

2007 Lab Data Collection Project

As we go to press with this edition of Network News, we are fast approaching the annual collection of 4th quarter patient-specific data. Unchanged from last year, LDO patient data will be submitted directly from the corporate offices—no facility-level assistance is needed. Non-LDO facilities, including all National Renal Institutes (NRI) units, will be asked to enter and submit their patient data via Excel spreadsheet that will be supplied by the Network.

While many of you completed yellow (hemodialysis) or blue (peritoneal dialysis) CPM forms last summer, that data was only collected on 5% of patients

nationwide. The annual lab data collection is the only comprehensive, patient and facility-specific data that we receive. Without this data, we are unable to optimally assist facilities with QI activities, and, we are also unable to recognize those with superior outcomes.

Though we do realize the extensive effort this project requires for some clinics, most of you have “stepped up” and shown your commitment to quality patient care by submitting your data, regardless. We send our most sincere thanks to you for this. Your efforts do matter and you ARE appreciated! Please call us if you have any questions or need assistance with this process—we are here to help.

Upcoming Events

January

- 20th- FF monthly data report due to Network office
- 25th- Network 8 Medical Review Board meeting

February

- 6th- ANNA winter audio conference at Network office, 5:30 pm
- 10th- PAR due
- 15th- Network 8 Board of Directors meeting
- 20th- FF monthly data report due to Network office
- Memphis Area Fistula First Meeting – date to be announced
- Fistula First semi-annual report to clinics

March

- 10th- PAR due
- 20th- FF monthly data report due to Network office
- 21st- Memphis Quality Initiative Meeting
- 29th- Dr. Spergel visit to Memphis – Fistula First Event

April

- 10th- PAR due
- 20th- FF monthly data report due to Network office

May

- 1st-2nd- NKF of Alabama Meeting - Montgomery
- 10th- PAR due
- 20th- FF monthly data report due to Network office

June

- 1st- Renal Update, Jackson, MS
- 10th- PAR due
- 20th- FF monthly data report due to Network office

March Madness in Memphis

Though basketball will be on the minds of many Memphis fans, improved outcomes for patients with chronic kidney disease (CKD) will be our focus in Memphis to promote March as Kidney Month.

The Memphis Area Fistula First Coalition has been given the opportunity to promote ideas for quality improvement in CKD care during the Memphis Quality Initiative (MQI) quarterly meeting, March 21, 2007, at the University of Memphis/FedEx Institute of Technology. MQI is a collaboration of Memphis area hospitals' administrators, physicians, nurses, and pharmacists that partner in the development and implementation of city-wide, noncompetitive, quality improvement initiatives. The Fistula First Coalition will invite Memphis physicians to present the need for early diagnosis and appropriate treatment and referral of CKD patients, to include preparation for renal replacement therapy and dialysis access creation. This CME event will be open to all healthcare providers in the area.

The Memphis Area Fistula First Coalition is also planning a Fistula First day of events, March 29, that will feature Dr. Larry Spergel, Clinical Chair of the Fistula First project. Dr. Spergel, a vascular access surgeon, will make rounds in specific dialysis facilities to discuss vascular access options with facility physicians, staff and patients. Additional activities may include a lunch and/or dinner presentation for nephrologists, surgeons and nurses.

If you are in driving distance to Memphis, mark your calendar for these special events and stay tuned for more information!



Do we or don't we??

During the 2006 CPM data collection, once more it was noted that a large number of clinics answered “no” to vascular access stenosis monitoring questions shown below.

If a patient had AV fistula or graft.

1. Was surveillance for the presence of stenosis performed between 10/1/05 and 12/31/05?
 Yes No Unknown
2. If answer to question 1 is “Yes,” please check all methods of surveillance (below) that were utilized. (See instructions on page 6).
 Color-Flow Doppler at least once between 10/1/05 and 12/31/05
 Static Venous Pressure at least once every 2 weeks between 10/1/05 and 12/31/05
 Dynamic Venous Pressure every HD session between 10/1/05 and 12/31/05
 Dilution Technique at least once between 10/1/05 and 12/31/05
 On-Line Clearance (OLC) Based Access Flow at least once between 10/1/05 and 12/31/05
 Other _____
3. Did the patient have an active AV Fistula or Graft (being used for hemodialysis) **AND** an inactive catheter or port access not being used for hemodialysis) during the last hemodialysis session on or between 10/1/2005 and 12/31/2005?
 Yes No

While some clinics may not conduct routine access surveillance, most clinics, especially those owned by Large Dialysis Organizations, do—though individuals completing CPM forms may not know the actual name of the method used. For the sake of clarification, a brief review of the above listed methods is warranted.

1. Color-Flow Doppler: This is an outpatient radiological procedure done quarterly. In the past, this was frequently done in the dialysis clinic by mobile ultrasonography service. This study may also be referred to as a duplex ultrasound or duplex Doppler study. Doppler reports are helpful in documenting access flow pattern as well as areas of access stenosis.
2. Static Venous Pressure (SVP) monitoring involves following a unit-specific procedure for measurement of venous and arterial pressures at zero blood flow at least every two weeks. Venous pressure reading is obtained from the dialysis machine. Arterial pressure reading may be obtained either from the dialysis machine or a manometer connected to the arterial needle (Access Alert™). Measurements are then plugged into mathematical formula to calculate pressure ratio. Ratio > 0.5 is considered abnormal though findings must be trended over time. In general, 3 abnormal readings warrant referral for fistulagram.
3. Dynamic Venous Pressure (DVP) monitoring is conducted and recorded at the beginning of each dialysis treatment at a specified blood flow rate using a specified/consistent needle size. While all venous pressure readings taken with the blood pump on are indeed “dynamic” pressures, only measurements taken as described above are useful. For this reason, unstandardized dynamic venous pressures are considered as unacceptable monitoring method by the K/DOQI workgroup.
4. Dilution Technique monitoring is conducted quarterly and is also known as ultrasound dilution (Transonics technology), Crit-Line III (optodilution by ultrafiltration—requires bloodline reversal), or Crit-Line III TQA (direct transcutaneous—performed without reversing bloodlines).
5. On-Line Clearance (OLC) conducted quarterly (Fresenius technology).
6. Other—May include Magnetic Resonance Angiography/Magnetic Resonance Imaging procedure or differential conductivity monitoring (Gambro HDM).

Though only 5% of Network 8 clinics were selected to participate in the 2006 CPM data collection, it is important to note that the purpose of vascular access surveillance is not simply to be able to answer “yes” to a question posed by CMS. The K/DOQI workgroup recommends “an organized monitoring/surveillance approach with regular assessment of clinical parameters of the AV access and hemodialysis” as part of the clinic’s ongoing CQI program. Furthermore, the workgroup notes that vascular access-related complications accounted for 24% of all hospital admissions.

Vascular access monitoring practices reflect the quality of care given to hemodialysis patients. What do your clinic practices reflect?

Ongoing Network Services

Facilities with questions ranging from quality of care issues to forms processing should call us at 601-936-9260. We will do our best to help you or see to it that you are referred to a source of information for your technical assistance needs.

Patients with complaints or concerns may contact the Network by using the patients-only toll-free number: 877-936-9260. We recommend that patients first work with you directly to resolve their concerns, but we are available for first-line contact when that is the patient’s preference.

MedWatch Warnings

For more information on any of the warnings below, go to: <http://www.fda.gov/medWatch/>

Quinine products

Audience: Pharmacists, other healthcare professionals and consumers

[Posted 12/12/2006] FDA informed healthcare professionals and consumers that the Agency ordered firms to stop marketing unapproved drug products containing quinine, citing serious safety concerns, including deaths associated with quinine products. There are multiple unapproved products containing quinine currently on the market, used off-label to treat leg cramps and similar conditions. Since 1969, FDA received 665 reports of adverse events with serious outcomes associated with quinine use, including 93 deaths. Quinine drugs are associated with serious side effects, such as cardiac arrhythmias, thrombocytopenia, and severe hypersensitivity reactions. Quaaluan, manufactured by Mutual Pharmaceutical Company, is the only quinine product approved by the FDA.

Heparin Sodium Injection

Audience: Vascular surgeons, ER personnel, pharmacists, and other healthcare professionals

[Posted 12/08/2006] FDA and Baxter notified healthcare professionals of revisions to the WARNINGS section of the prescribing information for Heparin to inform clinicians of the possibility of delayed onset of heparin-induced thrombocytopenia (HIT), a serious antibody-mediated reaction resulting from irreversible aggregation of platelets. HIT may progress to the development of venous and arterial thromboses, a condition referred to as heparin-induced thrombocytopenia and thrombosis (HITT). Thrombotic events may be the initial presentation for HITT, which can occur up to several weeks after the discontinuation of heparin therapy. Patients presenting with thrombocytopenia or thrombosis after discontinuation of heparin should be evaluated for HIT and HITT.

Compounded topical anesthetic creams

Audience: Consumers, Pharmacists and other healthcare professionals

[Posted 12/06/2006] FDA notified healthcare professionals and consumers about the serious public health risks related to compounded topical anesthetic creams. FDA issued warning letters to five firms to stop compounding and distributing standardized versions of topical anesthetic creams, marketed for general distribution. Exposure to high concentrations of local anesthetics, like those in compounded topical anesthetic creams, can cause grave reactions including seizures, irregular heartbeats and death. Compounded topical anesthetic creams are often used to lessen pain in procedures such as laser hair removal, tattoos, and skin treatments. They may be dispensed by clinics and spas that provide these procedures, or by pharmacies and doctors' offices.

Tamiflu (oseltamivir phosphate)

Audience: Pediatric and primary care healthcare professionals and patients

[Posted 11/13/2006] Roche and FDA notified healthcare professionals of revisions to the PRECAUTIONS/Neuropsychiatric Events and Patient Information sections of the prescribing information for Tamiflu, indicated for the treatment of uncomplicated acute illness due to influenza infection in patients 1 year and older who have been symptomatic for no more than 2 days and for the prophylaxis of influenza in patients 1 year and older. There have been post-marketing reports (mostly from Japan) of self-injury and delirium with the use of Tamiflu in patients with influenza. People with the flu, particularly children, may be at an increased risk of self-injury and confusion shortly after taking Tamiflu and should be closely monitored for signs of unusual behavior. A healthcare professional should be contacted immediately if the patient taking Tamiflu shows any signs of unusual behavior.

Acetaminophen 500 mg Caplets by Perrigo Company

Audience: Healthcare professionals and consumers

[Posted 11/09/2006] FDA and Perrigo Company notified the public of a voluntary recall of 383 lots of acetaminophen 500 mg caplets manufactured and distributed under various store-brands as a result of small metal fragments found in a small number of these caplets. Consumers can determine if they are in possession of a recalled product by locating the batch number printed on the container label. A list of stores that carry store-brands potentially affected by this recall, as well as batch numbers affected, is located on FDA's website.

LifeScan One Touch Blood Glucose Test Strips — Counterfeit Alert

Audience: Pharmacists, other healthcare professionals and patients

[UPDATE 10/24/2006] FDA provided two additional lot numbers that are included in the distribution of counterfeit products, along with descriptions of how to identify them.

[Posted 10/13/2006] LifeScan and FDA notified healthcare professionals and the public of counterfeit blood glucose test strips being sold in the United States for use with various models of the One Touch Brand Blood Glucose Monitors used by people with diabetes to measure their blood glucose. The counterfeit test strips potentially could give incorrect blood glucose values—either too high or too low—which might result in a patient taking either too much or too little insulin and lead to serious injury or death.

Coumadin (warfarin sodium)

Audience: Pharmacists, other healthcare professionals, and patients

[Posted 10/06/2006] FDA and Bristol-Myers Squibb notified pharmacists and physicians of revisions to the labeling for Coumadin, to include a new patient Medication Guide as well as reorganization and highlighting of the current safety information to better inform providers and patients.

The FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. Information about all currently approved Medication Guides is available at http://www.fda.gov/cder/Offices/ODS/medication_guides.htm.

Ibuprofen and Aspirin Taken Together

Audience: Consumers and healthcare professionals

[Posted 09/08/2006] FDA notified consumers and healthcare professionals that taking Ibuprofen for pain relief and aspirin at the same time may interfere with the benefits of aspirin taken for the heart. Ibuprofen can interfere with the anti-platelet effect of low dose aspirin (81 mg per day) that may render aspirin less effective when used for cardioprotection and stroke prevention. Although it is all right to use Ibuprofen and aspirin together, FDA recommends that consumers contact their healthcare professional for more information on the timing of when to take these.

Certificates of Recognition

We would like to recognize and congratulate the following facilities for meeting or exceeding all Network 8 goals, in the areas of hemodialysis adequacy, anemia management and vascular access. Certificates were awarded to each of these facilities at the Network 8 annual meeting in November. Due to recent facility acquisitions, each facility was allowed to submit their preference for facility name on certificate. This accounts for the variation in the format of names below.

ALABAMA

Boaz Dialysis
DaVita Dialysis - Eufaula
DCI Cullman
DCI Phenix City
FMC Auburn
FMC Bay Minette
FMC Chambers
FMC Dadeville
FMC Dauphin Island Parkway
FMC East Mobile
FMC Hamilton
FMC Langdale
FMC Magnolia
FMC Opelika
FMC Prichard
FMC Scottsboro
FMC Shelby Dialysis
FMC Tombigbee
FMC Tuskegee

FMC West Mobile
FMCNA Eastern Shore
Landmark Dialysis
Physicians Choice Dialysis of Alexander City
Roanoke Dialysis Clinic

Tylertown Dialysis
Waynesboro Dialysis
Wiggins Dialysis

MISSISSIPPI

Collins Dialysis Unit
Columbia Dialysis
FMC Blue Bluff
FMC Eupora
FMC Macon
FMC Tunica
FMC North Gulfport
Fresenius Medical Care - SMKC Biloxi
Fresenius Medical Care - Starkville
Hattiesburg Clinic Dialysis
Renal Care Group - Greenwood
Renal Care Group Oxford
Richton Dialysis

TENNESSEE

DCI Chattanooga Broad Street
DCI Lyerly
DCI Southern Hills
Dialysis Clinic, Inc. Hixon
Dialysis Clinic, Inc. - Sevierville
FMC Bradley
FMC Dialysis Newport
NRA - Crossville Dialysis Clinic
RCG Portland
RCG Tullahoma
Vanderbilt Dialysis Clinic East

Epogen Controversy

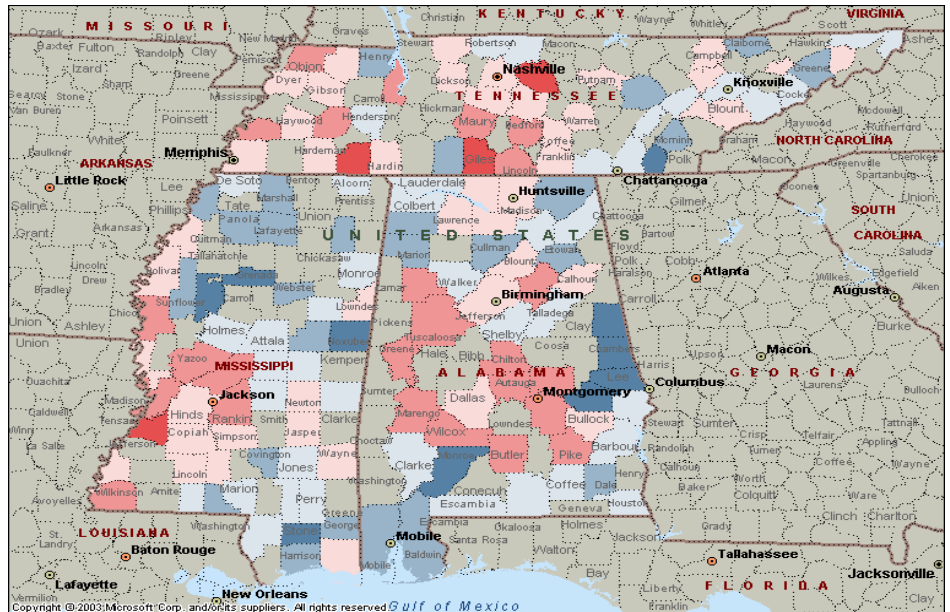
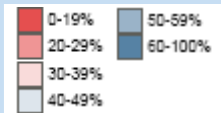
Two November 2006 articles in the New England Journal of Medicine have the National Kidney Foundation, founder of the K/DOQI guidelines, planning to re-assess anemia treatment goals. Current K/DOQI goals for anemia management state that hemoglobin levels should be 11.0 gm/dL or greater and note that *"in the opinion of the Work Group, there is insufficient evidence to recommend routinely maintaining Hb levels at 13.0 g/dL or greater in ESA-treated patients."*

One of the two articles stirring the controversy concludes that target hemoglobin levels of 13.5 are associated with increased cardiac risk and show no improvement in quality of life. The other article concludes "early and complete correction" of anemia in patients with CKD stages 3 and 4 does not lower risk of cardiovascular events.

Epogen prescribing guidelines target hemoglobin levels of 10-12 mg/dL. CMS reimbursement guidelines state that CMS will initiate monitoring once the hemoglobin reaches 13.0 g/dL. CMS policy also states Epogen dose must be decreased by 25% when hemoglobin reaches 13.0 g/dL unless medical documentation can support the higher dose. Furthermore, CMS policy does not reimburse for doses above the maximum of 500,000 IU Epogen and 1500 mcg Aranesp per month.

Given the facts that neither K/DOQI guidelines, product prescribing literature, nor CMS aim for hemoglobin levels of > 13.0 gm/dL, the "controversy" may be less of a controversy than the media is currently reporting. At this time, plans are underway for a January or February 2007 meeting of the K/DOQI workgroup. Stay tuned for details as they become available.

% AVF Use by County October 2006



NETWORK 8, INC.

PO Box 55868

Jackson, MS 39296-5868

Phone: 601-936-9260

Email: info@nw8.esrd.net

Website: www.esrdnetwork8.org

NETWORK NEWS

Publication Date January 2007

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

Editor: Ann Pridgen, Quality Improvement Director

Articles in this edition written by:

Sheila McMaster, Quality Improvement Coordinator
Ann Pridgen, Quality Improvement Director