LEHIGH VALLEY HEALTH NETWORK

PROGRESS NOTES

Medical Staff

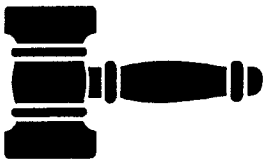
Lehigh Valley Hospital ⌘ Muhlenberg Hospital Center

June, 1998 ⌘ Volume 10, Number 6

In This Issue . . .

"The pure and simple truth is rarely pure and never simple."

Oscar Wilde



From the President

I think this month I'll start with the pure and simple before taking on the rare and never parts!

A new initiative is underway here at Lehigh Valley Hospital. Led by Joanne Lynn, MD, and Joe Vincent, MD, A Center for Improved Care of the Dying is attempting to develop an educational process for health care providers and coordinate a team approach for all caregivers who interact with those at the end of life. As more of us become involved in the patient and family dynamics of the dying, we will help define end of life care as more than just pain control. As a staff, I think we all should applaud Drs. Lynn and Vincent for their efforts with this project. For anyone interested in participating, I would ask that you contact Joe or Ms. Gale Brunst, the Critical Care secretary, at 402-8450.

On the political front, we won some and lost some. The contest between Pat Toomey and Roy Afflerbach for the 15th Congressional District seat in the fall will be an interesting and important one. I continue to urge your participation in the political process so that the voices of physicians will be heard in both Harrisburg and Washington.

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That voice was heard recently in one very important area. Due to both a grassroots outcry and effective lobbying by organized medicine, the new Evaluation/Management Guidelines, due to become effective July 1, 1998, have been tabled pending further consideration. The concerns of physicians that these guidelines were onerous and punitive garnered enough support to detour yet another governmental juggernaut. As time consuming as it may be, we owe it to our patients and ourselves to be a formidable, organized force. James R. Reagan, MD, Chair, Pennsylvania Medical Society, will be our guest at our next Quarterly Medical Staff meeting on June 8 to discuss the value of organized medicine.

The Lehigh Valley Hospital/Muhlenberg Hospital Center Medical Staff Transition Team continues to meet every other week. The consensus of this group is that four seats dedicated to representatives from the Muhlenberg Hospital Center campus should be added to the existing Medical Executive Committee. This structure would preserve both Muhlenberg Hospital Center cultural representation and an at-large member majority of this very important committee.

Now for the least pure and simple topic of my term: the exclusive contract between our Division of Cardiac Surgery and Lehigh Valley Hospital. As everyone knows, the Lehigh Valley Hospital Board of Trustees, at its May meeting, passed a resolution to require that our cardiac surgeons enter into a mutually exclusive arrangement with Lehigh Valley Hospital. This decision generated widespread unrest among the medical staff precipitating a Medical Staff/Administrative exchange session. During this meeting, the same concerns represented at the Board of Trustees meeting by the physician members were echoed by the vast majority of attendees. The physician board members in attendance will convey not only the content of, but also the visceral reaction generated by, this discussion during the June Board of Trustees meeting. In addition, a **special** meeting of the Medical Staff, dedicated to this topic, will take place on Thursday, June 4, 1998, at 5:45 p.m., in the hospital's Auditorium, prior to our Quarterly General Medical Staff Meeting on Monday, June 8, at 5:45 p.m.

If only we did not "live in such interesting times"....

Robert X. Murphy, Jr., MD
President, Medical Staff

For Your Calendar

- A SPECIAL meeting of the General Medical Staff will be held on Thursday, June 4, beginning at 5:45 p.m., in the hospital's Auditorium at Cedar Crest & I-78. Exclusive contracts will be the topic of discussion.
- A meeting of the General Medical Staff will be held on Monday, June 8, beginning at 5:45 p.m., in the hospital's Auditorium at Cedar Crest & I-78. All members of the Medical Staff are encouraged to attend.
- There will be a General Membership meeting of the Greater Lehigh Valley Independent Practice Association, Inc., on Monday, June 22, beginning at 6 p.m., in the Auditorium at Cedar Crest & I-78. Physicians attending this meeting will receive credit toward the Incentive Plan.

Year 2000 (Y2K) Compliant Project

An effort is underway at Lehigh Valley Hospital and Health Network to ensure a smooth transition at the end of the century when processor dates rollover from December 31, 1999 to January 1, 2000. Date problems may arise in a wide selection of products including computer hardware and software, systems with embedded chips for maintenance tracking, and in some bio-med equipment. Systems and equipment that will smoothly handle this date rollover are said to be Year 2000 Compliant. **Systems and equipment not Year 2000 compliant may simply stop working on January 1, 2000 or may continue to function but will process dates incorrectly.**

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The entire Year 2000 Project is directed by Harry Lukens, Chief Information Officer, and Fred Heller, Director, Internal Audit. Al Roeder is the Project Manager and is assisted by a group of Information Services analysts and coordinators from all areas of the hospital including Biomedical Engineering, Patient Care, Medical Records, Health Services Division, Supplier Services, Security, Facilities and Construction, Finance, and Engineering.

There are about 250 computer systems at LVH, plus another 200 in-house databases using multiple versions of software packages such as Powerpoint, Paradox, Access, Lotus, Foxpro, and Excel. A process is currently in place to identify systems at the Muhlenberg Hospital Center.

Enterprise-wide risk assessments have identified 66 computer systems as mission critical to the operation of the hospital. Workplans, test environments, and procedures for testing have been developed for each of the mission critical systems, and most of the bio-med devices.

Embedded systems may present us with the greatest challenge. Tiny microprocessor chips containing date and maintenance data exist in a variety of equipment and devices, from non-medical equipment (fax machines and security devices), to life supporting equipment (pacemakers and defibrillators). There is no guarantee that items from the same vendor and with the same model number are Year 2000 compliant, because the microprocessor chips come from different vendors.

At this time, most of the products that will be affected have been identified. Letters have been sent to vendors requesting information about the Year 2000 compliancy of their products. Many vendors promise to have solutions "sometime during 1999," which means 1999 will be a very busy year for Information Services.

To keep the Year 2000 problem at LVHHN from increasing in scope, vendors who supply products or systems are now required to guarantee every product purchased is compliant.

Information Services recently tested the PHAMIS hospital information system. Several compliance problems have been identified. Commitments have been made by PHAMIS to fix these problems within the next 180 days.

Information Services is available to answer any general questions you have about this problem, or about specific *hospital vendors*, however, they are not very knowledgeable about the office practice vendors. They will be happy to share whatever information they have, including sample letters to the vendors.

Information Services will continue to provide information about this effort on an e-mail bulletin board, as well as updates in the hospital's various communication pieces. The bulletin board will include a list of vendors used by the hospital, as well as contact names and addresses.

If you want to know more about the Year 2000 problem, the following is a short list of web sites with further information :

- Year 2000 - Countdown to year 2000 and links to many related articles
  http://www.year2000.com
- Rx2000 Solutions Institute - Links to Hospital related Y2K services
  http://www.rx2000.org
- Microsoft Year 2000 Resource Center
  http://www.microsoft.com/year2000/
- Year 2000...Are You Ready? - Lehigh University's Y2K site
  http://www.lehigh.edu/y2k/y2kdetail.html

If you have any questions regarding the Year 2000 Compliance project, please contact Al Roeder in Information Services at 402-1480.

Vascular Laboratory Receives Reaccreditation

Each year, two million people in the United States alone develop deep vein thrombosis-blood clots in the veins. This affliction becomes life threatening for 500,000 of those people when the blood clot breaks loose and travels to their lungs. With early detection through the use of non-invasive vascular testing, this disease can be prevented.

Although life threatening if undetected, early detection of these vascular diseases is possible through the use of non-invasive vascular testing techniques performed within vascular laboratories.

The Vascular Laboratory at Lehigh Valley Hospital was recently reaccredited in four areas by the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL). Those areas include: peripheral arterial testing, peripheral venous testing, intracranial cerebrovascular testing, and extracranial cerebrovascular testing.

Initially accredited in 1994, LVH's Vascular Laboratory was among the first 965 vascular laboratories in the United States, Canada, and Puerto Rico to be granted accreditation by ICAVL.

The ICAVL, a non-profit organization established with the support of 10 medical societies, provides a mechanism for accrediting facilities which perform comprehensive testing for vascular disease with non-invasive testing modalities. Ten sponsoring societies represent the medical specialties of radiology, ultrasonography, vascular surgery, neurology, cardiology, neurosurgery and internal medicine.

Accreditation status signifies that the facility has been reviewed by an independent agency which recognizes the laboratory's commitment of quality testing for diagnosis of vascular disease. Participation in the accreditation process is voluntary and demonstrates the laboratory's concern for high quality patient care and attention to quality assurance.

Library News

OVID Training

To schedule a one-on-one OVID (MEDLINE) training session, call Barbara Iobst in the Health Sciences Library at 402-8408.

New Books - Cedar Crest & I-78

The Dartmouth Atlas of Health Care
Author: Dartmouth Medical School
Call No. WA 900 AA1 D226

Cumulative Trauma Disorders
Author: A. Cassvan, et al.
Call No. WE 175 C9709

Concise Guide to Psychiatry, 2nd ed.
Author: J. Spar
Call No. WT 39 S736c

Clinical Hypertension
Author: N. Kaplan
Call No. WG 340 K17c

New Books - 17th & Chew

Medical Pharmacology at a Glance, 3rd ed.
Author: M.J. Neal
Call No. QV 38 N342m

Multidisciplinary Atlas of Breast Surgery
Author: D. Kinne
Call No. WP 17 M961

Critical Care of the Surgical Newborn
Author: D. Nakayama, et al.
Call No. WS 421 C934

Acute Care Psychiatry: Diagnosis and Treatment
Author: L. Sederer, et al.
Call No. WM 141 A189

Congratulations!

Richard S. MacKenzie, MD, Vice Chairperson, Department of Emergency Medicine, was recently appointed Chair of the Public Relations Committee of the American College of Emergency Physicians, a national association of over 19,000 physicians.

Papers, Publications and Presentations

Wayne E. Dubov, MD, Division of Physical Medicine/Rehabilitation, was a guest speaker at an Impairment Rating seminar sponsored by Tallman, Hudders, and Sorrentino, held at Lehigh University on May 6. His topic was "Impairment Rating Evaluations -- General Approach and Historical Background." Dr. Dubov also presented "Peripheral Nerve Injuries in the Trauma Population" at the Pennsylvania National Association of Rehabilitation Professionals in the Private Sector held on May 14 in Hershey.

.n addition, Dr. Dubov was taped for two television appearances on "Challenges" which is broadcast on Channel 69. The first appearance, "Future of Health Care," aired on May 18 at 8:30 p.m. The second, "Seat Belt and Helmet Legislation -- Choice to Choose," will air on Channel 69 on June 15 at 8:30 p.m.

John P. Fitzgibbons, MD, Chairperson, Department of Medicine, chaired a symposium on "Resident Scholarly Activity" at the Association of Program Directors in Internal Medicine meeting held March 31 in San Diego, Calif.

Mark A. Gittleman, MD, Division of General Surgery, presented an all day seminar on "Stereotactic Breast Biopsy" at the Summit Surgical Center in Voorhees, NJ. In addition, Dr. Gittleman was invited to deliver a lecture on "Breast Ultrasound and the Surgeon" at the Michigan Chapter of the American College of Surgeons annual meeting held May 8 and 9 in Lansing, Mich.

Peter A. Keblish, MD, Chief, Division of Orthopedic Surgery, was an invited guest speaker at the Japanese Orthopaedic Society meeting in Tokoshima, Japan, in April. The meeting was the 71st annual Japanese Orthopaedic Association/International Society which consists of over 10,000 members. Dr. Keblish spoke on issues of technique, approaches, and results of total knee arthroplasty and was also the moderator in the sessions that dealt with practical and theoretical aspects of knee replacement.

Colin P. Kopes-Kerr, MD, Department of Family Practice, was a guest speaker at the Annual Family Practice Review Course sponsored by the University of Tennessee in Memphis, Tenn. He gave two presentations -- **The Ten Most Under Used Prescriptions in the U.S.** (aspirin, beta-blockers post-MI, menopausal estrogens, antidepressants, anti-inflammatory medications for asthma, peripheral alpha-blockers for hypertension, ACE-inhibitors for hypertension, CHF, and diabetes, pneumococcal vaccine, fiber, and exercise); and **Management of the Complications of the Common Cold: What the Literature Tells Us**.

Vincent E. Lucente, MD, Chief, Division of Gynecology, and Section of Pelvic Reconstructive Surgery, was a speaker at the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists held in May. His talk was titled "Laparoscopic Reconstructive Pelvic Surgery -- Its Current and Evolving Role."

William L. Miller, MD, Vice Chairperson and Residency Program Director, Department of Family Practice, had a number of speaking engagements during the past few months. In March, Dr. Miller was an invited speaker at the Minnesota Research Network in St. Paul, Minn. His keynote speech was "Qualitative Research - Evidence that Really Matters." He also presented a one-hour workshop on "Doing Qualitative Research."

In early April, Dr. Miller was an invited speaker at the Pennsylvania Spring Family Medicine Conference held in Philadelphia, Pa., which was sponsored by Pennsylvania Family Practice. Dr. Miller co-presented "Turning Questions into Answers: Various Research Methods." He also gave a 30-minute presentation to medical students on "Choosing a Residency."

In late April, Dr. Miller presented "Creating Culture in Residency Training Programs" at the Society of Teachers of Family Medicine Annual Spring Conference which was held in Chicago, Ill.

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Lester Rosen, MD, Associate Chief, Division of Colon and Rectal Surgery, was an invited speaker at the American Society of Colon and Rectal Surgeons Annual Meeting, held May 2 to 7, in San Antonio, Texas. He presented the forum, "Survival Skills for the Clinical and Academic Surgeon," which covered the necessary framework for outcome analysis and its transition into a performance report card, useful for quality management, research and education. Additionally, he was one of the speakers in "Meet the Professor" forums, dealing with Quality of Care Indicators.

Alexander M. Rosenau, DO, Associate Vice Chair/Practice Management, Department of Emergency Medicine, joined the University of Massachusetts/ American College of Emergency Physicians emergency medicine mission to Israel as a visiting professor from March 9 to 12. He lectured and participated in panel discussions at the conference which occurred upon the first anniversary of Israel's recognition of Emergency Medicine as a distinct specialty in Israel. This conference was held in concert with the Fifth Annual Scientific Assembly of the Israeli Association for Emergency Medicine. Physicians from Australia, Canada, Israel, Jordan, and the United States participated. Last year, Michael S. Weinstock, MD, Chairperson, Department of Emergency Medicine, participated in this program on the day of official recognition of the specialty.

Michael S. Weinstock, MD, Chairperson, Department of Emergency Medicine, was recently a Visiting Professor at both Bowman Gray School of Medicine and at Geisinger Hospital where he presented "An Environmental Assessment of Emergency Medicine in Today's Health Care Environment" as well as clinical topics in emergency medicine.

Upcoming Seminars, Conferences and Meetings

OB/GYN Resident Research Day

The Department of Obstetrics and Gynecology will hold the Sixth Annual Joseph A. Miller, MD Resident Research Day on Friday, June 5, beginning at 7:30 a.m., in the hospital's Auditorium at 17th & Chew.

Keynote speakers William Droegemueller, MD, University of North Carolina, and Paula Hillard, MD, University of Cincinnati, will present "Burnout in OB/GYN" and "Pediatric Gynecology." In addition, eight OB/GYN residents will present their projects, representing the culmination of this year's research efforts.

To register for OB/GYN Resident Research Day, please call Bonnie Schoenberger at 402-1210.

Medical Grand Rounds

Medical Grand Rounds are held every Tuesday from Noon to 1 p.m., in the hospital's Auditorium at Cedar Crest & I-78.

Topics to be discussed in June include:

- June 2 - Kidney Transplantation - What the Internist Needs to Know
- June 9 - When Arms Become Legs

There will be no Medical Grand Rounds during the summer; however, they will resume on Tuesday, September 8. Have a Wonderful Summer!

For more information, please contact Evalene Patten in the Department of Medicine at 402-1649.

Department of Pediatrics

Department of Pediatrics conferences are held on Fridays at Noon in the hospital's Auditorium at 17th & Chew.

Topics to be discussed in June include:

- June 12 - Preoperative Evaluation of Children
- June 26 - Topic to be announced

Noon conferences will resume in September.

For more information, please contact Kelli Ripperger in the Department of Pediatrics at 402-2540.

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Customer Service Special Event

On Monday, July 13, Quint Studer, CEO of Baptist Hospital in Pensacola, Fla., will share his strategies with hospital staff and physicians as to how he used the Press, Ganey survey to improve customer service at Holy Cross Hospital in Chicago while he was employed there. Their scores went from the 14th percentile to the 98th percentile in one year. Using these strategies, Mr. Studer is accomplishing similar results at Baptist Hospital.

The sessions will be as follows:

9 a.m. to 11 a.m.	Department Heads and Physicians Auditorium, LVH, Cedar Crest & I-78
11:30 a.m. to 12:30 p.m.	Hospital staff and Physicians who couldn't make the first session Auditorium, LVH, Cedar Crest & I-78
2:30 p.m. to 3:30 p.m.	First Floor Conference Room Muhlenberg Hospital Center

If you have any questions, please contact Nancy Stevens, Patient Representative, at 402-8222.

How Much Does It Cost to Stay in the Hospital?

Beginning with this issue of ***Medical Staff Progress Notes***, information will be provided to inform members of the Medical Staff of the costs associated with the care of their patients at Lehigh Valley Hospital.

Listed below are the costs, per day, of the various levels of care. These nursing unit costs include staff, supplies, and unit management; they do not include fixed expenses or ancillary costs.

• Intensive bed	$ 638.00
• Intermediate bed - TTU, PCCU, TOHU	$ 258.00
• Med/Surg bed	$ 214.00
• Transitional Skilled Unit	$ 160.00

Reimbursement Clarification

To clear up a rumor that has been circulating regarding reimbursement for sigmoidoscopies and colonoscopies, the following information has been issued by Patient Accounting. At the present time, most payers will reimburse for sigmoidoscopies and colonoscopies that are performed in the hospital setting, with the following exception. Independence Blue Cross, which includes Personal Choice, Keystone Health Plan East, and Blue Choice, **will not** pay for sigmoidoscopies done in a hospital setting, including the clinic. Sigmoidoscopies are only reimbursed if done in the physician's office. Patients who have an Independence Blue Cross plan will be billed for the hospital service if the sigmoidoscopy is done at the hospital. The physician reimbursement will not be affected.

Please inform your patients that if they are covered by an Independence Blue Cross plan, they will receive a bill from the hospital if they choose to use the hospital setting.

If you have any questions, please contact Sandra Colon, Director of Patient Accounting, at 402-9461.

Who's New at LVH

The Who's New section of Medical Staff Progress Notes contains an update of new appointments, address changes, status changes, etc., for members of the Medical Staff of Lehigh Valley Hospital.

Medical Staff

New Appointments

Serena A. Jung, MD
Allentown Anesthesia Associates Inc.
1251 S. Cedar Crest Blvd.
Suite 212C
Allentown, PA 18103-6243
(610) 402-8810
Fax: (610) 402-8008
Department of Anesthesiology
Provisional Active

John G. Pearce, MD
Medical Imaging of LV, PC
Breast Health Services
1240 S. Cedar Crest Blvd.
Suite 203
Allentown, PA 18103-6218
(610) 402-0690
Fax: (610) 402-0695

Leave of Absence

Richard M. Herman, MD
Department of Surgery
Division of Otolaryngology
From 3/1/98 to 2/28/2000

Change of Practice

Eric J. Bodish, MD
From LVPG-Emergency Medicine
to McGorry & Bodish
Allentown Medical Center
401 N. 17th Street
Suite 105
Allentown, PA 18104-5088
(610) 432-2013
Fax: (610) 432-6559

Address Changes

Harold J. Goldfarb, MD
Liberty Square Medical Center
501 N. 17th Street
Suite 111
Allentown, PA 18104
(610) 776-1935

Howard A. Silverman, MD
Park Professional Building
2200 Hamilton Street
Suite 103
Allentown, PA 18104-6329

Status Changes

Eric J. Bodish, MD
From Department of Emergency Medicine
Division of Emergency Medicine
to Department of Medicine
Division of General Internal Medicine
Provisional Active

Malcolm L. Cowen, MD
Department of Pathology
Division of Forensic Pathology
From Active to Emeritus Active

Bruce A. Frankenfield, MD
Department of Medicine
Division of General Internal Medicine
From Associate to Emeritus Associate

Donald B. Kopenhaver, MD
Department of Obstetrics and Gynecology
Division of Primary Obstetrics and Gynecology
From Affiliate to Honorary

Joseph N. Nader, MD
Department of Medicine
Division of Cardiology
From Active to Emeritus Active

Raymond A. Rachman, MD
Department of Pathology
Division of Clinical & Anatomic Pathology
From Active to Emeritus Active

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John S. Wheeler, MD
Department of Pediatrics
Division of General Pediatrics
From Associate to Emeritus Affiliate

Appointments to Leadership Positions

George A. Arangio, MD
Associate Chief
Division of Orthopedic Surgery

Weldon E. Chafe, MD
Chief
Section of Gynecologic Oncology

Stephen C. Matchett, MD
Medical Director
Special Care Unit

Resignations

F. Michael Adams, MD
(Kutztown Primary Care Associates)
Department of Family Practice

C. Daniel Hendrickson, MD
(LVPG-Medicine)
Department of Medicine
Division of General Internal Medicine/Ambulatory Care

Ellen M. Joyce, MD
(College Heights OBGYN Associates, PC)
Department of Obstetrics and Gynecology
Division of Primary Obstetrics and Gynecology

Allied Health Professionals

Appointments

Geoffrey P. Carlson, PA-C
Physician Extender
Physician Assistant
PA-C
(Coordinated Health Systems - Brett Godbout, MD)

Mary A. Cox, CRNA
Physician Extender
Professional
CRNA
(Allentown Anesthesia Associates Inc. - Alphonse Maffeo, MD)

Eugenia P. Gilbert, CRNP
Physician Extender
Professional
CRNP
(Candio, Kovacs & Lakata, PC - Robert Kovacs, MD)

Sharon R. Monahan, CRNA
Physician Extender
Professional
CRNA
(Allentown Anesthesia Associates Inc. - Alphonse A. Maffeo, MD)

Cynthia Papaz Kelly, RN
Physician Extender
Professional
RN
(Oncology Specialists of Lehigh Valley - Gregory R. Harper, MD)

Resignations

John D. Eckinger, PA-C
Physician Extender
Physician Assistant
PA-C
(LVPG-Emergency Medicine - Michael Weinstock, MD)

Lori S. Lesak, PNP
Physician Extender
Professional
PNP
(LVPG-Pediatrics - Charles Smith, MD)

NEWS FROM MUHLENBERG HOSPITAL CENTER

Glucose Monitoring System Implemented at MHC

Effective May 4, the Sure Step Pro (glucose monitoring system) was implemented at Muhlenberg Hospital Center on the following units -- CVU, ICCU, 3 South, and 4 South. A physician's order is required to use the Sure Step Prometer to obtain a capillary blood glucose measurement (except in an emergency) to help rule out hypoglycemia or hyperglycemia. The order must specify the timing and frequency of performing the blood glucose tests and state **Blood Surgars per glucose meters**.

Insulin infusion protocol can also be instituted with a physician's order.

The Bedside Glucose Monitoring Flow Sheet will be used by nursing to document monitor readings, serum glucose comparisons, and continuous insulin infusion information. Intermittent insulin administrations will be documented on the medication record.

The flow sheet will be kept at the patient's bedside and placed on the chart in the graphics section when completed.

The institution of the glucose meter is one of the first steps taken to standardize practice at Lehigh Valley Hospital and Muhlenberg Hospital Center.

If you have any questions regarding this issue, please contact Sharon Rabuck, RN, Clinical Instructor, at 861-2413.

For Your Calendar

The Annual Meeting of the Muhlenberg Hospital Center Medical Staff is scheduled for Monday, June 15, beginning at 6:30 p.m., in the hospital's cafeteria. Harry Lukens, Senior Vice President and CIO, will be present to speak to the Medical Staff about Information Services at Muhlenberg Hospital Center.

THERAPEUTICS AT A GLANCE

The following actions were taken at the March - April, 1998 Therapeutics Committee Meeting - Rebecca Hockman, Pharm.D., BCPS, Monica Yost, Pharm.D., Patti Fatzinger, BS, Pharmacy Candidate, Dorothy McFadden, MA, R.D., CNSD, Clinical Nutrition
pt/498.hi

PLAVIX FOR PLATELET INHIBITION

Clopidogrel (Plavix® - Sanofi / Bristol Myers Squibb Company), a new inhibitor of platelet aggregation, has recently been approved for formulary inclusion at LVH. Antiplatelet agents have been proven to prevent the development and progression of thrombosis by inhibiting platelet activation and aggregation at sites of atherosclerosis. In comparison to other antiplatelet agents currently on formulary (ie. aspirin and ticlopidine), clopidogrel may possess superior efficacy, and has been associated with a higher safety profile.

Clopidogrel is a selective ADP receptor antagonist, acting irreversibly through direct inhibition of ADP binding to its platelet receptor and of subsequent ADP-mediated activation of the glycoprotein IIb/IIIa complex. Unlike aspirin, clopidogrel has no effect on cyclooxygenase or thrombin synthesis. Clopidogrel is currently indicated for the reduction of atherosclerotic events including myocardial infarction, stroke, and vascular death in patients with documented atherosclerosis.

Clopidogrel undergoes first-pass metabolism in the liver to an unidentified active metabolite that is responsible for irreversibly modifying the ADP receptor on the platelet surface. Platelets exposed to clopidogrel are affected for their entire life span of 7 days. Platelet inhibition is observed within 2 hours of a single 75mg dose, and steady state is reached within 3-7 days following repeated 75mg doses. Following the last administration of clopidogrel, inhibition of platelet aggregation and prolongation of bleeding time return to baseline values within 5 days.

At high concentrations in vitro, clopidogrel inhibits cyp 450 (2C9) and may therefore interfere with the metabolism of phenytoin, tamoxifen, tolbutamide, torsemide, fluvastatin, and many nonsteroidal anti-inflammatory drugs; however, there is no data to support the magnitude of these interactions. Co-administration with warfarin, aspirin, and heparin has not been established and should be used with caution.

The CAPRIE trial (the Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events trial) compared the use of Plavix® 75mg daily (n=9599) to aspirin 325mg daily (n=9586). The primary outcome of the study was the time to first occurrence of new ischemic stroke, new myocardial infarction, or other vascular death. Clopidogrel was associated with a lower incidence of outcome events of every kind and represented an overall risk reduction of 8.7%.

The CAPRIE trial found the drug to be very well tolerated. Clopidogrel was found to have a safety profile similar to aspirin, but was associated with a lower incidence of gastrointestinal disturbances. Compared to ticlopidine, clopidogrel was associated with a much lower incidence of neutropenia and therefore does not require blood monitoring. Clopidogrel was associated with a higher incidence of diarrhea, pruritus, and purpura. With regard to benefit, side effects and cost, aspirin is still recommended as first line of therapy in the prevention of ischemic events.

The recommended daily dose of Plavix® is 75mg once daily with or without food. No dosage adjustment is necessary in elderly patients or in patients with renal impairment, but experience

is limited in patients with severe hepatic disease. The drug was added to formulary with the intent that it be used as an alternative to ticlopidine in patients status post stroke.

Dosage	LVH cost/day
Aspirin 325mg daily	$0.02
Ticlopidine 250mg BID	$3.15
Clopidogrel 75mg daily	$2.39

COUMADIN: WHAT ABOUT THE GENERIC?

The FDA has recently approved the release of generic crystalline warfarin sodium products by manufacturers, Invamed and Barr Laboratories. Invamed has not marketed or released any information regarding their product; however, Barr's product is currently available. The generic products are receiving widespread attention regarding questions of bioequivalence with DuPont Pharma's Coumadin®.

The skepticism regarding generic warfarin is inevitable since historically generic warfarin products, such as PanWarfarin®, have not been therapeutically successful. [1,3] The narrow therapeutic index of warfarin, risk of adverse effects, numerous intra-and interpatient variables affecting drug response, and many drug interactions make bioequivalence and therapeutic equivalence especially concerning with Coumadin® and generic warfarin products.[4]

According to the FDA, a generic product may be marketed if it meets the required bioequivalence guidelines for rate and extent of absorption of 80-125% relative to the brand name product, and if it meets USP content uniformity standards. [1-3,5] While these variables support bioequivalence, they may not assure therapeutic equivalence, especially with respect to medication with a narrow therapeutic index. In an attempt to improve the anticoagulant stability and reduce any potential overlap with the available dosage strengths, Dupont Pharma (makers of Coumadin®) has voluntarily chosen to employ guidelines which are approximately twice as stringent as those required by the USP. [6] Barr's product follows the standards by the USP. [7] The differences in these production standards may raise questions about potential variations between brand and generic warfarin formulations.

Questions about such variation are especially warranted with narrow therapeutic index medications and potentially harmful adverse effects. The most appropriate way to address these concerns is through clinical trials showing efficacy and safety by interchanging the brand with the generic products. In February, Barr released clinical trial data "proving" interchangeability between Coumadin® and their generic product[8]. This was a randomized, crossover study conducted to compare the efficacy and tolerability of Barr's warfarin sodium to Coumadin®. The study was performed in VA patients with atrial fibrillation, who were on stable doses of Coumadin® for at least six weeks before entering the study. Patients were randomized to receive either generic warfarin or brand Coumadin® for 21 days, and were then switched to the alternative for 21 days, and remained on that same agent for an additional 21 days.

The study enrolled fifty-five subjects randomized to treatment, but only 39 patients included in the primary analysis. No significant difference was demonstrated in averaged INR values between Coumadin® and Barr generic formulations during the crossover study. The authors reported no significant differences in adverse effects, with seven Barr product patients reporting at least one anticoagulation effect versus three Coumadin® brand patients reporting at least one anticoagulation effect. There was no mention of any of the adverse events requiring hospitalization, ER visits or unexpected office visits. The authors concluded that the "warfarin sodium preparations can be safely interchanged with no additional patient monitoring requirements as a result of the switch."

Previous generic warfarin manufacturers have not attempted to support products with therapeutic equivalency trials. The Neutal and Smith trial[8] intended to demonstrate efficacy and safety

interchangeability between the Barr product and Coumadin® product. The limitations of the study include: 1) a small sample size secondary to patient elimination and 2) the elimination of patients requiring a dosage adjustment makes extrapolation to the general population difficult. A larger patient population is needed to conclusively say that the products may be interchanged without need for additional laboratory monitoring.

The average wholesale prices for a thirty day supply of the brand name drug, Coumadin®, ranges from $16.96 to $28.15 as compared to $15.26 to $25.34 for Barr's generic warfarin. Thus, the use of the generic product will represent a total savings in drug cost of about $2-$3 per month. The overall cost of warfarin therapy is also related to the cost of monitoring and treatment of bleeding episodes. It is still unknown if the differences in product manufacturing will result in more intra-subject INR variability.

Until a larger study evaluates the interchangeability of the Coumadin® and Barr warfarin products, it is our recommendation that patients being managed effectively on Coumadin® not be switched to a different warfarin product. If a generic product is initiated on a "warfarin naive patient" or interchanged for Coumadin® brand, there are still unanswered questions as to whether the production variations will result in wider drug content/tablet variation, and therefore fluctuations in INR measurements. In our judgement, a larger clinical trial is needed to conclusively verify therapeutic and safe interchangeability between Coumadin® and Barr Laboratories generic product, without the need for additional laboratory management. Many physicians are facing insurance plans or patient income requirements that are forcing change to generic therapy, despite the minimal difference in cost. If one must change to the generic formulation, we do not recommend the change without laboratory INR assessment. In our clinical judgement, an evaluation of the INR within 5-7 days of the product interchange is necessary. Subsequent dosage changes based on INR monitoring, and monthly INR assessment should then continue in the same manner as that used with the Coumadin® product. Please remember that another generic product by Invamed is scheduled for release, date unknown, and no information is available for bioequivalence or therapeutic equivalence for this product. If a generic product is prescribed, we recommend specifying Barr generic until more information is released for the Invamed product.

Please call the clinical office Ext. #8884 for additional questions.

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CEFEPIME FOR CEFTAZIDIME

As reported in an earlier Medical Staff Progress News (February 1998), the Therapeutics Committee approved the formulary addition of cefepime (Maxipime®) in November 1997. This addition included the approval of an automatic substitution policy between ceftazidime and cefepime, that would occur when efficient laboratory testing was available to the Microbiology Department at LVH. Exceptions to the auto-substitution policy include the following patient populations:

- pediatrics
- neutropenic fever
- meningitis

Ceftazidime will remain on formulary for these restricted patient populations.

The Automatic Therapeutic Substitution Policy will begin on June 8, 1998. All orders written on Monday June 8, 1998 for the initiation of ceftazidime therapy will be substituted, without contact to the physician, with cefepime in the following manner:

cefepime 1gm Q12H will be substituted for ceftazidime 1gm Q8H
and
cefepime 2gm Q12H will be substituted for ceftazidime 2gm Q8H

For patients requiring ceftazidime dosing regimens other than 1 or 2gm IV Q8H, the ordering physician will be contacted by the inpatient pharmacists to discuss equivalent cefepime dosing regimens. Patients already on ceftazidime on the date of automatic substitution, will continue on ceftazidime therapy. For any indications where physicians wish to use ceftazidime over cefepime, the physician should include on the written order for ceftazidime, a statement of "DO NOT SUBSTITUTE." The automatic substitution will occur for all ceftazidime orders EXCEPT those marked "Do Not Substitute" by the physician, or for therapy in pediatrics, neutropenic fever, and meningitis patient populations. Please contact the pharmacy at #8886 or #8884 with questions.

NUTRITION SUBCOMMITTEE UPDATE

The nutrition subcommittee met to review the composition of the enteral formulary and to determine the most appropriate and cost effective enteral formulas. Specialty formulas, such as Impact with Fiber, Glucerna, Peptamen VHP and Vivonex Plus are substantially more expensive than standard enteral formulas and should not be used routinely . Justification for use of higher cost specialty products has traditionally been that use of these products reduces length of stay or complications. Articles published by Richard Barton, MD and Jeffery Saffle MD were reviewed concerning the effectiveness of immune-enhancing formulas. As per discussion, it was decided that immune enhancing formulas are only effective for certain patient populations, and should not be used exclusively in the trauma and burn population. Reducing the use of Impact with Fiber by half will save the hospital $25,000 annually. Criteria are being developed for use of specialty formulas to identify those patient populations where these products are beneficial. Some initial changes that were approved by the subcommittee and presented to Therapeutics Committee:

Change	Benefit
Replacement of Resource Fruit Beverage with Nutrashake Citrus as po supplement for clear liquid diets	Cost Savings: $3020
Replacement of Ensure pudding with Resource Nutritious Pudding	Cost savings: $1300
Replacement of Vivonex Peds with Peptamen Jr for malabsorption, altered GI function and food allergies	Cost savings: $175 Improved continuity with outpt Less waste and contamination

The Food and Nutrition Services department is working with Supplier Services to obtain competitive bidding for the enteral formulary products. Muhlenberg Hospital Center will also be included in the contract negotiations for pricing of these products. The Nutrition Subcommittee will continue to meet to develop guidelines for the use of specialty products. Please review the attached list of enteral formulary products and the cost for each product. Keep in mind the appropriate use of each product and the cost when ordering tube feedings for patients.

COSTS OF ENTERAL PRODUCTS

		Standard	
1.	Osmolite	Isotonic Non fiber containing Standard 1 cal/cc	$ .58/can $ 2.32/liter
2.	Jevity	Isotonic Fiber containing Standard 1 cal/cc w/fiber	$ .92/can $3.68/liter
3.	TwoCal	Nutrient dense Non fiber containing 2 cal/cc For fluid restricted patients	$ .91/can $ 3.64/liter
4.	Promote w/fiber	High Protein 1cal/cc Fiber containing Indicated for trauma, burns high protein needs	$ .92/can $ 3.68/liter
		Specialized	
5.	Glucerna	Reduced carbohydrate 1 cal/cc, Fiber containing For uncontrolled diabetes after trial of Jevity	$ 1.76/can $ 7.02/liter
6.	Nepro	Moderate Protein, low K 2 cal/cc For dialysis patients	$ 2.43/can $9.72/liter
7.	Impact w/fiber	Immune enhancing 1 cal/cc, fiber containing. For sepsis, abdominal trauma, TBSA>40%	$ 6.17/can $24.68/liter
8.	PeptamenVHP	Semi elemental, 1 cal/cc For use with prolonged NPO hypoalbuminemia, protein losing enteropathy	$ 5.00/can $20.00/liter
9.	Vivonex Plus	Elemental, minimal fat, 1 cal/cc Pancreatitis, IBD, fistulas SBS, gut atrophy, radiation enteritis	$ 4.92/packet $ 16.40/ mixed liter* *includes labor for mixing
10.	Renalcal	Low Protein, electrolyte free 2 cal/cc For renal failure without dialysis	$5.97/can $23.88/liter
11.	Nutrihep	Low protein, high BCAA 1.5 cal/cc For encephalopathy	$12.26/can $29.04/liter

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HEALTH NETWORK
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May 14, 1998

TO: MEDICAL STAFF

RE: TEMPLATE BLEEDING TIME

FROM: DAVID PRAGER, M.D.
MEDICAL DIRECTOR
HEMATOLOGY AND COAGULATION LABS

THE TEMPLATE BLEEDING TIME (TBT) – WHAT IS ACCOMPLISHED?

The template bleeding time was first described in 1901 by Milian (1) and subsequently modified by Duke (2) and Mielke (3). Besides leaving a permanent scar, the TBT is not a useful test to predict a patient's propensity to bleed excessively during or after a surgical procedure. The following are some facts based upon the medical literature concerning the TBT.

Cardiac surgery

A. There is no correlation between the TBT and either a decrease in the hemoglobin level or the amount of chest tube drainage in a prospective study of 43 patients undergoing cardiopulmonary bypass. (4)
B. 9 of 65 patients undergoing cardiac surgery had excessive bleeding, but their mean TBT's did not differ from those of the remainder, who did not bleed excessively. (5)
C. In a retrospective study of 92 patients undergoing cardiopulmonary bypass, 14 patients had prolonged TBT's. Those patients did not receive greater amounts of blood products than did patients with normal TBT's. (6)
D. No significant correlation between chest tube drainage or the number of red cells transfused and the TBT. (7)

Non-cardiac surgery

A. In patients undergoing hip surgery with prolonged TBT, there was no excessive bleeding. (8)
B. Retrospective review of 1,941 general surgery patients and 110 patients had a prolonged TBT. There was no correlation between the TBT and bleeding. (9)
C. 101 patients underwent preoperative TBT screening prior to thyroid and abdominal surgery. Preoperative TBT was not felt to be helpful in predicting surgical bleeding. (10)
D. 52 consecutive patients underwent emergency or unplanned operations. In patients with prolonged TBT's , there was no increased intraoperative bleeding compared to patients with normal TBT's. (11)
E. In 282 general and vascular surgery patients who had normal and abnormal TBT's, there was no excessive bleeding in patients with abnormal TBT's compared to patients with normal TBT's. (12)

Summary Statements by Various Authors

1. There is no medical literature evidence that a prolonged TBT predicts which patients will experience excessive surgical bleeding. (13)
2. There is little reason to perform the TBT for screening purposes outside the confines of a study. (13)
3. The use of the TBT as a routine screening test is not warranted at the present time. (13)
4. No evidence exists that the TBT is indeed a predictor of surgical blood losses during or after surgical operations and that no evidence exists that efforts in standardizations have resulted in any significant enhancement in the utility of the test.(14)
5. Based on our results, we suggest not using the TBT in the preoperative screening of patients undergoing coronary surgery without a history of bleeding. (14).
6. The TBT is often an unreliable measure of platelet function. (15)
7. Preoperative TBT is not warranted simply because the patient is taking an "anti-platelet drug" (13)
8. Relatively few of the "anti-platelet" drugs that affect platelet aggregation in vitro prolong the TBT (13).

Suggestions

1. Do not order a TBT for use as a predictor of intra-operative or postoperative bleeding.
2. Do not order serial TBT's for any reason.
3. Do not order a TBT in order to determine why a postoperative patient is bleeding.
4. Do not order a TBT in a patient with thrombocytopenia (platelets less than 100,000/mm.3).
5. There is not a single test available that will accurately evaluate all aspects of platelet function.

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Medical Staff Progress Notes

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