 59 prevalent home HD patients in the Northern Alberta Renal Program in Edmonton and 35 patients in Ottawa. Mean age is 52 years, and 40% of patients are women. Most patients live in urban Edmonton or Ottawa, whereas more than one-third are widely dispersed in rural Alberta and Ontario, often hundreds of kilometers removed from the primary care team. Since their dates of inception, these 2 home HD programs have trained 190 patients.

Patient Selection

Interested patients are referred to home HD from the conventional HD or peritoneal dialysis units or from predialysis and transplantation follow-up clinics. A multidisciplinary team evaluates all prospective patients to determine appropriateness. Particular attention is given to dexterity, vision, cognitive capacity to learn the home HD protocols and procedures, and the social context in which home HD will be performed.

Patient Training

Patients typically have 4 training sessions per week for 6 weeks in conjunction with their HD treatments, although training is individualized as necessary for patients requiring additional time before being deemed safe to self-administer dialysis at home. There is a 1:1 nurse to patient ratio for this period. The home HD training curriculum includes all aspects of dialysis setup and takedown, machine maintenance and disinfection, water quality, drawing blood work, and access cannulation. Considerable time is devoted to troubleshooting machine alarms and responding to emergency situations, such as power outage and accidental disconnection. Patients in the Northern Alberta Renal Program are administered an open-book quiz after each week of training and are expected to complete a final examination prior to graduation from the program.

Dialysis Prescription

Conventional HD machines modified for home use are used exclusively in our programs (Formula Domus [Bellco] and Fresenius K [Fresenius Medical Care]). Although most home HD patients are encouraged to maximize the frequency and duration of dialysis by performing nocturnal HD, only half are using this modality, with significant variation in treatment frequency, from 3-6 nights per week. The rest perform a variation of conventional HD from 3-6 times weekly; none of our patients receives short daily HD. Typical dialysate composition for nocturnal HD is as follows: sodium, 137-139 mEq/L; potassium, 2-3 mEq/L; calcium, 1.5 mmol/L; and bicarbonate, 32-35 mEq/L. Blood and dialysate flow rates are 200-300 mL/min and 300 mL/min, respectively, whereas for patients prescribed a more conventional HD regimen, a blood flow rate of 300-400 mL/min and dialysate flow rate of 500 mL/min are used. Patients routinely receive systemic anticoagulation with heparin as in facility-based HD.

Patient Follow-up

A nurse and technologist are present for the first home treatment. The first follow-up in the clinic typically occurs after 1 month and then at 3-month intervals. Patients may call the unit for nursing or technical support on weekdays and have access to 24-hour nursing and technical support at all other times. Blood work is monitored monthly, as is water for endotoxins. There is no fixed patient recertification schedule, although technique audits are performed when patients are experiencing difficulties with aspects of home dialysis.

RESULTS

Overview

Since the inception of our contemporary home HD programs in Edmonton and Ottawa, Canada, we have trained 190 patients who have dialyzed for more than 500 patient-years. Assuming that a typical patient dialyzes 4-5 times weekly (the precise frequency cannot be determined from available records), this constitutes approximately 117,000 home HD treatments of experience. We describe 1 death (from exsanguination) and 6 life-threatening procedure-related adverse events, resulting in a crude procedure-related adverse-event rate of 0.060 event/1,000 home HD treatments (death rate, 0.0085 event/1,000 treatments [8.5 deaths in 1,000,000 treatments or 2 deaths/1,000 patient-years]). These events are summarized in Tables 1 and 2.

Case 1

During nocturnal HD, the patient was awoken repeatedly by audio and visual alarms. Without identifying the cause of the alarms, the patient simply reset the machine each time and returned to sleep. Subsequently, in the early morning, the patient awoke when the arterial connection to the dialyzer blew off and created a significant blood splatter on the wall; another 4-L pail allegedly half-full of blood was present under the dialyzer. Emergency medical services responded to a telephone call from the patient's wife and transported the patient to a local hospital.

Review of the incident revealed that the patient had incorrectly cross-threaded the arterial tubing of the extracorporeal circuit to the dialyzer. The multiple alarms arose due to high venous pressures from a progressively thrombosing dialyzer. The combination of an elevated back pressure along with the dialyzer misconnection allowed blood to eventually escape from the system with high velocity. The wetness detector, usually placed on the floor at the base of the HD machine, did not sound because the patient had

Table 1. Patient Characteristics

Case No.	Age (y)	Sex	Year of Adverse Event	Home HD Vintage (mo)[a]	Vascular Access	Home HD Type	Heparin Bolus Dose (U)	Infusion Rate (U/h)	Alone[b]
1	65	M	2007	7	AVF: double-needle, single-pump	Nocturnal[c]	2,500	1,000	No
2	40	F	2007	<12	CVC	Nocturnal[c]	1,000	1,000	No
3	46	F	2011	48	CVC	Nocturnal[c]	600	1,100	No
4	59	M	2011	<1	CVC	Nocturnal[c]	1,500	500	Yes
5	50	F	2012	35	AVF: double-needle, single-pump	Nocturnal[c]	1,800	1,300	Yes
6	35	M	2012	<24	AVF: single-needle, double-pump	Nocturnal[c]	2,000	1,200	No
7	59	M	2012	24	AVF: double-needle, single-pump	Conventional[d]	2,000	1,500	No

Abbreviations: AVF, arteriovenous fistula; CVC, central venous catheter; HD, hemodialysis.
[a]Vintage at time of adverse event.
[b]Dialyzing alone at time of adverse event.
[c]Nocturnal: typically performed 4-6 nights per week for 6-8 hours per dialysis session.
[d]Conventional: typically performed 3 days per week for 4 hours per dialysis session.

placed a pail under the dialyzer (as he usually did) to catch saline and not sully his floor during the priming of the tubing prior to starting dialysis. We hypothesize that the pressure was intermittently relieved as blood escaped from the system and the cascade of events recurred each time the patient reset the alarm until the pressure was finally so high that the arterial tubing blew off the dialyzer head.

Case 2

As the patient was disconnecting herself from the machine after her dialysis treatment, she did not clamp the arterial port of her central venous catheter (CVC), allowing air to enter the lumen. The patient recognized the effect of the breach in technique, clamped the tubing, promptly lay down on her left side, and called emergency medical services. The patient was hypotensive and responded to volume resuscitation in the emergency department. Given the antecedent history, it was assumed that she sustained an air embolism, although an echocardiogram was not performed.

This event occurred in an era prior to the use of specific closed connector devices (eg, Tego Needle-free Hemodialysis Connector [ICU Medical Inc] caps) between the ports of the CVC and dialysis tubing.

Case 3

During the dialysis treatment in question, the patient awoke with blood on her leg and bed sheets. She later reported that her vital signs were stable (though there is no formal documentation of this) and she disconnected herself from the HD machine. She presented herself to the home HD unit the following

Table 2. Causes of Adverse Events

Case No.	Human Error(s) or Machine/ Disposable Defects	Immediate Cause of Adverse Event	Details
1	Human error	Blood loss	Ignored machine alarms; improper threading of connections; placement of wetness detectors in incorrect position
2	Human error	Air embolism	Neglected to clamp CVC
3	Possible human error, possible disposable defect	Blood loss	Possible failed integrity of cap; possibly did not correctly thread connections
4	Possible human error, possible disposable defect	Blood loss	Improper placement of clamp; failed integrity of cap
5	Human error	Blood loss	Improper machine setup; neglected to use wetness detectors
6	Human error	Blood loss	Improper threading of connections; placement of wetness detector in incorrect position
7	Human error	Blood loss	Did not follow machine setup protocol specific to local home HD program

Abbreviations: CVC, central venous catheter; HD, hemodialysis.

day to report the incident. The patient stated that she became disconnected from the CVC Tego connector cap, which she suggested had a broken membrane; the connector cap had been discarded, thus precluding investigation. When reviewed by the nursing team, she demonstrated proper technique for machine setup, including all tubing connections.

Case 4

The patient was found early one morning by his spouse, unresponsive on his bedroom floor with a large volume of blood surrounding him. Prior to this, he had successfully returned his extracorporeal blood and completely disconnected himself from the dialysis machine (as he was so discovered by his spouse). Each lumen of the dialysis catheter was secured by a clamp, although the arterial clamp was misaligned and blood was flowing freely from around an incorrectly threaded Tego connector cap (Fig 1). Cardiopulmonary resuscitation efforts were unsuccessful.

An autopsy attributed the cause of death to exsanguination from the CVC. However, it is speculated that this was preceded by a vasovagal loss of consciousness or arrhythmia because the flow of blood from the lumen otherwise would have been slow enough for a conscious person to notice and intervene.

Case 5

The patient telephoned the on-call nurse 1 hour into her HD treatment describing nausea and lightheadedness. She noticed blood on the floor, estimated to cover 1-2 m^2. Her self-performed blood pressure and pulse measurements reportedly were normal for her. The patient remained home against medical advice.

Debriefing with the nursing team revealed that the patient had inadvertently connected the heparin syringe to the medication port of the arterial chamber instead of to the heparin tubing. The heparin tubing thus was left unconnected, allowing blood to leak through an open port as it exited the blood pump (Fig 2A and B). In addition, the patient had neglected to use the respective wetness detectors underneath the dialysis machine, under the dialyzer, and under the water treatment equipment, as is routine for home HD patients in our programs.

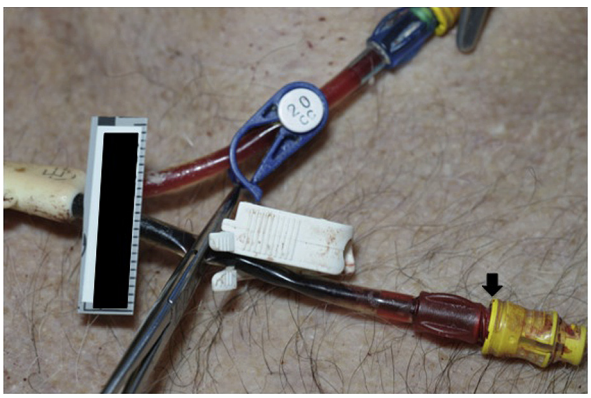

Figure 1. Photograph of dialysis catheter connectors in case 4. The placement of the white clamp was misaligned and the Tego connector cap (arrow) was incorrectly threaded. The metal clamp was placed after the exsanguination had already occurred. Photograph taken at autopsy.

Case 6

The patient awoke one morning with significant presyncope and discovered a large pool of blood on the floor. Attempt at rinse-back was unsuccessful, so the volume of blood within the extracorporeal circuit was also lost; an emergency medical services call was initiated. A hemoglobin concentration of 6.6 g/dL was noted (it had been 12.3 g/dL 3 days prior to this incident).

Evidence of blood leakage from the venous tubing connection on the dialyzer head was found, suggesting that the patient may not have threaded the catheter properly. We hypothesize that improper threading resulted in slow but steady blood loss. An incident review showed that although the patient had been adherent in placing a wetness detector under his dialyzer as per protocol, he had moved his HD machine after setup to better see its screen, such that the wetness detector was no longer in the correct position.

Case 7

While on vacation, the patient dialyzed in a unit that used an HD machine similar to the one he used at home. However, in the vacation unit, the nursing staff performed an extracorporeal circuit priming procedure that is different from the one our home HD patients are taught (Fig 3). The patient attempted to mimic this procedure at home. After standard saline solution priming of the entire extracorporeal circuit, the alternate procedure involves connecting the arterial portion of the circuit to the patient and the venous portion to an empty drain bag. Thus, when the pump is engaged, the blood pushes the saline solution into the drain bag. A blood detector in the venous circuit subsequently stops the pump when blood is detected. This detector prevents blood from entering the drain bag and signals the patient to connect the venous circuit to his vascular access. Patients in our home HD programs are taught a different procedure and the home HD machines currently in use are not configured with such a detector. In this case, the patient initially failed to notice blood filling the drain bag until it had collected a significant volume (the patient estimated this to have been ~1 L by looking at the drain bag). He felt well and reported the incident the following day.

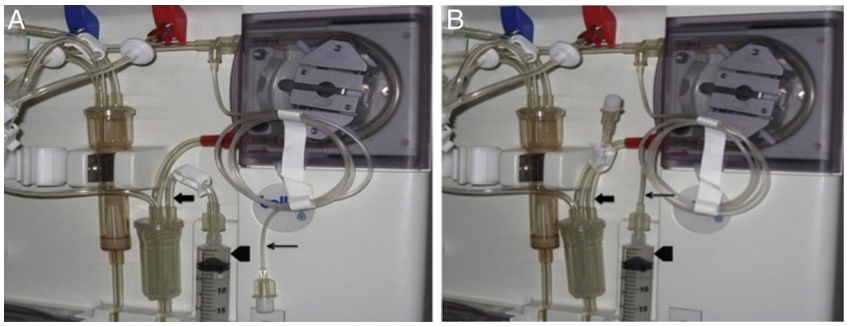

Figure 2. **(A)** Mock setup of misconnection of the heparin syringe (arrowhead) to the medication port (thick arrow) of the arterial chamber. As a result, the heparin tubing (thin arrow) was unconnected. (B) Mock setup of proper connection of the heparin syringe (arrowhead) to the heparin tubing (thin arrow). The medication port (thick arrow) of the arterial chamber is intended to be left unattached.

DISCUSSION

A retrospective quality assurance review of our programs identified 7 life-threatening adverse events unique to the home HD setting, including a single death. This results in a crude event rate of 0.060/1,000 home HD treatments, which seems acceptably low and confirms the overall safety of home HD. To our knowledge, this is the first report to benchmark this key performance indicator.

Although home HD generally is assumed to be very safe, there are sparse data about adverse events. Two small crossover studies of the NxStage System One (NxStage Medical Inc) and the Fresenius 2008K@home (Fresenius Medical Care) machines involved 32 and 29 patients, respectively, and neither reported an increase in adverse events while patients were dialyzing at home.[13,14] However, the small number of patients and short follow-up (≤6 months) suggest that these reports are not adequate to observe catastrophic events. Thus, comparing these studies to the present report of life-threatening procedure-related adverse events is not germane because they are limited to minor incidents, such as back pain, arthralgias, and nausea.

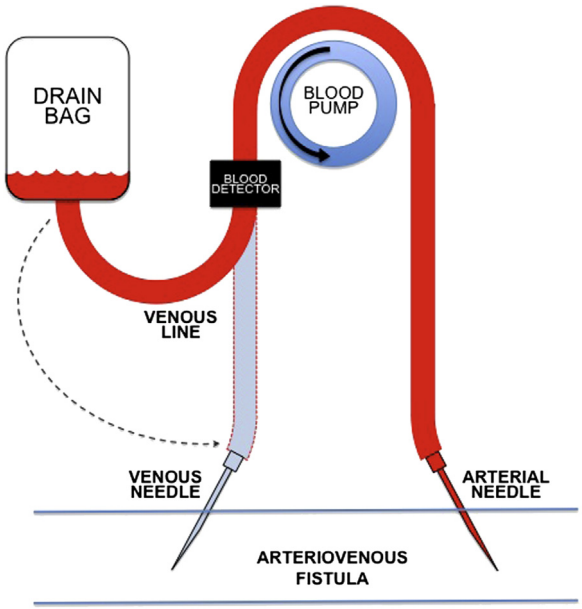

Figure 3. Extracorporeal circuit priming procedure. When the blood detector senses blood, the patient is to stop the pump, disconnect the end of the venous tubing from the drain bag, and connect to the patient (curved dashed arrow). This did not occur in case 7. Rather, the machine was not equipped with a functioning detector, so the patient was not alerted to the need to connect the tubing to the needle; instead, blood started to fill the drain bag and a correction was not made until the patient noticed the blood himself (without being alerted by the machine).

A single case report from New Zealand documented exsanguination of a home HD patient as a result of an incorrect wash-back procedure at the end of a dialysis session, when blood was inadvertently pumped out of the patient and into a saline bag.[15] Due to the unsupervised nature of home HD, there also is the risk of major hemorrhage from needle dislodgement, though only 2 such cases are alluded to in the literature (neither of which was described in detail).[16] This is to be distinguished from exsanguination related to vascular access rupture, often associated with aneurysmal dilatation, which has been described extensively.[17-19] Such deaths can occur in anyone with an arteriovenous fistula or arteriovenous graft, do not appear temporally related to the HD procedure, and have never been described as occurring in patients undergoing home HD specifically. Other potentially devastating complications include chloramine contamination and air embolism, although these are not specific to home therapies. One might argue that although certainly not common, even a single avoidable death related to the home HD technique is one too many, and thus this topic warrants careful scrutiny.

Several important themes emerge from the cases we present (Table 2). First, blood loss (either into or from the circuit or from the vascular access [usually a CVC]) is the most common mechanism of a life-threatening adverse event, having occurred in 6 of 7 described cases. Causes such as air embolism, hemolysis, or hemodynamic collapse from inadvertently high ultrafiltration related to a dialysate leak were

either very rare or not observed. Second, human error played a confirmed contributory role in 5 of 7 cases (and perhaps more) even when an antecedent cause may have precipitated the event (eg, a closed connector device malfunction). Such human errors almost always resulted from patients not adhering to prescribed protocols. This is important to note because adverse events typically are not related to the absence of dictated safety precautions, but rather to not operationalizing such measures in the home. For example, all patients are taught to use wetness detectors to alert the user of blood or dialysate leaks, but these were either absent or useless in 3 of 7 cases. It is not known how often a potentially catastrophic event is averted with proper safety mechanisms in place. Table 3 delineates the adverse events considered in the present quality assurance review and outlines the safety measures that, if adhered to, are aimed to mitigate their occurrence. Finally, patients will find creative and unexpected ways to deviate from protocols either by experimentation, serendipity, complacency or from other patients. Patients need to be aware that even seemingly minor deviations from protocol may have unintended and even catastrophic sequelae (eg, an alternative rinse-back procedure may be acceptable only if the device is equipped with the requisite sensors, which the patient is unlikely to know).

Importantly, there does not appear to be an obvious relationship between the experience of the program and the occurrence of these events. The majority of life-threatening incidents occurred in the last 2 years of observation and not in the first few years from program inception. Also, there did not seem to be a correlation between adverse events and patient familiarity with the technique, with almost half of all events occurring in patients with at least 2 years of home HD experience. Additionally, although there is considerable variation in programmatic policy concerning the prerequisite for a care partner to attend patients during home HD treatments, with many programs (including ours) not having such a requirement, it should be noted that 5 of 7 events occurred while a care partner was home. It is not clear whether the presence of a partner would have made a material difference in the 2 cases in which none was present. Of the 94 prevalent home HD patients currently in our home HD programs, 27 (29%) are regularly performing HD at home alone. A similar proportion of adverse events (2 of 7 [29%]) occurred in patients who were dialyzing alone, suggesting that a policy mandating the presence of a care partner is overly restrictive and unlikely to reduce the event rate.

Each of these cases resulted in prompt reviews with the patient, the nursing and technologist teams, and the physician to ascertain the cause of the adverse events, maximize our learning from their occurrence, and prompt directed action to the patient in question or for the program more broadly. Box 1 summarizes a 3-step framework we now find helpful in approaching adverse events and guiding us to an appropriate response. This is an essential quality assurance step resulting in iteratively improved patient care. One adverse event resulted in the adoption of a closed connector device (Tego connector cap) for all patients using CVCs. This device prevents blood from leaking out of a CVC and air from entering when the lumen is not clamped. Each event now prompts an automatic technique audit to ensure that the patient is aware of

Table 3. Potential Adverse Events With Home HD

Adverse Event	Prevention Plan
Exsanguination into the circuit	Priming and rinse-back procedures to make it impossible to bleed into circuit by eliminating disconnection and reconnection of arterial and/or venous tubing to/from patient
Exsanguination from the circuit	Unimpeded placement of wetness detectors in correct positions; ensure proper threading and integrity of connectors
Exsanguination from the access	Placement of wetness detectors in correct positions; use of closed connector devices (for CVCs); ensure proper placement of clamps (for CVCs)
Air embolism	Use of closed connector devices (for CVCs)
Inadvertent hemodynamic decompensation due to ultrafiltration	Increase frequency and duration of treatments to decrease overall ultrafiltration rate; continued education regarding salt and water intake (particularly important because patients may have the false assumption that intensive HD absolves them of dietary restrictions); regular careful assessment of patient's dry weight; consider a care partner requirement; lower dialysate temperature; avoid intradialytic food ingestion
Inadvertent hemodynamic decompensation from dialysate leak	Placement of wetness detectors in correct positions; ensure proper threading of dialysate tubing to dialyzer
Hemolysis	Ensure absence of kinks in tubing; regular monitoring of water quality

Abbreviations: CVC, central venous catheter; HD, hemodialysis.

Box 1. Quality Assurance Framework

Step 1 – Case review to determine cause and contributing circumstances of the adverse event
Step 2 – Technique audit to ensure ongoing patient competence at performing home HD
Step 3 – Specific questions to ask of the program:
1. Is this patient safe to continue home HD?
2. Was the adverse event avoidable? If so, how specifically?
3. Was human error the primary or a contributing factor in the adverse event?
4. Was a device defect the primary factor in the adverse event?
5. Does this event require communication with a device manufacturer (machine or disposable)?
6. Are there specific interventions required for this patient to continue home HD?
7. Is there a specific protocol or procedure that affects other home HD patients and what preventative measures should be implemented programmatically?
8. How should the information or process from question 7 be disseminated to present and future patients?
9. Does this adverse event necessitate review of the home HD recruitment or retention criteria?

Abbreviation: HD, hemodialysis.

current best practices to maintain his or her safety. Our programs have a low threshold to perform such technique audits even for patients who have not experienced an overt adverse event, and all events have informed teaching for subsequent home HD patients.

Unlike a typical quality improvement initiative in which an action results in measurement of an outcome to ascertain the effect of an intervention (ie, the act-plan-do-study cycle), quality improvement measures aimed to avert future life-threatening adverse events in home HD are difficult to evaluate quantitatively because the event rate is so low. This represents a major limitation of any improvement initiative because its effect will take many patient-years to be discernible. The systematic collection of cases of serious adverse events into a registry would be desirable to accurately estimate their incidence and determine common themes and areas for intervention; unfortunately, such a registry does not yet exist.

The cases presented here also may spur human factors research combined with engineering innovations to produce safer, more user-friendly HD machines that are specifically designed for home use. Review of our teaching protocols confirms there are about 100 individual steps to initiating home HD. Any complex human task such as this is prone to errors, and device manufacturers would do well to design home dialysis machines that minimize patient interaction with the machine and automate as much of the process as possible.[20] For example, 4 of the 7 cases could have been averted had the various connections (ie, between CVCs and dialysis tubing, dialysis tubing and the dialyzer, or the heparin syringe and the dialysis circuit) been designed in such a way that a unique locking mechanism must be engaged before dialysis can be initiated. A fifth adverse event may have been prevented if the dialysis machine was capable of automated priming and/or rinse-back. Designers of future home HD equipment should consider such adverse events and minimize the user interaction with plug-and-play technology, rather than make small modifications to machines more suitable for facility-based HD.

In summary, we have presented a case series of life-threatening home HD procedure-related adverse events from 2 experienced home HD programs in Canada. Although home HD generally is very safe, the potential for catastrophic events exists and provides an opportunity for ongoing quality assurance measures to make this therapy even safer. We present a 3-step framework to approach such adverse events to help determine what patient- or program-specific measures can be implemented to avert similar future events.

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