Patient Safety and Transitions

Creating a Culture of Quality September 11, 2012 J. Michael Lazarus, M.D.



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Hemodialysis Adverse Event List

Abusive/violent behavior Acute and severe psychotic event Air Embolus Allergic Reaction-Medication Allergic Reaction-Blood transfusion Wrong Blood Transfused (incorrect typing) Allergic Reaction-Dialyzer Allergic Reaction-Other

Arrhythmia-Bradyarrhythmia during dialysis (<50) Arrhythmia-Tachyarrhythmia during dialysis (>120) Aspiration Blood loss >100mlfrom vascular access

Blood loss >100mlnon access related Blood loss >100ml- Dialyzer leak Blood loss >100ml-System separation Cardiopulmonary Arrest Congestive heart failure/Symptomatic Fluid overload Contaminated Needle -Patient only Exposure-Blood and/or body fluids (Patient) Exposure-Chemical solution (Patient) Fall-Patient only Hypoglycemia-symptomatic Hyperglycemia-symptomatic Hemolysis- Dialysis related Incorrect Dialyzer used Incorrect dialysate formula used Infection-AV Catheter Tunnel Infection Infection -AVF Infection -AVG Infection-Septicemia



Hemodialysis Adverse Event List

Medication Error- wrong medication

Medication Error- wrong patient

Medication Error- wrong dose

Medication Error- wrong route

Medication Error- omission

Non-adherence to procedure/policy with clinical consequence

Prolonged bleeding from needle stick requiring patient to go to the emergency room

Seizure related to dialysis

Sustained loss of consciousness

Suspected pyrogenic reaction-Fever suspected secondary to endotoxin or bacteria in dialysate

Suspected pyrogenic reaction-Cluster event

Vascular access-Accidental cutting of vascular catheter

Vascular access-AVF or AVG clotting during the dialysis procedure

Vascular access-Infiltration extending into upper limb and Trunk

Vascular access-Infiltration severe enough to interfere with dialysis Rx

Weight variance (>2Kg) from weight entered into dialysis machine (Not a measure of EDW correctness)



Peritoneal Dialysis Adverse Event List

Allergic Reaction-Medication

Allergic Reaction-other

Cardiopulmonary arrest

Constipation-Severe constipation related to PD

Dialysate-Use of inappropriately heated dialysate

Dialysate-Wrong dialysate volume used

Dialysate-Wrong dialysate composition used

CHF, pulmonary edema or severe and symptomatic fluid overload

Fall-Patient only

Hernia- abdominal wall hernia related to PD

Hernia-Scrotal hernia related to PD

Hypoglycemia- symptomatic

Hyperglycemia- symptomatic

Hypertension- persistent and symptomatic

Hypotension- persistent and symptomatic

Medication error- wrong medication Medication error- wrong patient Medication error- wrong dose Medication error- wrong route Medication error - omission Non-adherence to procedure/policy with clinical consequences Peritonitis-Bacterial Peritonitis Peritonitis-Fungal Peritonitis Peritonitis-Aseptic Peritonitis PD Catheter-Catheter malfunction PD Catheter-Damaged external catheter PD Catheter-Exit site/tunnel infection Pleural effusion with diaphragm/peritoneal connection Seizure related to PD Skipped Exchange's



Review of database found there was no Root Cause analysis category regarding "communication" or "transition". This is now a specific entity that is evaluated with each adverse event.

With regard to this presentation I have no accumulated data on communication or transition errors but will report pertinent Case Reports.



Hemodialysis Adverse Event List



Case #1

On 1/19/12, a 60 y/o male patient from the XXXXXXXX facility sustained a cardiac arrest approximately 1 hour into his dialysis treatment. Resuscitation was unsuccessful, and he was pronounced dead at the facility by EMS. This was his first outpatient dialysis treatment after a lengthy hospitalization.

XXXXXXXX started dialysis 12/13/11 during a 45 day hospitalization for polycystic kidney and hypertension. PMH included morbid obesity, cardiomyopathy with EF of 10–15%, CAD with MI in December 2011,CHF, obstructive sleep apnea, s/p pacemaker, CVA disease and recent history of HIT.



On 1/19/12 the patient arrived at the outpatient facility on a stretcher 2 hours late for scheduled 1st dialysis. The inpatient facility staff had not communicated with the outpatient staff regarding the patient's discharge from the Hospital. Orders in the outpatient dialysis facility were dated 12/24/11 and were not signed by a physician. It was unclear if the dialysis orders were verbal or telephonic or which physician provided the dialysis prescription. Staff at the outpatient facility did not contact the Inpatient facility for information upon patient's arrival at the outpatient facility.

No assessment was performed by an RN; there was a minimal assessment performed by an LPN/GN and a PCT performed the dialysis. The patient was 7.4 kg below stated EDW. Pre B/P was 114/53, pulse 84.

The decision was made to run him for only 2 hours instead of the ordered 4 hours at a BFR 200 ml/min. The treatment was initiated with administration of 8000 units of heparin. The PCT initiating the treatment set the UFR for 1330. No physician was notified of any of these decisions.



Upon initiation of treatment, B/P dropped to 83/40and UF was discontinued. Approximately 30 minutes into the treatment, the extracorporeal system clotted and was changed. This event was not documented in the treatment record and it is unknown if additional heparin was administered. The machine alarmed twice, being reset by the PCT each time. When the machine alarmed a third time, the PCT noted that the patient was unresponsive. Normal saline was administered and CPR initiated. 911 was called. EMS arrived within 15 minutes and administered further medications but pronounced him dead approximately 15 minutes later.



Potential root causes identified:

- Failure of the Inpatient staff to notify outpatient facility staff of patient's d/c from hospital and to send current orders.
- Failure of the physician to communicate the patient's discharge, his condition and to provide proper dialysis order
- Failure to communicate complication of Heparin with possible HIT.
- Failure to communicate important cardiovascular complications.
- Failure of the inpatient staff to obtain current and proper orders for outpatient dialysis:
- Failure of RN to provide oversight, perform comprehensive assessment or review available records before initiating treatment.
- Failure of the outpatient staff to contact physician and performing outside of scope of practice.



Case #2

XXXXXXXXXXXX is an 82 year old female ESRD patient, who was admitted to XXXXXXXX Hospital on March 19, 2012, with chest pain, gangrene of toes and cellulitis. XXXXXXXX had additional co-morbidities including cardiomyopathy, hypertension, dementia, peripheral vascular disease, hypothyroidism and atrial fibrillation. During the course of admission she had an MRSA bacteremia and was treated with appropriate antibiotics. Despite these measures she became progressively obtunded from sepsis and underwent bilateral above the knee amputation.

On April 9th XXXXXXXX's dialysis was started as usual, and the dialysis nurse had three medications (Vancomycin, Gentamycin and Zemplar) to administer during treatment. All three medications were received from the hospital nurse and placed on the table in the patient's room to give later in the treatment.



Approximately 3 hrs into dialysis the hospital nurse responded to an IV pump alarm which was dripping Vasopressin 100 units in 250cc over 24 hrs. The hospital nurse re-set the pump and left a new bag of Vasopressin on the table with intention of returning to hang the new bag. Dialysis nurse accidentally picked up the Vasopressin bag instead of Vancomycin and infused half of the drug over 30 minutes before realizing it was the wrong medication administered at a very rapid pace. The dialysis nurse informed the hospital nurse of the error and patient's physician was also notified. XXXXXXXX's vital signs remained stable and she did not exhibit any

immediate adverse reactions to rapid infusion of Vasopressin. BP post dialysis was 103/58, pulse 95, temp 97.8. However, in the following days the liver enzymes significantly elevated: AST from 321 to 1992 and ALT from 92 to 566.



Patient's nephrologist spoke with the family members to explain the nature of the medication error and the expected prognosis. At the time of this report, patient's liver enzymes were slowly returning to normal.

The dialysis nurse involved in the incident had 4-5 years experience as an RN; however under 6 months in dialysis.

Potential root causes were:

Failure of hospital nurse and dialysis nurse to communicate Dialysis nurse is relatively new to dialysis Look-alike/ sound-alike medications Hospital nurse left the medication on the table, unattended Failure to follow the *Guidelines for Administration of Medication* Policy



Case #3

On April 4, 2011, clinical staff arrived at the XXXXXXXX facility to begin their day. They were surprised to find telecommunication contractors at the facility completing a new television system installation without oversight of any facility staff.

- The contractors informed the clinical staff opening the facility that a leak had occurred in the back room but they had fixed the problem and there was no longer an issue. The clinical staff continued with their start up procedures.
- During the testing of the carbon tanks for total chlorine they noted that results exceeded the action levels of 0.10ppm. Staff performed additional testing after the polisher carbon tank (Tank #2) and the water in the SDS system were all noted as exceeding action threshold of 0.10ppm.
- Clinical staff contacted the facility Biotech staff and the Technical Program Manager informing them of the total chlorine results they had obtained and the Technical staff promptly responded to the clinic to investigate.



Upon arrival at the facility, the Technical Program Manager discovered several bypass valve had been opened. As the investigation progressed, it was discovered that the telecommunication contractors had been in the facility overnight without the knowledge of the technical staff or the Clinic Manager. Further investigation revealed that the outside contractor had inadvertently drilled a hole in the RO distribution loop piping during the night. They began opening and closing various valves in an attempt to stop the flow of water, opening both of the carbon tank bypass valves in the process thus allowing chlorinated water to feed the RO machine and ultimately the RO holding tank. The contractors purchased plumbing parts at a local hardware store and repaired the hole they had drilled into the RO distribution line and turned the water back on...



The contractors had not contacted their supervisor or any FMS staff that a leak had occurred and they did not return the valves in the water room into their correct positions following their repairs.

Patient safety was never jeopardized as patient treatments were not started in accordance with facility policy and were sent to a neighboring clinic for dialysis while an investigation was conducted.



Case #4

had ESRD since June 31, 2004 due to Tubular Necrosis. XXXXXXXXX started home-hemodialysis at the XXXXXXX facility in March of 2011. Patient was on NxStage assisted by spouse, using buttonhole technique for cannulation. XXXXXXXXXXX has history of multiple access failures, liver transplant, pulmonary embolism, CAD, and on was Coumadin daily for DVT prophylaxis (5 mg on MWF/ 7.5 mg all other days). She had a right upper arm AV-fistula which was placed in 2007 and is prescribed to receive heparin 6,000 units each dialysis treatment.



On 10/6/2011 patient's spouse contacted the nurse on call to report that he had to take his wife off the machine early due to bleeding from the arterial needle site throughout dialysis. The nurse conducted a home visit and instructed the spouse to switch to sharp needles, cannulate away from the buttonhole sites and call the facility if problem persists. There is no documentation of the access assessment, any physician notification or anticoagulation review. A routine follow up clinic visit was scheduled for October 25 at which time Ms. Crouse was seen by the nephrologist. At this time an appointment with vascular surgeon was made for November 1st. Again there is no documentation of the access assessment, or anticoagulation review.



Two days later, October 27, 2011, patient's spouse reported that after the dialysis treatment, he provided post-dialysis access care as usual and left to go to the store. Upon his return after an hour, he found Ms. Crouse in the bathroom dead from apparent exsanguination from her dialysis access. Patient's last URR was 46% (5 days a week on NxStage). Platelet or PT & INR labs were not drawn. According to the Clinical Manager, under the direction of the nephrologist, the management of Coumadin was left with the prescribing physician.



Case 5

A 32 year old male dialysis patient from an out-patient dialysis facility was admitted to a local hospital on 06/21/2010 for shortness of breath, cough and emesis of blood. He had a history of Hepatitis B positive serology since 07/31/2009 which was documented in the out-patient dialysis facility lab results and co-morbid diagnoses. He had been dialyzed in isolation in the out-patient facility for the past year. His most recent hepatitis B antigen result on 06/03/2010, just prior to hospitalization, was positive.

The patient was admitted to ICU and was initially dialyzed in a single patient room in the ICU. Later he was moved to the hospital dialysis unit and continued to dialyze with other patients in that setting with no isolation techniques between 6/22–7/8/10. After 2 weeks, his attending physician notified the dialysis nurse during rounds that the patient was known hepatitis B antigen positive. The dialysis nurse then noted the patient's positive antigen status in a communication from the patient's out–patient dialysis facility as well as in the physician's admission assessment.



On further investigation, 14 patients were identified as having possible exposure. Of these 14 patients, 2 are deceased (unrelated to exposure), 1 has been identified as having positive antibodies. All others remained hepatitis B negative at follow-up.

Potential root causes of this adverse event (actually a near miss since no patients were injured) involving multiple patients include:

- Failure to communicate with the referring facility to ensure continuity of care
- Failure of physician to communicate Hepatitis status
- Treatment sheets used by this facility were not the recommended sheets and lacked area for documenting Hepatitis status
- Failure to follow policies and procedures
- Dialyzing with unknown hepatitis status

- Agency nurse possibly unaware of company policies regarding hepatitis B policies
- Failure to review patient's medical record adequately
- Lack of understanding by inpatient acute dialysis staff regarding hepatitis lab test and meaning of results
- Poor understanding by the contracted hospital of the need for required isolation procedures



This adverse event is not an unusual occurrence. Other recent episodes of hepatitis B contamination within the last year in inpatient acute services are listed in the following table:

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Dates:	Patient Hx	Summary
6/22/2010 to	Known HBsAg Positive ESRD	11 potential exposures
07/08/2010	patient – since 2009.	
7/6/2010 to	Known HBsAg Positive ESRD	3 potential exposures.
07/14/2010	patient	
09/07/10	Known HBsAg Positive ESRD	4 potential exposures
	patient	
10/07/10 to	Known HBsAg Positive ESRD	2 potential exposures
10/09/10	patient since 2006	
02/11/2011	HBsAg Positive ESRD patient	Unknown potential exposures
	dialyzing at acute setting	
02/0710 to	HBsAg Positive ESRD patient	11 potential exposures
02/14/2011	dialyzing at acute setting	
02/18/2011	Newly diagnosed HBsAg positive	2 potential exposures
	patient started on CRRT then	
	switched to HD.	
03/07/2011	Established ESRD patient	HBV vaccination on 02-23-2011, possible
		transient antigenemia

Case 6

XXXXXXX was a 72 year old female with ESRD since June 31, 2004 due to Tubular Necrosis. She started home-hemodialysis at the XXXXXX facility in March of 2011. Patient was on NxStage assisted by spouse, using buttonhole technique for cannulation. She had a history of multiple access failures, liver transplant, pulmonary embolism, CAD, and was on Coumadin (5 mg on MWF/ 7.5 mg all other days) for DVT prophylaxis. The patient had a right upper arm AV-fistula placed in 2007 and was prescribed heparin 6,000 units each dialysis treatment.

On 10/6/2011 patient's spouse contacted the nurse on call to report that he had to taken his wife off the machine early due to bleeding from the arterial needle site throughout dialysis. The nurse conducted a home visit and instructed the spouse to switch to sharp needles, cannulate away from the buttonhole sites and call the facility if problem persists. There was no documentation of the access assessment, any physician notification or anticoagulation review.



XXXXXXX was seen by her nephrologist for a routine follow up clinic visit on October 25. At this time an appointment with vascular surgeon was made for November 1st. Platelet or PT&INR labs were not drawn. According to the Clinical Manager, under the direction of the nephrologist, the management of Coumadin was left with the prescribing physician. There was no documentation of the access assessment or anticoagulation review by the physician. According to the CM, there was a scabbed-over lesion on the AV-fistula about the size of a dime. Two days later, October 27, 2011, the patient's spouse reported that after the dialysis treatment, he provided post-dialysis access care as usual and left to go to the store. Upon his return after an hour, he found XXXXXXX in the bathroom dead from apparent exsanguination from her dialysis access.



Potential root causes are:

Failure of nurse to communicate with physician

Failure to adequately address skin breakdown with scab around the AV-access

Failure to address persistent bleeding from a previous cannulation site in the presence of Coumadin therapy

Failure to establish responsibility for monitoring anticoagulation Failure to communicate or refer the patient to a vascular surgeon in a timely manner



Case # 7

XXXXXXXXXXX is a 71 year old male, who has been on hemodialysis since September 6, 2005. His primary cause of ESRD is HTN with comordid diagnoses of cardiomyopathy, CHF, CAD. The patient is on Coumadin 2 mg daily for atrial fibrillation. Patient had a right upper arm AV fistula placed in 2006 which was used for hemodialysis until recently. On November 7, the patient called the facility to let them know he would not be there for dialysis because he was on his way to the hospital due to bleeding from his AV fistula. The patient was hospitalized for a week and returned to the facility with a right IJ catheter and pressure bandages over the AV fistula.

The patient told the staff that according to the vascular surgeon he should not have any heparin on dialysis. The order was not confirmed by the nephrologist or updated in the patient's record. No communication or report was obtained from the vascular surgeon regarding the recent access intervention. According to the Clinical Manager, the patient had an appointment on November 23 with the vascular surgeon. Facility medical records were not updated to indicate an IJ catheter was in use, and no documentation of dressing assessment is available on record.



On November 22, the nations started dialysis as usual with the U satheter

On November 23, the patient started dialysis as usual with the IJ catheter and did not receive heparin. Two hours into dialysis he developed copious bleeding through the dressing on his right upper arm. Direct pressure and tourniquet was applied by staff, 911 was called and the patient was transported to the hospital via EMS. Staff estimated the blood loss to be about 300cc. The attending physician was notified. Platelet or PT&INR labs had not been drawn. According to the CM, the management of Coumadin was left with the primary care physician.

The patients was observed and released the same day from the hospital. He saw the vascular surgeon the next day for access repair and follow up angioplasty. Patient returned to the dialysis facility and since the incident has received treatment through the IJ catheter with reduced heparin dose. Control of coumadin dosing remained in the hands of the primary care physician.

Potential root causes:

Failure to provide and receive orders.

Failure to adequate assess surgical wound.

Failure to communicate regarding recent access intervention by the vascular surgeon

Failure to establish a plan to monitor Coumadin therapy.

