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Patient Safety in Home Hemodialysis: Quality Assurance and Serious Adverse Events in the Home Setting

Robert P Pauly, MD, MSc, FRCPC¹

Deborah O Eastwood, BBus, PG Cert Health Sciences, MSc²

Mark R Marshall, MBChB, MPH, FRACP^{3,4}

¹Division of Nephrology and Transplant Immunology, University of Alberta, Edmonton, Alberta, Canada;

²Department of Medicine and Health of Older People, Waitemata District Health Board, Auckland, New Zealand;

³Faculty of Medical and Health Sciences, University of Auckland, Auckland, New Zealand;

⁴Department of Renal Medicine, Counties Manukau District Health Board, Auckland, New Zealand



Implementing
Hemodialysis in the Home
A Global Perspective

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Abstract

Interest in home hemodialysis (HD) is high because of the reported benefits and its excellent safety record. However, the potential for serious adverse events (AEs) exists when patients perform HD in their homes without supervision. We review the epidemiology and literature on dialysis-related emergencies during home HD, and present a conceptual and practical framework for the prevention and management of serious AEs for those patients performing home HD. In addition, we recommend and describe a formal monitored and iterative quality assurance program, and make suggestions for the future development of safety strategies to mitigate the risk of AEs in home HD.

Introduction

Patients and their care partners acknowledge the benefits of home hemodialysis (HD) compared with traditional facility-based dialysis. However, as home HD training progresses, the initial positive attitudes expressed by patients and their care partners about home HD oftentimes change to an increasing apprehension about accepting responsibility for independently performing this complex medical therapy, and fear about managing potentially life-threatening dialysis-related emergencies alone.¹ Clinicians at facility-based dialysis centers who do not have experience working with home HD often share similar concerns about patient safety.²

Despite these fears, serious adverse events (AEs) during home HD are uncommon. Experienced home HD clinics have safeguards in place to mitigate serious AEs and, if they do occur, to manage them effectively. New home HD programs will benefit from these lessons and must instill a culture of safety – without inciting alarm or undermining assurances – that home HD is a generally safe therapy. To maintain a good safety record, vigilance by patients, care partners, and center personnel is paramount in avoiding and managing emergencies experienced in home HD programs.³

In this module, we describe a conceptual and practical framework for dialysis healthcare providers to help them address preventable serious AEs for patients during home HD, emphasizing those AEs that result from technical error with the potential to be life-threatening and/or have the capability to derail a home HD program. We highlight the life-threatening emergencies described in the literature, suggest a quality assurance process, and provide specific strategies to facilitate expeditious care in emergency situations.

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Epidemiology of Dialysis-Related Emergencies in Home HD

There is little published literature of the epidemiology of dialysis-related emergencies. Notwithstanding, it can be assumed that relatively minor and common complications of HD seen in facility-based dialysis still occur to some degree when this treatment is administered at home. More concerning is the paucity of literature regarding dialysis-related emergencies with the potential to cause death. For the purpose of this module, such life-threatening emergencies include: blood loss (either from needle dislodgement or disconnection from a central venous catheter, bleeding *from* the dialysis circuit, or bleeding *into* the dialysis circuit), air embolism, hemodynamic compromise from aggressive ultrafiltration or dialysate leak, hemolysis, and acute electrolyte abnormalities associated with the treatment. While these complications are not unique to home HD, there is an inherently greater risk when they occur in a setting where trained staff cannot administer immediate emergency interventions. Infectious complications are not considered further but are addressed within a separate module (see “Increased Risk of Infection with Buttonhole Cannulation” in the “Care and Keeping of Vascular Access for Home Hemodialysis Patients” module)

A 2013 quality-improvement study involving 2 home HD programs in Canada evaluated the frequency of these AEs, and reported 1 death and 6 potentially fatal AEs in their programs over 12 years.⁴ This translates into a crude death rate of 2 per 1000 patient-years and a cumulative life-threatening procedure-related AE rate (ie, death plus potentially lethal AEs) of approximately 14 events per 1000 patient-years.⁴ These findings are in line with a more detailed single-center analysis also from Canada, which reported a corresponding life-threatening, procedure-related AE rate of 9 per 1000 patient-years.⁵

The only direct comparison between home and facility HD comes from a cohort study from New Zealand, which posed the question: “For those on HD in New Zealand, does HD in the home setting result in a higher mortality risk from angioaccess bleeding or infection than HD in the facility setting, over a 15-year time frame?”⁶ In this analysis, there were 11 such events recorded over 8755 patient-years for those patients undergoing facility HD (1.2 events per 1000 patient-years) and 1 per 2571 patient-years for those patients undergoing home HD (0.4 events per 1000 patient-years). After multivariate adjustment, the relative risk of angioaccess bleeding or infection in home vs facility HD patients was 0.30 (0.09-0.84).⁶ While both the Canadian and New Zealand studies have limitations (retrospective, observational, registry-based, etc), they provide a reassuring signal that home HD is a safe therapy. Indeed, administrative data from the Scottish Renal Registry of conventional in-center

hemodialysis recipients yielded a population incidence of death due directly to renal replacement therapy complications of 1.35 deaths/1000 renal replacement therapy patients per year; hyperkalemia was the most commonly attributable cause of death.⁷ This indirectly suggests that home HD is no more risky than in-center hemodialysis though the nature of AEs is different.



Take-Home Messages

- Serious AEs during home HD are rare due to the use of patient safety heuristics within experienced home HD programs.
- Ongoing vigilance is paramount to avoid and manage emergencies experienced in home HD programs.

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Conceptual Framework for Patient Safety in Home HD

As defined by the Institute of Medicine (IOM), “Patient safety is the prevention of harm to patients”.⁸ This definition is further expanded by the United States Agency for Healthcare Research and Quality (AHRQ) to include, “[Fundamentally] patient safety refers to freedom from accidental or preventable injuries produced by medical care”.⁹ However, these concepts require modification when referring to home HD. While traditional patient safety focuses on the care provided by healthcare professionals, safety in home HD involves patient vigilance in partnership with their care partners *and* healthcare professionals, with discrete safety practices specific to each group. In addition, traditional patient safety doctrine emphasizes almost exclusively the prevention of error. Patient safety during home HD must also include a proactive stance to minimize patient injury in the event that such an error does occur.

A formally monitored and iterative quality assurance program is strongly recommended to enhance patient safety, as illustrated in Figure 1. This framework will be most effective if it can be implemented as a formally monitored and iterative quality assurance program, emphasizing systems of care that (1) prevent procedure-related AEs; (2) minimize harm from those events that do occur; (3) provide a means to learn from the events

that have already occurred; and (4) build a culture of safety among healthcare professionals, patients, and their care partners.

In the next sections, we discuss serious AEs reported in the home HD literature, outline strategies for their mitigation and management, and provide guidance on how to close the loop from serious AEs and continue ongoing quality improvement.

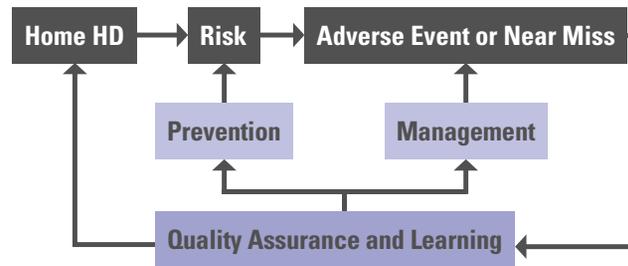


Figure 1. Patient Safety Quality Assurance Framework

Types of Procedure-Related Serious Adverse Events During Home HD

While patients dialyzing at home are subject to many of the same complications as those dialyzing in-center (eg, experiencing vascular access complications, infections, chloramine contamination), the current discussion is limited to emergencies that are unique to the home setting, either because such events cannot happen in a facility-based unit or are less likely to escape notice from trained personnel and escalate into a serious AE. The literature describes 9 cases of fatal or life-threatening AEs in home HD (Table 1), and several of these events are depicted in Figures 2 through 7.^{4,10,11} Blood loss was the most common cause: 7 in total. Three episodes of bleeding from the circuit (due to poor connections between tubing and dialyzers, or the incorrect attachment of a heparin syringe to the circuit), 2 episodes of bleeding from central venous catheters due to poor connections or clamping, and 2 episodes of bleeding into the dialysis circuit (bleeding into drain bags during priming at the start of HD or during rinse-back at the end) were reported. Murlidharan et al report a case of near fatal hypercalcemia in a patient due to the inadvertent reversal of the reverse osmosis machine product water and drain solution lines, with the product water being inappropriately discarded while the drain solution (having a very high calcium concentration) being used to generate dialysate.¹¹

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Table 1. Severe Procedure-Related Adverse Events in Home Hemodialysis Described in Published Literature

Case ^a	Patient Age, year	Year of Event	Experience with Home HD (mo)	Home Alone ^b	Adverse Event	Human Error	Details
1	65	2007	7	No	Blood loss	Yes	Multiple contributing factors including ignoring alarms, misthreading of arterial tubing to dialyzer head, and incorrect placement of wetness detectors. (See Figure 7)
2	40	2007	<12	No	Air embolism	Yes	Unclamped central venous catheter
3	46	2011	48	No	Blood loss	Possible	Possible misthreading of dialysis tubing to the central venous catheter. Possible closed connector device malfunction.
4	59	2011	<1	Yes	Blood loss	Possible	Possible failed integrity of closed connector device. Improper clamp placement.
5	50	2012	35	Yes	Blood loss	Yes	Incorrect machine setup. Failure to use wetness detectors.
6	35	2012	<24	No	Blood loss	Yes	Misthreading of venous tubing to dialyzer header. Inappropriate placement of wetness detectors. (See Figure 7)
7	59	2012	24	No	Blood loss	Yes	Failure to adhere to machine setup protocol as instructed. (See Figures 2-4)
8	67	2010	<1	Yes	Blood loss	Yes	Connecting the venous (instead of arterial) tubing to a saline rinse bag during rinse-back procedure. (See Figures 5 and 6)
9	46	2011	72	No	Hypercalcemia	Yes	Reverse osmosis waste water hooked incorrectly to dialysis machine to generate dialysate and product water to drain.

^aTable adapted from the following publications: Cases 1-7 from Wong et al⁴; Case 8 from Allcock et al¹⁰; Case 9 from Murlidharan et al.¹¹

^bHome Alone indicates whether a patient was dialyzing with an attendant care partner present at the time of the adverse event.

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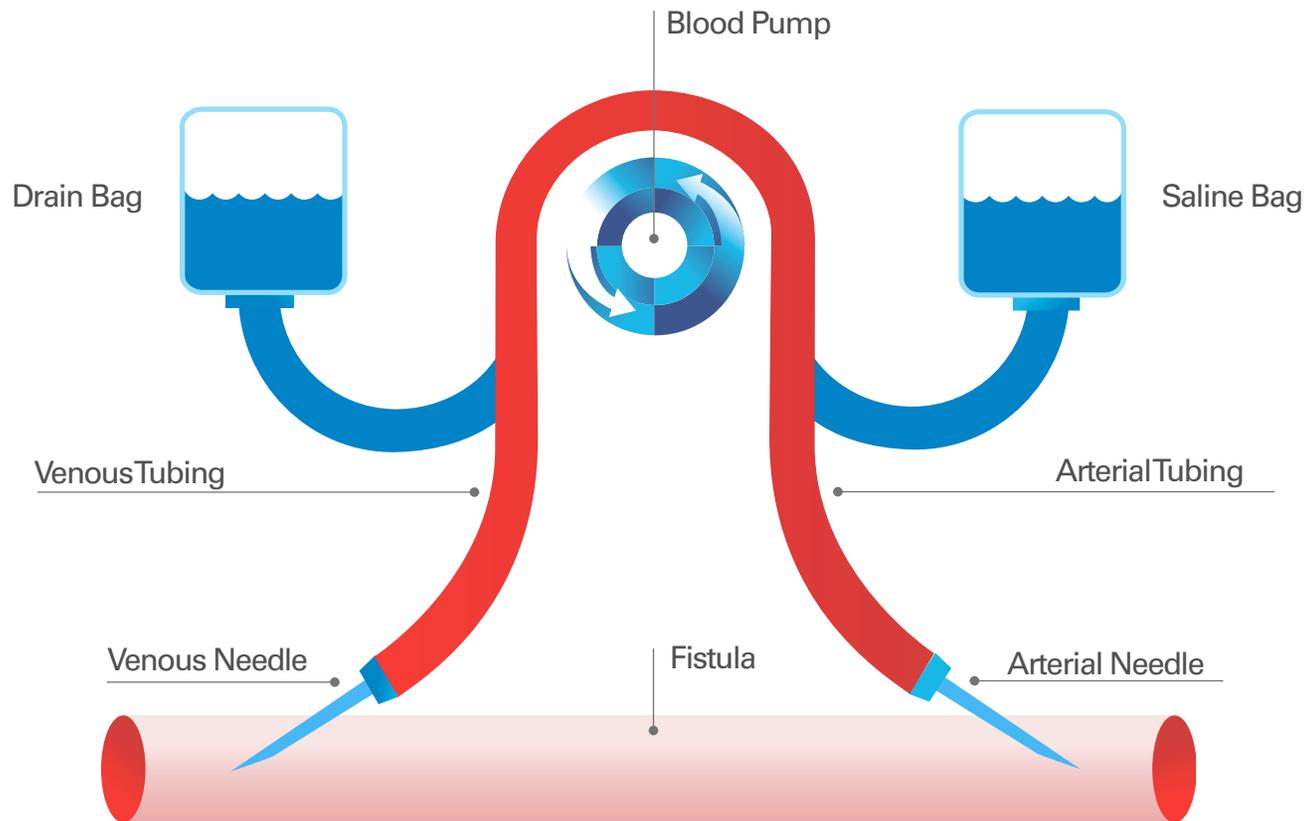


Figure 2. Generic Hemodialysis Setup

This figure depicts dialysis tubing connected to a patient's arteriovenous fistula by an arterial needle, with tubing passing around a standard pump, through a dialyzer, and returning through a venous needle into the fistula. The saline and drain bags are used variably during the saline priming and rinse-back procedures.

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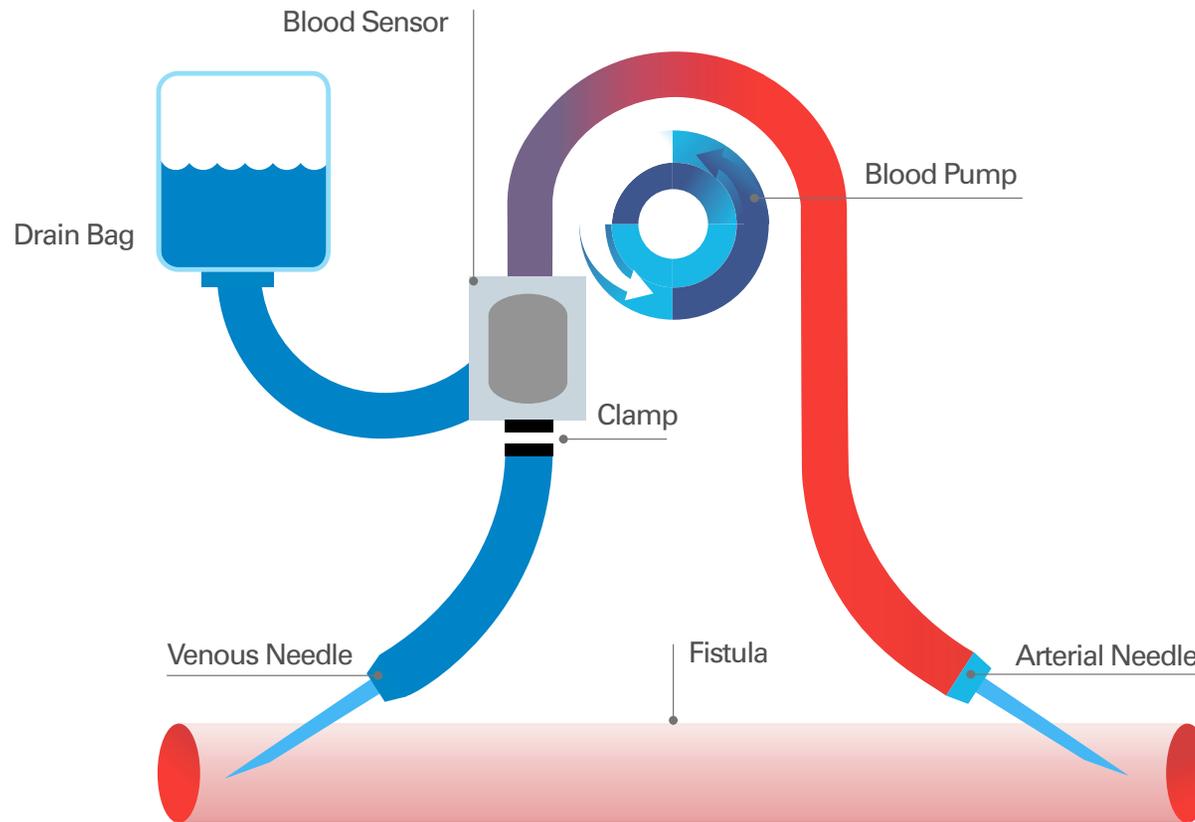


Figure 3A. Routine Blood Priming of the Hemodialysis Circuit

After the hemodialysis circuit has been primed with saline, the circuit must then be primed with blood before dialysis can commence. To do so, the arterial needle is connected to the patient's fistula, the pump is engaged, and blood is drawn out of the fistula into the tubing, around the pump, and through the dialyzer, pushing the saline ahead of it. In a typical priming protocol, the saline is diverted into a drain bag (and not infused into the patient) until blood is detected by the blood sensor.

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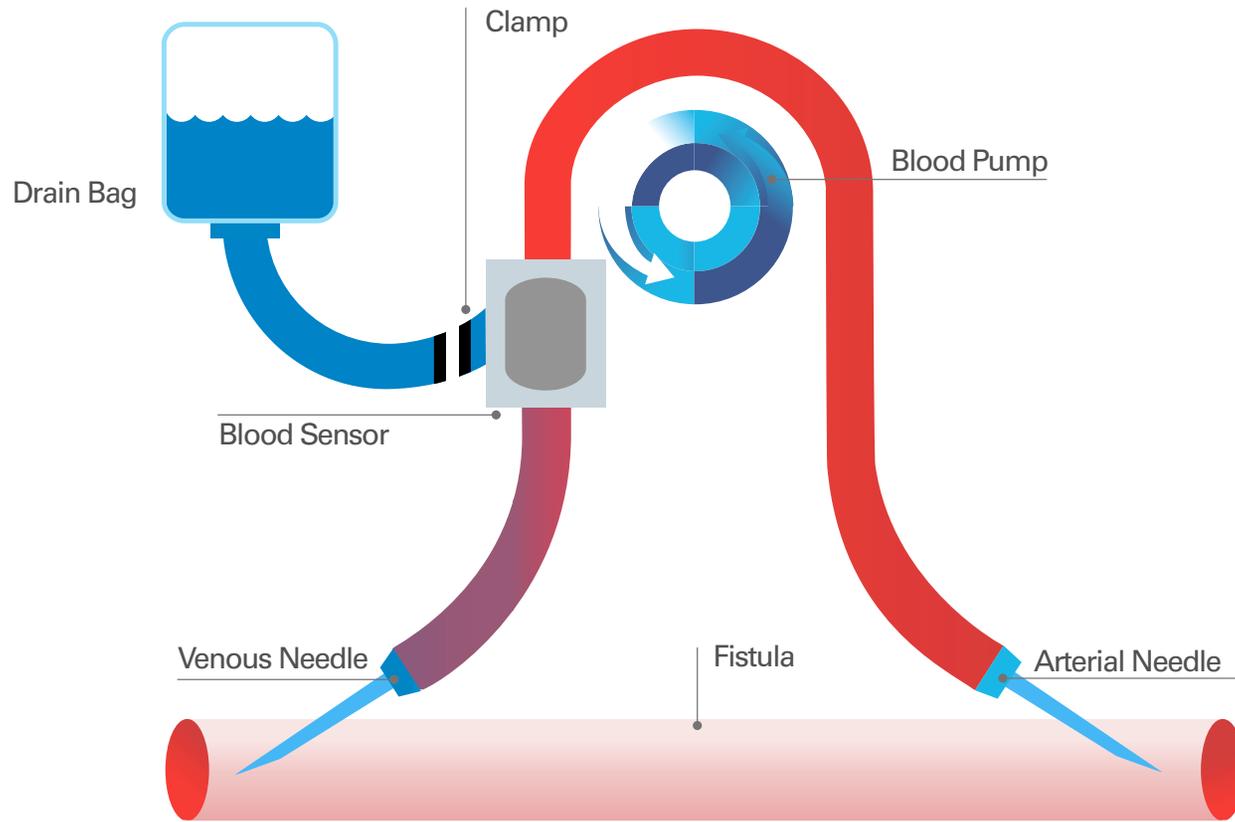


Figure 3B. Routine Blood Priming of the Hemodialysis Circuit

Once blood is detected by the sensor, the patient is cued by the machine to temporarily stop the pump, clamp the tubing to the drain bag, and open the clamp to his or her venous tubing to have blood flow through the venous needle into the fistula, thereby completing the circuit priming with blood.

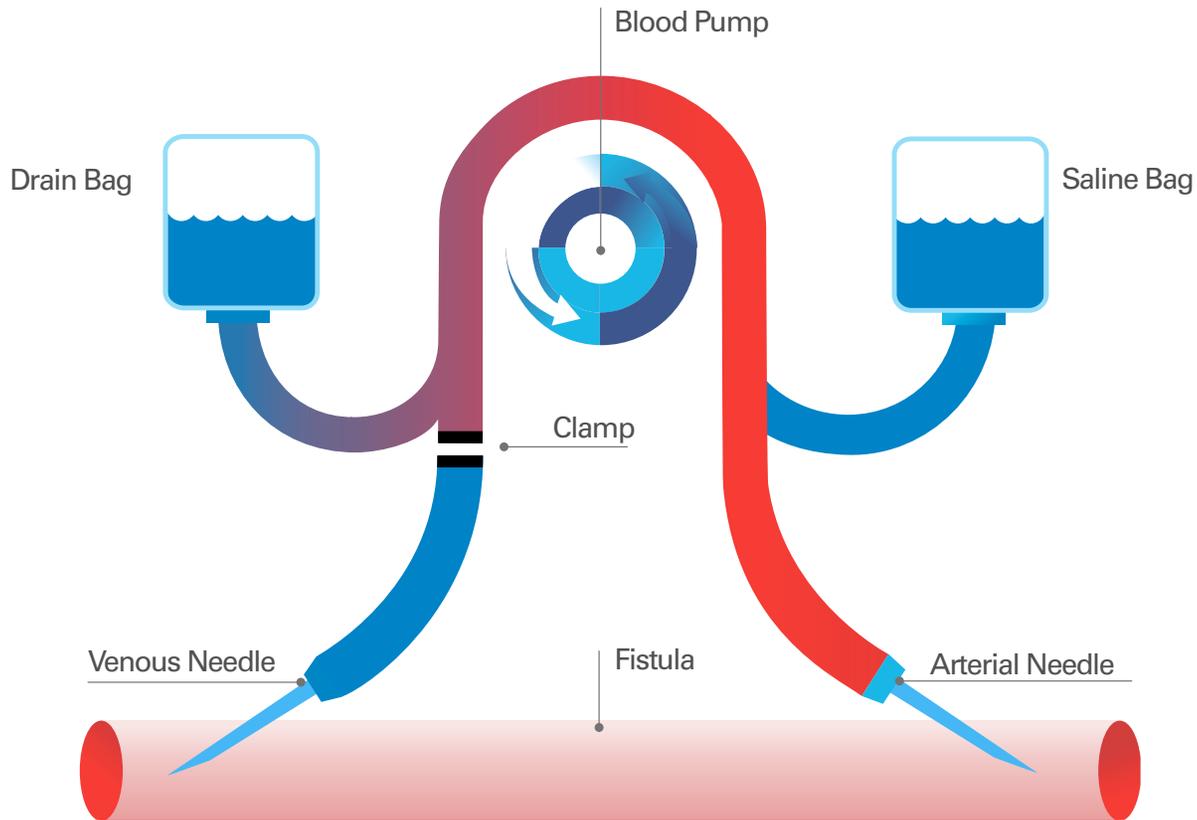


Figure 4. Variation of Blood Priming Without a Blood Sensor

If a patient is performing the same blood priming procedure as depicted in Figure 2 in the absence of a blood sensor, blood could enter the drain bag if the patient is not vigilantly watching the tubing as there is no automated cue signaling the patient to clamp the tubing to the drain bag and open the circuit to the fistula. Given the speed of the pump during priming, a patient losing concentration for even a minute or two can result in significant blood loss into the drain bag.

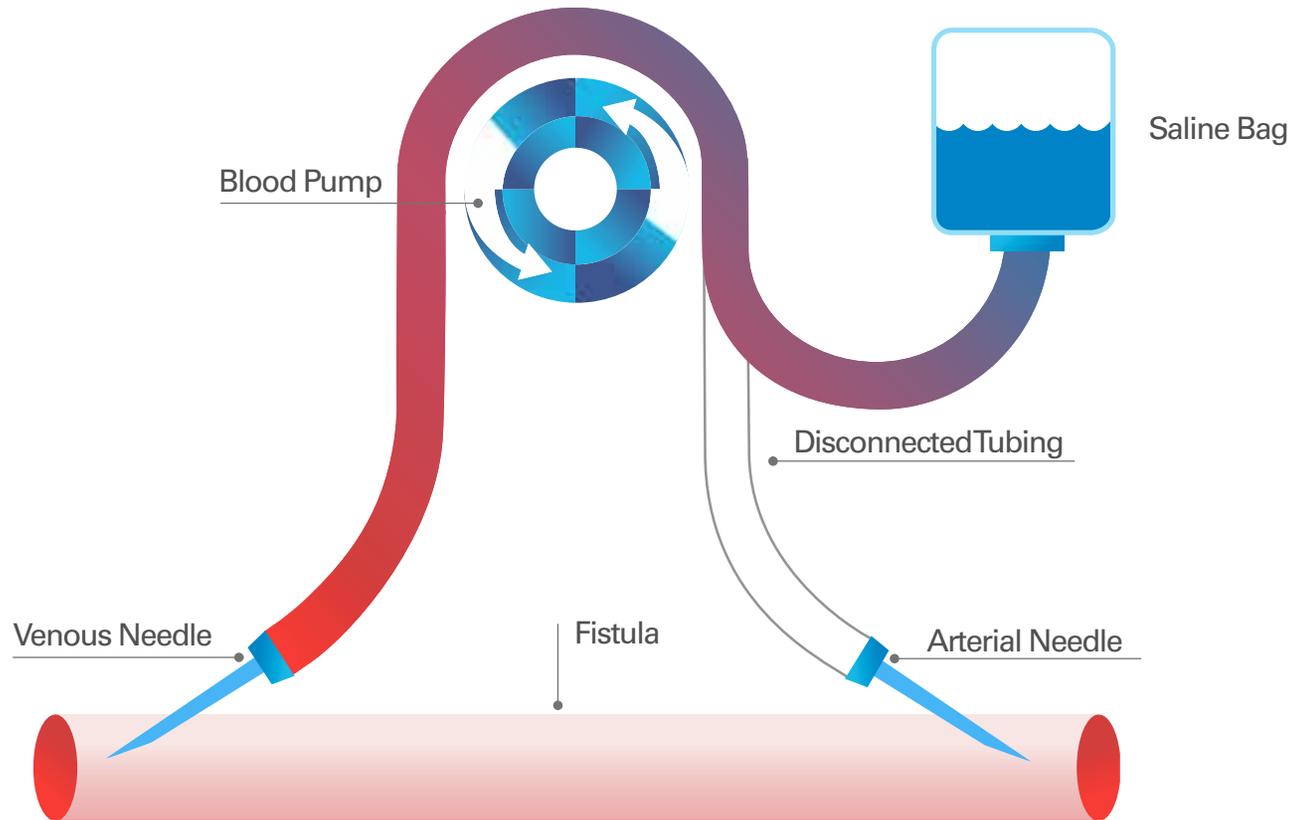


Figure 5. Routine Rinse-back After Dialysis Completion

After the hemodialysis treatment is completed, the tubing must be cleared of blood by rinsing it with saline. To do this, the patient disconnects the arterial tubing from the arterial needle and then connects the arterial tubing to a saline bag. The pump is then engaged and saline is drawn out of the saline bag through the circuit thereby pushing the blood ahead of it back into the venous side of the fistula ("returning blood to the patient").

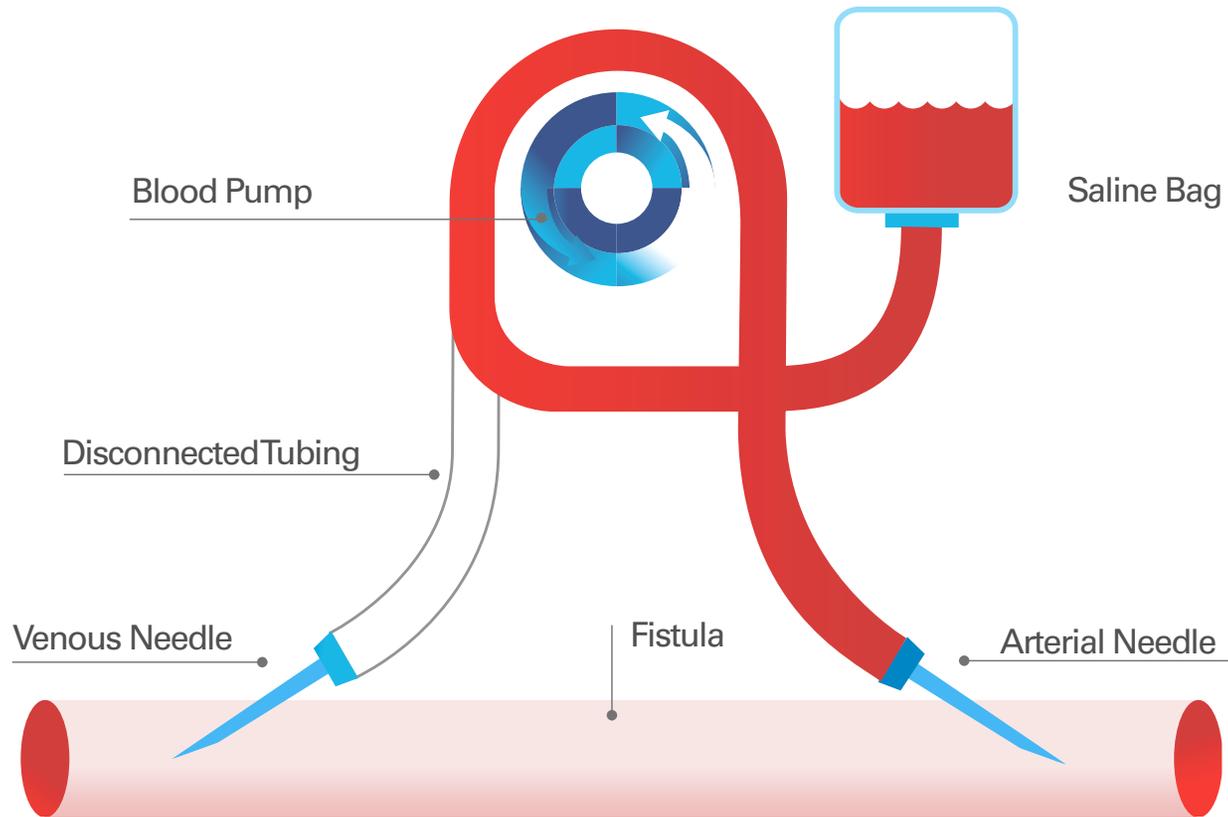


Figure 6. Rinse-back Procedure With Inadvertent Disconnection/Connection Errors

The usual rinse-back procedure requires the patient to disconnect the arterial tubing and connect it to the saline bag (see Figure 4). However, if the patient inadvertently disconnects the venous tubing from the fistula and connects it to the saline bag instead, blood will be drawn incorrectly from the arterial line, pushing it into the saline bag. Blood will not be returned to the patient when the pump is engaged.

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Wong et al describe a single case of air embolism in a patient occurring during disconnection from a central venous catheter.⁴ No episodes of hemolysis or profound hemodynamic collapse from ultrafiltration or dialysate leaks have been described, even though such events are conceivable and, in the case of hypotension, are likely underreported.

A number of key themes emerge from these cases. First, blood loss from a variety of mechanisms is most often the cause of life-threatening AEs, as outlined above. Second, human error was implicated in 7 of 9 cases and probable in the other 2. Indeed, the reported home HD-related AEs did not occur because of an absence of safety measures, rather, they occurred because patients failed to follow prescribed procedures; for example, ignoring machine alarms or neglecting to appropriately use wetness detectors (see “Fistula Hemorrhage” in “The Care and Keeping of Vascular Access for Home Hemodialysis Patients” module). This underscores the importance of human error and the observation that patients will find a multitude of unpredictable ways to modify their dialysis that contravene standard operating procedures (SOPs) specifically designed to mitigate the risk of accidents. Third, there may be a lack of patient awareness that even small, seemingly insignificant changes in a procedure may lead to serious consequences. Fourth, Wong et al note in their case series that there does not seem to be a relationship between the experience of the program and the occurrence of a catastrophic event. The majority of their reported cases

occurred in the last 2 years, even though the programs had been in existence for over a decade.⁴ Fifth, there is no clear correlation between AE and patient experience with home HD. Four of the 8 relevant cases in the literature occurred in individuals having more than 1 year of independent dialysis experience at the time of their event. Finally, the presence of a care partner did not prevent the AE from occurring, although care partner presence may have prevented a fatality: 2 of the 3 events that occurred while patients were alone ended in death, while none of the 6 events that occurred while a care partner was present resulted in a fatal outcome.



Take-Home Messages

- The most frequently reported serious AEs during home HD involve blood loss, although air embolism, catastrophic electrolyte abnormalities, hemolysis, profound hemodynamic collapse from ultrafiltration, or dialysate leaks are also possible.
- Most reported serious AEs arise in part from human error, and have occurred as a result of some degree of nonadherence to SOPs.

Prevention of Procedure-Related Serious Adverse Events

Prevention is key in avoiding serious AEs, and there are technological, patient, and system factors that not only contribute to AEs, but by extension can also lead to their prevention.

Technological and Environmental Factors

At the present time, there are few home HD machines on the market that are specifically designed for home use, and most are in-center machines that are adapted for self-care at home; however, it is likely that future advances in home HD technology will provide increasing layers of safety features. In the meantime, there are still some programmatic measures that can be implemented.

Current home HD machines can and should be preset to preclude any erroneous actions or lack of actions. For instance, ultrafiltration rates for conventional home HD (short hours thrice weekly) might be set to avoid excessive fluid removal (eg, maximum of 1 L/hr) as determined by the care team. Various alarm parameters might also be preset to appropriate levels to detect deviation from SOPs, although care should be taken not to do so in a manner that causes excessive machine alarming and desensitization of the patient. The dialysis equipment should also permit rapid adjustment in therapy as required by an

emergent situation (eg, rapid administration of fluid boluses, adjustments in ultrafiltration rates). Some renal programs may wish to implement real-time remote monitoring (ie, of vital signs, treatment parameters, or physiological markers such as hematocrit, etc), the advantages and disadvantages of which are discussed below and elsewhere.¹² Though not yet on the market, venous disconnect devices that automatically stop the blood pump if a needle is dislodged will likely be available soon and should also be considered as a possible safety mechanism.

The treatment environment, too, should be designed with safety and comfort in mind: a patient must have a direct line-of-sight to all screens and monitoring devices, wetness detectors should be placed around the access site and under the dialysis machine, and seating should be ergonomic for long treatment duration yet still permit rapid adjustment to a supine position in case of symptomatic hypotension (see “Infrastructure” in the “Infrastructure, Water, and Machines in the Home” module).

Patient Factors

Patient selection and training are perhaps the key elements in preventing serious AEs. We recommend that home HD programs develop an explicit policy for patient selection (see “Patient Selection and Training” module). For the staff, a policy is essential for driving program recruitment, and also for implementing a timely transition of patients to alternative modalities if and when home HD becomes inappropriate. For

the patients, a policy makes explicit the medical requirements for home HD. It facilitates recognition that the therapy is more than simply a lifestyle choice and that there might be situations in which harm may outweigh benefits.

In general, patients should be physically and intellectually able and motivated to perform home HD and its related activities, including following the treatment prescription, maintaining equipment, monitoring water and blood work, and correctly executing procedures/protocols related to troubleshooting. Patients with skill barriers will require extra training or additional support at home to ensure their safety, or support to transition to an alternative modality if no solution offsets their increased risk. Communication plays a key role in the avoidance of error. Training staff should provide clear messages around safe practices and clear communication and demarcation of responsibility between patients and care partners around procedures/protocols, while emphasizing the final objective for training: technically excellent dialysis performed in the home, without compromise to safety. Depending on the patient, training may be an ongoing process to achieve this end result, with either formal or informal recertification of patients on an annual or biannual basis. Recertification is particularly important in those patients who are deemed at risk for a procedure-related AE but for whom this modality cannot reasonably be denied a priori.

Systems for Support of Patients at Home

Well-defined systems for technical support are essential for maintaining patient safety once patients have completed training. These systems will vary between programs and according to the needs of their home HD patients. In general, it is adequate to support patients through patient- or provider-initiated contact rather than by routine real-time telemetry monitoring of dialysis. While certainly not standard of care, some may see a role for real-time monitoring in assuaging anxieties in patients transitioning to home HD.¹³ In our experience, however, lack of real-time monitoring is not borne out as a meaningful barrier to home



Useful Resources

- [National Institute for Health and Care Excellence, Guidance on home compared to hospital haemodialysis for patients with end-stage renal failure \(TA48\)](#)
- [Method to Assess Treatment Choices for Home Dialysis \(MATCH-D\)](#)



Practice Tip

- Appropriate patient selection and training are the cornerstones of ensuring patient safety.
- Patients with identified risks for AEs (eg, skill barriers, attitudinal barriers, nonadherence) should have individualized training with recertification at specified intervals, as appropriate.

HD. Clinical and technical assistance for patients and their care partners should be easily accessible 24 hours a day. An automatic alarm contact to the local paramedic unit is an option for high-risk patients. Assistance by either means may detect warning signs of impending problems, and can facilitate transfer of patients to emergency departments or respite facilities for diagnostic and therapeutic measures before an AE arises.

An important tool for maintaining patient safety is regular clinical review in the form of outpatient or home visits or telephone/telemetric assessments. The frequency of follow-up is variable, but in Canada and New Zealand, the interval between clinic appointments is typically every 3 and 6 months, respectively, while blood work is monitored monthly. Whatever the arrangement, clinical review should include careful questioning regarding patient safety. Proper protocols and procedures should be reinforced at each visit, and appropriate reeducation given when gaps are identified.

One important area for inquiry is around near misses—those events that did not cause serious harm but had the potential to do so. Inquiries should be made in a manner that avoids undue criticism of the patient or instills a culture of blame (eg, “Have you had any accidents that we should tell people about who are training at the moment?”). Open disclosure by patients is important to identify opportunities for program development, and allows near misses to be used in a constructive fashion as a teachable moment. As noted elsewhere, home HD patients may

find risky improvisations to simplify or speed up their treatments. Although not described in the original case report, 1 patient who died was using a self-built home HD station, which the patient designed and customized without the knowledge of his treating team. His setup did not allow him to have a direct line of sight to his saline bag, which almost certainly contributed to the AE.¹⁰ Nurse- or care partner–assisted home HD may be a helpful option to enable patients with worsening disability or frailty to continue dialysis at home.^{14,15} Nurse-assisted home HD is typically performed for residents of extended-care facilities, although this can also involve nurses attending patients in their own houses if allowed/facilitated by the local healthcare system. This initiative is useful to extend technique survival. However, assisted home HD can be counterproductive in some circumstances: there may be a tendency for patients to not take full responsibility for their care by consciously or unconsciously limiting their understanding and competence of the equipment and the HD process if they know there is someone available to assist them in their home HD care.

The requirement for a care partner at home varies by program and by patient. Some centers require that the patient have a care partner routinely present during the entire treatment; other programs may require that the care partner be present only at specific times during a treatment, if at all. Care partners are useful for those patients needing a high degree of support, either for performing routine tasks such as initiating

or discontinuing a treatment, or for emergencies that patients are not able to manage on their own. In the extreme, a care partner may perform the entire treatment for a patient who is otherwise incapable of doing so. In general, such arrangements have been shown to be safe.¹⁴ However, the same scrupulous attention is required for training and maintaining competence of care partners as it is for the patients themselves. The best care partners are those who can provide reliable long-term assistance to the patient, and this is correlated with a stable social environment and a lack of concurrent medical problems. Notwithstanding, all care partners should be routinely monitored for burnout, which can compromise the quality of the support and consequently patient safety.

Finally, support for patients undergoing machine-based home HD should include a procedure for their timely transition to an alternative modality, either peritoneal dialysis (PD) or facility-based HD, if machine-based home HD is no longer feasible. This decision should be motivated by changes in medical, technical, or social circumstances that might impact patient safety and should be guided by the same principles used for patient selection. This transition should be made compassionately, and only after all other avenues of support have been exhausted.

Patient Access to Emergency Services for Advice and Care

When and how patients should access emergency care should be explicitly outlined before they complete home training. At minimum, patients should be clear about how to contact emergency medical services (EMS) and know the location and contact details for their nearest hospital emergency department. This may be self-evident in many jurisdictions (eg, by simply telephoning 9-1-1), but not so elsewhere (eg, remote locations or jurisdictions without centralized activation of EMS). Patients who subscribe to a personal medical alert system (a Lifeline®- or Alert 1®-type system) should be aware of how to activate that system. Patients should also know where to go for urgent respite dialysis in the event they cannot care for themselves (eg, as a result of acute illness, power outage, natural disaster). The primary center or associated hospital HD facility will usually be the unit providing respite dialysis for those patients living near the training center. For those living remotely, emergency care may be provided at satellite or local hospital facilities. Previous arrangements should be made with healthcare professionals at those sites to broker emergency care for patients, should it become necessary.

Communicating Risk to Patients

Because until very recently there has been no published empiric data concerning absolute risk of home HD, our communication of risk to patients has been largely predicated on the fact we have successfully managed patients self-administering home HD for decades. The conversation we have with patients aims to balance the benefits of home HD (ie, the flexibility of self-treatment and modality-specific benefits such as reduced dietary restrictions and pill burden with intensive home HD therapies like short-daily or nocturnal HD) with the risks and increased burden of independent home HD (ie, responsibility for one's own treatments/machine maintenance/water quality/supply ordering, rare and unforeseen procedure-related accidents, and risk of social isolation). It is not our practice to quote a specific procedure-related serious AE rate explicitly. Rather, all potentially life-threatening violations of SOPs are discussed in detail at the relevant point in patients' training. While the risk for home HD will never be zero, patients are reminded that home HD is very safe and that great care has been taken to design resources, policies, and procedures specifically aimed to minimize risk, where possible.

Emergency Management of Procedure-Related Adverse Events

Our experience with fatal and near-fatal procedure-related catastrophic events has taught us that despite the best-intentioned prevention strategies, a serious AE will eventually occur in a program. Thus, it is paramount to educate patients on emergency procedures and practice these as part of routine training and recertification. We advocate a simple "clamp-and-call" plan that should be initiated as soon as patients or care partners notice significant blood loss, air entry into the access, deteriorating level of consciousness, or any other atypical symptom while the patient is undergoing dialysis (Figure 8). This necessitates access to a personalized medical alert system or telephone that is within reach at all times. Clamping will stop



Practice Tip

- Telephone or Internet monitoring of dialysis function has been done by some centers, but is not generally warranted.
- Regular clinical review provides an opportunity for careful questioning regarding patient safety. Proper protocols and procedures should be reinforced at each visit, and appropriate reeducation given when gaps are identified.
- Care partners are useful for those patients who require a high degree of support, either for performing routine tasks or for emergencies that patients are not able to manage on their own.

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the blood pump and prevent further blood loss (the most common cause of procedure-related events) and give patients time to call for help. For patients who dialyze with someone else in the home, the patient should call that person into the room where the dialysis is taking place to either activate the personalized medical alert system or call EMS if the patient's situation deteriorates. If no one else is present, patients are asked to activate their personalized medical alert system or call EMS themselves if there are atypical symptoms that may suggest a potential impending emergency (eg, presyncope, palpitations, chest pressure, focal neurological symptoms, deteriorating level of consciousness). In the absence of such symptoms, patients should contact their center-based on-call home HD staff (eg, the training unit directly

or the after-hours on-call service) to discuss and appropriately manage problems. The on-call nurses or technologists should have a low threshold to initiate EMS on behalf of a reluctant or deteriorating patient.

We encourage all patients to have a preemptive emergency kit readily available and prominently positioned near their home HD machine. At the very least, kits should contain:

- Emergency contact information for the EMS, the home HD training unit, and the nephrologist
- A copy of the patient's medical history, including an up-to-date medication list

- An open letter addressed to EMS staff and hospital emergency department personnel (Table 2)

This open letter should communicate basic instructions to disconnect a patient from a hemodialysis machine (relevant for EMS crews who may be called to attend an unconscious subject still connected to a dialysis machine), contact information for home HD on-call services and the patient's nephrologist, and a request to contact the home HD on-call service if the AE occurred while the patient was actively dialyzing. This latter issue is important because home HD equipment may need to be inspected and interrogated in a timely manner if an AE is potentially linked to hardware malfunction. More elaborate kits can be individualized and incorporate bridging therapy to stabilize patients while definitive treatment is being sought or accessed (eg, may contain blood culture sets and empiric antibiotics for likely blood stream infection).

Table 2. Open Letter to Emergency Medical Service (EMS) and Emergency Room Personnel

To EMS Personnel:	To Emergency Room Personnel:
<p>The patient bearing this letter has end-stage kidney disease and undergoes home hemodialysis. If the subject is found connected to the hemodialysis machine and is not capable of disconnecting him/herself, please do the following:</p> <p>INSERT SIMPLE MINIMUM INSTRUCTIONS TO REMOVE PATIENT FROM MACHINE.</p> <p>Perhaps include a diagram</p> <p>This Emergency Kit/Envelope contains a medical history, a medication list, and contact information for the home hemodialysis unit. Please take this documentation with you when transporting the patient to hospital.</p>	<p>The patient bearing this letter has end-stage kidney disease and undergoes home hemodialysis. Please find included a patient history, medication list, and contact information for the home hemodialysis on-call service and/nephrologist. Once stabilized, please contact the home hemodialysis on-call service to discuss whether the patient's presentation to the hospital is related to the home hemodialysis procedure.</p>

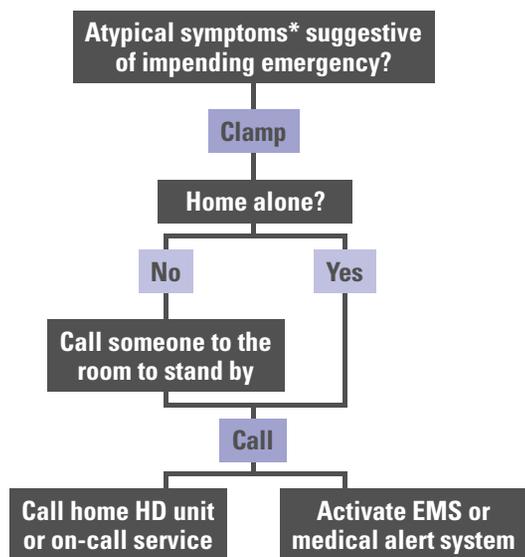


Figure 8. Home Hemodialysis “Clamp and Call” Emergency Management Algorithm

*Atypical symptoms include but are not limited to presyncope, heart palpitations, chest pressure, focal neurological symptoms, or deteriorating level of consciousness.

EMS = emergency medical services.

Quality Assurance Process

Central to any patient safety framework is an iterative quality assurance loop intended to prevent or minimize the occurrence or recurrence of an AE for an individual patient, and also for other patients within the same program.

The first step in developing a quality assurance process is certification and/or accreditation. In some parts of the world, it may be appropriate or required to have certification and/or accreditation of the home HD program itself. Irrespective of local standards, we recommend that new programs undergo a regular review by an external, experienced home HD training unit for a certain period after new program inception, if at all possible. There should be a robust training program for trainers, with regular credentialing of staff.

The second step in the development of the quality assurance loop is the establishment of robust SOPs for home HD. Quality assurance will be defined by variability of practice in relation to these procedures. SOPs need to be thoroughly understood by the staff as well as patients, and they should be individualized to meet local requirements. The importance of having SOPs cannot be overemphasized—ensuring quality assurance is not possible without them.

The third step is the documentation of process measures related to outcomes and safety. Process measures should include

a key performance indicator of near misses. In addition, regular near-miss conferences should be held among the clinical staff within the training unit. Where possible, lessons learned from near misses and serious AEs should be incorporated into the home HD patient teaching curriculum. Existing patients within the program should be made aware of changes in policies and procedures during follow-up visits or by use of periodic communication from the program (eg, patient newsletters).

If a serious AE does occur, a specific Adverse Event SOP should be initiated (processes for consideration in creating such an SOP are outlined in Table 3). The purpose of this SOP is to provide guidelines in how to direct the investigation so that the appropriate parties can learn from the event. The Adverse Event SOP also provides guidance in how to disseminate the results of the investigation to appropriate stakeholders.

We feel there is potential benefit in 2 initiatives that do not yet exist but may provide the opportunity for knowledge discovery and enhancement of patient safety. The first is a global registry of serious AEs experienced by patients performing home HD, which could be set up and funded on a membership basis with information sharing among members. The second is a Web-based self-reporting system of AEs and near misses for home HD patients. This could ensure timely and comprehensive logging of events and yield valuable insight into patient-perceived concerns. Both of these initiatives are worth exploring as value-added components within a quality assurance process.

Table 3. Processes to Initiate After a Serious Adverse Event or Near Miss

The machine and consumables should be impounded as is from the patient's home, without being stripped or cleaned, and stored for examination in the home hemodialysis training unit.

All documentation resulting from the treatment should be impounded as is. We recommend that copies be made, and that the originals are stored securely to prevent inadvertent loss of key paperwork.

The sequence of events and context of the event should be ascertained as clearly as possible, from those present at the scene and through the liberal use of photography of the scene and machine.

Depending on the nature of the event, the machine should be interrogated for any stored information (eg, blood pressure measures, alarms, alarm overrides).

Depending on the nature of the event, hemodialysis technical staff (ideally from an external, independent home HD training unit) should ensure that the machine meets standard operational checks.

There should be immediate communication of the potential for the specific error in question to the home hemodialysis training staff and existing home hemodialysis patients.

Depending on the nature and severity of the event, there might be an external review of the home hemodialysis training program and its resources by the quality improvement team of the parent hospital or another home hemodialysis training unit with more experience. The review may involve root cause analysis or failure mode and effects analysis (ie, techniques for delineating errors that are usually beyond the capabilities of clinical staff).

Depending on the nature of the event, there might be communication with the manufacturer of the dialysis machinery to ascertain whether the event has occurred previously, and whether a technical solution is available to prevent similar events.

Depending on the nature of the event, consideration might be given to publication in an open-source medical journal, since this is likely the best method of communicating widely with clinicians.

Depending on the nature of the event, consideration might be given to communication of the event on a reputable Web-based patient discussion forum, in conjunction with a patient advocacy group.

We recommend that each unit keep a registry of serious adverse events, and communicate these events and near misses to other providers in the region to share experience.

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