



Exsanguination: the action or process of draining or losing blood (Merriam-Webster)

Several months ago, an article in the Baltimore Sun highlighted the number of Maryland dialysis patient deaths due to exsanguination. As the article details, the Maryland medical examiner's concern over 24 exsanguination-related deaths from 2000-2006 prompted the issuance of advisories to dialysis facilities encouraging patient education on vascular access care.

In follow-up to the Maryland probe, we analyzed the number of patient deaths in the Network 8 region that were attributed to exsanguination, be it hemorrhage from vascular access, ruptured vascular access aneurysm or blood loss via the dialysis circuit. To our dismay, the numbers, while only a fraction of

total patient deaths, were much higher than we would have suspected.

For the years 2001-2006, there were 158 patient deaths, of which 80 were attributed to hemorrhage from vascular access, 75 were attributed to rupture of vascular access aneurysm, and 3 were related to blood loss via the dialysis circuit. Of these patients, 110 died in the hospital, 2 died in the dialysis facility, 5 locations were listed as "other" (defined as "in-transit or 'dead-on-arrival'" by CMS form 2746), and 41 deaths occurred at home. Numbers of deaths per year are noted below.

Year	Deaths caused by exsanguination
2001	20
2002	21
2003	23
2004	21
2005	26
2006	19

As is readily apparent, these numbers have not improved at all over the past six years and it is time for serious scrutiny of practice patterns in order to identify potential changes that can improve patient survival outcomes. To safeguard the lives of your patients, please make certain to follow the simple steps outlined below.

- Ensure that vascular accesses are assessed by licensed personnel each and every treatment, including catheters. The Nephrologist should routinely evaluate accesses with notable aneurysms or pseudo-aneurysms and refer to surgeon as needed.
- Ensure that vascular accesses are uncovered and visible during treatment UNLESS this presents a greater likelihood of blood loss, as may be the case with pediatric or confused/demented adult patients. There may be times when an access that is securely taped is better left "out of sight, out of mind". In this instance, be sure that facility policy allows this and that a physician's order has been obtained for such.
- Ensure that all connections to the dialysis circuit are securely Luer-locked. If non-Luer connections are in use, be certain that connections are securely taped to prevent accidental disconnection.
- Ensure that all dialysis machine alarms are functioning properly prior to each dialysis treatment. Venous pressure alarms should be set narrowly in order to rapidly respond to significant pressure change. Venous pressure alarms should

References

http://www.network13.org/Workshops/spring_2004/Vascular%20Access%20Assessment%20and.pdf

<http://www.meiresearch.org/CoreCurriculum/CC2006m5.pdf>

<http://www.artery.org.uk/files/ARTXXX0002/Documents/ARTDocuments/ArteryNewsletter/venous%20needle%20dislodgement%20Final%20ARTArticle%20020407.doc>

<http://www.dhmh.state.md.us/mdckd/hemopatients.html>

http://www.mdsr.ecri.org/summary/detail.aspx?doc_id=8300

<http://www.va.gov/OCA/testimony/hvac/sh/doherty108.asp>

<http://www.bardaccess.com/pdfs/patient/pg-hemodialysis.pdf>

http://www.hmpvascular.com/library/lifejetF16_pated.pdf

never be silenced without first investigating the cause of the alarm.

- If patients are "bled-on", that is, if the arterial needle is connected to the vascular access and the pump initiated while the venous return line is diverted to drain (rather than connected to venous needle), it is imperative that the staff member focus solely on this task, preferably physically holding the venous line from the time the pump is started until the venous line is connected to the vascular access. If this practice is common in your unit, please ensure that the policy and procedure addresses safety issues to prevent accidental exsanguination.
- Never use scissors or other sharp objects near hemodialysis catheters! While this seems to be common sense, there are documented reports of both staff AND patients severing catheter limbs, some of which have resulted in death.
- Ensure that ALL facility staff, including non-direct patient care staff such as dieticians and social workers, have been instructed and are fully aware of facility policy regarding vascular access monitoring and care.
- Finally, teach your patients and their family members how to care for their dialysis access, including emergency care for bleeding. Specifically, teach patients what "prolonged" bleeding is according your facility policy and what actions must be taken for such. Once this has been done, repeat, repeat, and repeat the information until patients and/or family members are able to repeat it to you without hesitation or error.

Fistula First Update

As Network 8 nears the end of a contract year, CMS will evaluate our performance in improving vascular access outcomes. We are close to achieving the assigned goal of AVF use in 45.5% of prevalent patients, with a rate of 44.8% reported in December. We thank each of you who has worked so diligently in making this happen!

Catheter rates in prevalent patients remain relatively the same as last year, with **total catheter** use reported at 25.3% in December 2007 and 25.4% in December 2006. **Catheters as only access** were reported in 16.1% of prevalent patients in December 2007 and 16.4% in December 2006. Probably the area in greatest need of improvement is catheter use in incident patients, with a reported rate of 59.6% in December 2007, up from 54.6% in December 2006. As we know, this work begins before dialysis is initiated and is in the hands of nephrologists, primary care physicians, physician extenders and surgeons.

As we move ahead in the year, we encourage you to continue your work in vascular access improvements, never forgetting what is best for the patients, and often times letting them make that decision. While number goals are important, they should never come before sound medical and nursing judgments, made at the chair side, and patients' personal rights.

2008 Lab Data Collection Project

Increased pollen counts, income taxes, and the lab data collection project—spring has arrived! This year, letters and instructions were sent to each non-LDO facility on March 14 along with encrypted jump drives containing the Excel spreadsheet for data reporting.

For those of you new to this process, it is important to note that, unlike taxes, the lab data project is completely voluntary. On the other hand, without patient-specific data, we have no way of identifying facilities that are exceeding CMS goals, and are therefore unable to recognize these facilities in the newsletter, at the annual meeting, or otherwise. Similarly, we are unable to offer technical assistance to facilities struggling in one or more clinical areas.

Last year, 46 of 50 eligible facilities (92%) participated in this project and it is our hope that each of you will again do so this year. For any of you that wish to participate but do not have the technical resources to complete the electronic spreadsheet, please give Sheila McMaster or Casey Magee a call at 601-936-9260.

New Resources Available On Website

National Healthcare Decisions Day and Related Resources

The Kidney End-of-Life Coalition, along with other national, state and community organizations, are leading a coordinated effort to highlight the importance of advance healthcare decision-making, culminating in the formal designation of April 16, 2008 as the inaugural National Healthcare Decisions Day (NHDD).

April 16 will come and go, and that is why a website has been created with information and tools for the public to talk about future healthcare decisions and execute written advance directives (healthcare power of attorney and living wills) in accordance with their applicable state laws.

There is a link to the new website (nationalhealthcaredecisionsday.org) on the Network 8 website. It offers

tips on how advocates can raise awareness in their communities and offers resources for free or reduced cost state-specific advance directives for all 50 states that meet the legal requirements for each state. An official poster is also attached on the website for display at your unit. For more details, you can visit the website, email nhdd@nhpco.org or call 800/658-8898.

Home Dialysis Assessment Tool

The Medical Education Institute, Inc. in Madison, Wisconsin has developed a tool known as MATCH-D to help nephrologists and dialysis staff identify and assess candidates for home dialysis therapies (PD and HHD). Three categories describe patients that are excellent candidates, those who may need to have a barrier addressed first and those who may require an alternate modality choice. This tool is linked at our website. For more information you can visit any of the MEI websites, Medical Education Institute, Life Options, Kidney School or Home Dialysis Central or call 608/833-8033.

E-Mail Is Not Secure

The Centers for Medicaid and Medicare Services (CMS) has informed Networks that they are not allowed to send or receive emails that contain patient information such as name, SSN, dates of services, etc. **CMS considers email communication non-secure and a potential violation of the HIPAA regulations regarding patient confidentiality.** The new CMS Security Policy requires that Networks report incidences of personal identity information and/or personal health information sent via email. Network 8 began enforcing this policy effective November 30, 2007.

Do NOT e-mail the monthly Patient Activity Report (PAR) to the Network. This can be faxed, and facilities should ensure that the fax address is correct and that the fax is received by the Network; or the PAR can be mailed.

Do NOT e-mail Fistula First Reports that contain patient names. Only the Facility Summary tab of the worksheet tool should be sent. Please call the network for assistance if you are having problems with this. The FF Report can be e-mailed as long as only the Facility Summary worksheet (tab) is included (no patient names).

Do NOT send an email inquiry or response to us that includes the name or SSN of a patient. This is considered a violation of PHI or PII. Please call instead of emailing.

Be sure that your Social Worker, your Data Contact, and your Anemia and Fistula First coordinators are aware of and will comply with these security regulations.

Thank you for working with us to safeguard the personal information of the patients we are charged with serving.

Medwatch Warnings

Fentanyl transdermal system CII Patches

Audience: Pain management specialists, risk managers, other healthcare professionals, patients
[Posted 02/19/2008] Actavis Inc. announced a nationwide recall of certain lots of Fentanyl transdermal system CII Patches sold in the United States and labeled with an Abrika or Actavis label. The product may have a fold-over defect, which can cause the patch to leak and expose patients or caregivers directly to the fentanyl gel. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal. The lots covered by this recall include doses of 25, 50, 75, and 100 mcg/hr and are listed in the firm's press release.

Duragesic 25 mcg/hr (fentanyl transdermal system) CII Pain Patches

Audience: Pain management specialists, other healthcare professionals, patients
[Posted 02/15/2008] PriCara and Sandoz Inc. announced a nationwide recall of all lots of 25 mcg/hr Duragesic Patches sold in the United States. The product is being recalled because the patches may have a cut along one side of the drug reservoir within the patch, which may result in the possible release of fentanyl gel that may expose patients or caregivers directly to fentanyl gel on the skin. Fentanyl is a potent Schedule II opioid medication and exposure to the gel may lead to serious adverse events, including respiratory depression and possible overdose that may be fatal. Patches with a cut edge should not be used. These recalled patches have expiration dates on or before December 2009 and are all manufactured by ALZA Corporation.

Chattem Icy Hot Heat Therapy Products

Audience: Consumers, healthcare professionals
[Posted 02/11/2008] Chattem, Inc. and FDA informed consumers and healthcare professionals of a voluntary nationwide recall of its Icy Hot Heat Therapy products, including consumer "samples" that were included on a limited promotional basis in cartons of its 3 oz Aspercreme product. The products were recalled because of consumer reports of first, second and third degree burns, as well as skin irritation. All lots and sizes of the following Icy Hot Heat Therapy products were recalled:

Icy Hot Heat Therapy Air Activated Heat - Back
Icy Hot Heat Therapy Air Activated Heat - Arm, Neck, and Leg
Icy Hot Heat Therapy Air Activated Heat - Arm, Neck, and Leg single consumer use "samples" on a limited promotional basis in cartons of 3 oz. Aspercreme Pain Relieving Cream.

Consumers who have the Icy Hot Heat Therapy products under this recall should immediately stop using the products, discard them, and /or return them to the manufacturer.

Varenicline (marketed as Chantix)

Audience: Neuropsychiatric and other healthcare professionals, consumers
[Posted 02/01/2008] FDA informed healthcare professionals and consumers of important revisions to the WARNINGS and PRECAUTIONS sections of the prescribing information for Chantix regarding serious neuropsychiatric symptoms experienced in patients taking Chantix. These symptoms include changes in behavior, agitation, depressed mood, suicidal ideation, and attempted and completed suicide. While some patients may have experienced these types of symptoms and events as a result of nicotine withdrawal, some patients taking Chantix who experienced serious neuropsychiatric symptoms and events had not yet discontinued smoking. In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following withdrawal of Chantix therapy. See the FDA Information for Healthcare Professionals Sheet for recommendations and considerations for healthcare professionals on using Chantix therapy for patients.

Antiepileptic Drugs

Audience: Neuropsychiatric healthcare professionals, other healthcare professionals, patients
[Posted 01/31/2008] FDA informed healthcare professionals that the Agency has analyzed reports of suicidality (suicidal behavior or ideation) from placebo-controlled clinical studies of eleven drugs used to treat epilepsy as well as psychiatric disorders, and other conditions. In the FDA's analysis, patients receiving antiepileptic drugs had approximately twice the risk of suicidal behavior or ideation (0.43%) compared to patients receiving placebo (0.22%). The increased risk of suicidal behavior and suicidal ideation was observed as early as one week after starting the antiepileptic drug and continued through 24 weeks. The results were generally consistent among the eleven drugs. The relative risk for suicidality was higher in patients with epilepsy compared to patients who were given one of the drugs in the class for psychiatric or other conditions.

Healthcare professionals should closely monitor all patients currently taking or starting any antiepileptic drug for notable changes in behavior that could indicate the emergence or worsening of suicidal thoughts or behavior or depression.

The drugs included in the analyses include (some of these drugs are also available in generic form):

Carbamazepine (marketed as Carbatrol, Equetro, Tegretol, Tegretol XR)

Felbamate (marketed as Felbatol)

Gabapentin (marketed as Neurontin)

Lamotrigine (marketed as Lamictal)

Levetiracetam (marketed as Keppra)

Oxcarbazepine (marketed as Trileptal)

Pregabalin (marketed as Lyrica)

Tiagabine (marketed as Gabitril)

Topiramate (marketed as Topamax)

Valproate (marketed as Depakote, Depakote ER, Depakene, Depacon)

Zonisamide (marketed as Zonegran)

Although the 11 drugs listed above were the ones included in the analysis, FDA expects that the increased risk of suicidality is shared by all antiepileptic drugs and anticipates that the class labeling changes will be applied broadly.

Bayer Diabetes Care Contour Test Strips (TS)

Audience: Endocrinologists, healthcare professionals, diabetic patients, and pharmacies

[Posted 12/26/2007] Bayer Diabetes Care notified healthcare professionals and consumers of a voluntary market recall of test strips (sensors) used exclusively with the Contour TS Blood Glucose Meter. The product was recalled because test strips from specific lots could result in blood glucose readings with a positive bias that could demonstrate 5 - 17% higher test results. This issue is unrelated to the Contour TS meter itself and pertains only to certain test strips used with the meter. There is no impact on the performance of strips with other Bayer meters.

Healthcare professionals, retailers, patients, and other customers who use Contour TS are advised to check the lot number of the test strips in their inventory and contact Bayer Diabetes Care for information regarding the return and replacement of strips. See the manufacturer's press release for specific product lot numbers affected by this recall.

Avandia (rosiglitazone maleate) Tablets

Audience: Cardiologists, endocrinologists, other healthcare professionals, consumers

[UPDATE 11/19/2007] Information for Healthcare Professionals Sheet highlights changes to the prescribing information for rosiglitazone, including a new BOXED WARNING and changes to the WARNINGS, PRECAUTIONS, and INDICATIONS sections of the product's prescribing information about the potential increased risk of myocardial ischemia.

[Posted 11/14/2007] FDA informed healthcare professionals of new information added to the existing boxed warning in Avandia's prescribing information about potential increased risk for heart attacks. The new information refers to a meta-analysis of 42 clinical studies, most of which compared Avandia to placebo that showed Avandia to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction. At this time, FDA has concluded that there isn't enough evidence to indicate that the risks of heart attacks or death are different between Avandia and some other oral type 2 diabetes treatments. People with type 2 diabetes who have underlying heart disease or who are at high risk of heart attack should talk to their healthcare professional about the revised warning as they evaluate treatment options. Healthcare professionals are advised to closely monitor patients who take Avandia for cardiovascular risks.

Cefepime (marketed as Maxipime)

Audience: Healthcare professionals

[Posted 11/14/2007] FDA issued an early communication about the ongoing review of new safety data and the request for additional data to further evaluate the risk of death in patients treated with cefepime. An article in the May 2007 issue of The Lancet Infectious Diseases (Efficacy and safety of cefepime: a systematic review and meta-analysis) raised the question about increased mortality with the use of cefepime, a broad spectrum B-lactam antibiotic

currently approved for the treatment of a variety of infections due to susceptible strains of microorganisms. The article describes a higher all-cause mortality in patients treated with cefepime compared to other B-lactam antibiotics. Until FDA's evaluation is completed, healthcare professionals who are considering the use of cefepime should be aware of the risks and benefits described in the product's prescribing information and the new information from this meta-analysis.

Welch Allyn AED 10 Automatic External Defibrillators

Audience: Emergency services personnel, risk managers, and consumers

[UPDATE 11/28/2007] Recall expanded to include Welch Allyn AED 10™ Automatic External Defibrillators, manufactured between March 29, 2007 and August 9, 2007, part numbers 970302E, 970308E, 970309E, 970310E, and 970311E.

[Posted 11/05/2007] FDA issued a Class I recall for Welch Allyn AED 10 Automatic External Defibrillators manufactured between March 29, 2007 and August 9, 2007, part numbers 970302E, 970308E, 970310E, and 970311E. These devices are used by emergency or medical personnel, or by others who have taken the appropriate training in cardiopulmonary arrest (heart attack). They analyze an unconscious patient's heart rhythm and automatically deliver an electrical shock to the heart if needed to restore normal heart rhythm.

There is a possibility that these recalled devices may experience failure or unacceptable delay in analyzing a patient's ECG resulting in possible failure to deliver the appropriate therapy. The possible failure or delay depends on the location of the defective part that stores an electrical charge on the circuit board. The company plans to replace all affected units and has set up a call center for customers.

Byetta (exenatide)

Audience: Endocrinologists, other healthcare professionals, consumers

[Posted 10/16/2007] FDA has reviewed 30 postmarketing reports of acute pancreatitis in patients taking Byetta (exenatide), a drug used to treat adults with type 2 diabetes. An association between Byetta and acute pancreatitis is suspected in some of these cases. Amylin Pharmaceuticals, Inc. has agreed to include information about acute pancreatitis in the PRECAUTIONS section of the product label.

Healthcare professionals should be alert to the signs and symptoms of acute pancreatitis and instruct patients taking Byetta to seek prompt medical care if they experience unexplained, persistent, severe abdominal pain, which may or may not be accompanied by vomiting. If pancreatitis is suspected, Byetta should be discontinued. If pancreatitis is confirmed, Byetta should not be restarted unless an alternative etiology is identified.

MRL/Welch Allyn AED 20 Automatic External Defibrillators

Audience: Emergency Services personnel and risk managers

[Posted 09/18/2007] FDA issued a Class I recall for MRL/Welch Allyn AED 20 Automatic External Defibrillators manufactured between October 2003 and January 2005, serial numbers 205787 through 207509. These devices are used by emergency or medical personnel to treat adult and pediatric patients in cardiopulmonary arrest (heart attack). The recalled devices may display a "Defib Comm" error message on the device display during use, which may result in a terminal failure of the device to analyze the patient's ECG and deliver the appropriate therapy.

FDA advises healthcare professionals and patients to stop using the recalled product and contact the manufacturer for a replacement.

Calling All Nephrology Nurse Practitioners...

We want to hear from you! There are times that we have educational offerings that may be of specific interest to you, and there are times we need your input. Our current database lacks any information on NPs and we want to change that.

Please give us Ann, Sheila, or Casey a call at 601-936-9260 and let us know the following: Name, credentials, employer, and contact information. If you prefer, you can fax this information to 601-932-4446 or email to smcmaster@nw8.esrd.net

On the same note, Dr. Doug Lanier, of South Mississippi Nephrology, would like to recognize one of their nurse practitioners, Stephanie Romero, CFNP, who recently passed the Certified Nephrology Nurse – Nurse Practitioner exam with flying colors. Congratulations Stephanie! We would like to say thanks to all of the nephrology nurse practitioners who are so helpful to nephrology practices, dialysis staff and individuals with chronic kidney disease!

New "I Count" Project Emphasizes Importance of Patient Education

The Patient Advisory Committee (PAC) of Network 8, working in conjunction with the Medical Advisory Board, has developed a new project to increase patient understanding and staff perception of the critically important role of the patient as an active member of the healthcare team. The project is currently being piloted in nine facilities in the Network area: four in Tennessee, three in Mississippi and two in Alabama.

As the project was being developed, one key area of concern expressed by the

PAC was whether current methods of distributing patient educational materials were effective. Several PAC members mentioned that they never received the patient newsletter and never saw it in the waiting rooms of their units.

We will be discussing different aspects of the "I Count" campaign as it is rolled out to all Network facilities, and the campaign will take the position that an educated patient is an adherent patient. The more a patient

can learn about their healthcare, the longer they will live and thrive and contribute to society.

Please continue to distribute all patient materials that are sent to your unit for your patients. If at all possible, hand newsletters, brochures, postcards and booklets directly to your patients and put posters in an area where all patients can see them. Let them know what videos are available and play these videos during their treatment sessions whenever possible. We will be happy to supply you with any additional materials that you need. Stay tuned for more information on the "I Count" project in your location.

April Meeting

Network 8, in collaboration with the University of Mississippi School of Medicine, Mississippi Kidney Foundation, and Information and Quality Healthcare is hosting a two-part workshop on Chronic Kidney Disease on April 12 and 13 at the UMC Norman C. Nelson Student Union. Day one is intended for physicians, nurse practitioners, and nurses and focuses on CKD management from diagnosis to diabetes and hypertension management as well as preparation for renal replacement therapy and renal transplantation. Day two is intended for direct patient care staff and focuses on vascular access assessment and cannulation, basic hemodialysis principles, interpretation of common dialysis lab values, CQI, and professionalism in practice. Please visit us on the web at www.esrdnetwork8.org for registration information and to view the program brochure.

Upcoming Events

April 2008

- 10th—PAR due
- 12th—Truth *and* Consequences: Diabetes, CVD and CKD—UMC Student Union, Jackson, MS. Intended audience: Physicians and Nurse Practitioners
- 13th—Truth *and* Consequences, Part II: Patient Care from Cannulation to CQI—UMC Student Union, Jackson, MS. Intended audience: Direct patient care staff.
- 20th—Fistula First data due

May 2008

- 8th—Network 8 Medical Review Board meeting, Network office.
- 10th—PAR due
- 20th—Fistula First data due
- 21st-23rd—Healthy MS Summit—Hilton Hotel, Jackson
- 26th—Memorial Day Holiday. Network 8 offices closed.
- 30th Renal Update, UMC Medical Mall

June 2008

- 10th—PAR due
- 20th—Fistula First data due

Network NEWS

Publication Date March 2008

This material was prepared under CMS contract Number HHSM-500-2006-NW008C, and the contents may not reflect CMS policy.



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A Continuing Education
Program for Primary
Care Physicians,
Nephrologists, Dialysis
Providers, Surgeons and
Vascular Access
Interventionalists

Norman C. Nelson
Student Union

University of Mississippi
Medical Center

Jackson, Mississippi

The registration deadline
has been extended to April
11, 2008. Pre-registration is
required.

Payment

Checks should accompany
this form and be made pay-
able to Mississippi Kidney
Foundation. Mail to **Missis-
sippi Kidney Foundation,
P.O. Box 55802, Jackson,
MS 39296**

Truth and Consequences: Diabetes, CVD and CKD

Saturday, April 12, 2008

8:00 a.m. - 4:45 p.m.

Truth and Consequences, Part Two: Patient Care from Cannulation to CQI

Sunday, April 13, 2008

8:00 a.m. - 4:00 pm.

Registration

Please mark which date(s) you choose to attend.

- Saturday, April, 12, 2008 (for physicians and nurses) - **\$100.00**
- Sunday, April 13, 2008 (for nurses and patient care technicians - **\$50.00**
- Saturday AND Sunday - **\$75.00**

PLEASE PRINT CLEARLY.

Name: _____ Credentials: _____

Address: _____

City: _____ State: _____ Zip: _____

Social Security number (last 4 digits required for credit): _____

Phone: _____ Fax: _____

Email: _____

Affiliation: _____

Please check the appropriate occupation.

Primary Care Physician _____ Nephrologist
(discipline)

Surgeon RN LPN Nurse Practitioner

Vascular Access Interventionalist Social Worker

 Check here if you require special accommodations. Someone from
our office will contact you.

Include me in the count for lunch (provided).

YES NO