

CHAOS REIGNS



A couple of months ago, Dr. Chuck Coltman recommended that I read a book entitled *Chaos*, which suggests that there is some order to random disorder. I sure hope all this theory is right, because we have some serious chaos in the system. For instance: At the National Cancer Institute, Dr. Vince DeVita exits after nearly eight years of dominating the field. Vince left an indelible mark on the Institute and the national cancer program. Whether you love him or hate him or both, things happened during the past eight years. While many bureaucrats are practiced at indecision, Vince plunged ahead. Vince's rapid exit surprised us all, but its another

example of Vince's ability to make a decision and then implement it without hesitation. With Vince gone, we will see major disruptions at NCI. That's okay. Most organizational literature suggests that every 10 years or so, major bureaucracies need a shake up; things get too routine and the need for chaos overwhelms the need for regularity. For new ground to be plowed, you need to get a new leader who can try new things.

To add to the changes at NCI, Dr. Bob Wittes is taking a position at Bristol Myers. Wittes has brought order to the clinical trials review program at NCI—one area that does not need disorder! We'll pray that his successor continues his organizational progress.

Much, much closer to home, chaotic reimbursement problems are continuing to impact cancer care. As part of my consulting work, I've been wandering around the Midwest, the Northwest, and the West listening to hospitals and physicians express their concerns about what is happening. In California, they talk about increased competition and more managed care plans owned by competitors. In Wisconsin, you can hear about a hospital without a cancer program that suddenly is managing 100 additional cancer patients after a shift in the managed care plan. In Indiana, there's a new interpretation of an old ruling that physicians treating patients in hospital outpatient clinics can only be reimbursed for their fees when they rent the space and pay the nurses. In Minneapolis, they talk about hospital consolidations, closures and tight, tight budgets. The entire reimbursement scene promotes random, chaotic approaches to cancer care. All too often now, I see a hard-working clinician literally lower his head while he tells me about how he's had to deliver less care to a managed care patient. There is order to this disorder here, but not the kind you want to see.

On another front, ACCC and other groups were successful last month in persuading Congress that the *U.S. Pharmacopeia Drug Information* and the *AMA Drug Evaluations* should be cited as standard references in the Medicare Catastrophic Coverage Act. Yet, some of the folks at the National Blues are looking at using PDQ as a standard reference for what should be paid, while HMOs, such as Maxicare, and some Blues plans are apparently reimbursing for only those indications included on FDA labeling—a strategy that effectively eliminates about half of all current chemotherapy (see the Spring 1988 issue).

Then there's the continuing development of Freestanding Cancer Centers and mini-FCCs; the state-by-state implementation of HCFA 1200; the now well-documented reimbursement denials for patients on formal clinical trials; the increasing squeeze from DRGs; the ongoing national negotiations with third parties and self-insured companies; and the fundamental changes in the power relationships between the American College of Surgeons, the American Cancer Society, the National Cancer Institute, the Joint Commission and the American Medical Association. You need more than a scorecard, you need a video terminal.

If you want a good laugh, one of the women's magazines recently suggested to all of its readers that if their oncologist does not have PDQ in their office, they should demand that the physician borrow another physician's PC so he can access the latest information on patient management! Sure. You walk out past the 35 people sitting in your packed waiting room and announce: "I'll be back in an hour. I've got to go next door, dial up PDQ, and see if the committee has changed anything in the last month or two. It won't be a total waste though; I can also find out whether the treatment I've

WELLCOVORIN® TABLETS

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The Proven Considerate Rescue



5 mg and 25 mg tablets

Before prescribing WELLCOVORIN® Tablets, please consult complete prescribing information. The following is a brief summary.

INDICATIONS AND USAGE: Wellcovorin (leucovorin calcium) is indicated for the prophylaxis and treatment of undesired hematopoietic effects of folic acid antagonists (see WARNINGS).

CONTRAINDICATIONS: Leucovorin is improper therapy for pernicious anemia and other megaloblastic anemias secondary to the lack of vitamin B₁₂. A hematologic remission may occur while neurologic manifestations remain progressive.

WARNINGS: In the treatment of accidental overdose of folic acid antagonists, leucovorin should be administered as promptly as possible. As the time interval between antifolate administration (e.g. methotrexate) and leucovorin rescue increases, leucovorin's effectiveness in counteracting hematologic toxicity diminishes.

PRECAUTIONS:

General: Following chemotherapy with folic acid antagonists, parenteral administration of leucovorin is preferable to oral dosing if there is a possibility that the patient may vomit and not absorb the leucovorin. In the presence of pernicious anemia a hematologic remission may occur while neurologic manifestations remain progressive. Leucovorin has no effect on other toxicities of methotrexate, such as the nephrotoxicity resulting from drug precipitation in the kidney.

Drug Interactions: Folic acid in large amounts may counteract the antiepileptic effect of phenobarbital, phenytoin and primidone, and increase the frequency of seizures in susceptible children.

Pregnancy: Teratogenic Effects: Pregnancy Category C. Animal reproduction studies have not been conducted with Wellcovorin. It is also not known whether Wellcovorin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Wellcovorin should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Wellcovorin is administered to a nursing mother.

Pediatric Use: See "Drug Interactions."

ADVERSE REACTIONS: Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

OVERDOSAGE: Excessive amounts of leucovorin may nullify the chemotherapeutic effect of folic acid antagonists.

DOSAGE AND ADMINISTRATION: Leucovorin is a specific antidote for the hematopoietic toxicity of methotrexate and other strong inhibitors of the enzyme dihydrofolate reductase. Leucovorin rescue must begin within 24 hours of antifolate administration. A conventional leucovorin rescue dosage schedule is 10 mg/m² orally or parenterally followed by 10 mg/m² orally every six hours for seventy-two hours. If, however, at 24 hours following methotrexate administration the serum creatinine is 50% or greater than the pre-methotrexate serum creatinine, the leucovorin dose should be immediately increased to 100 mg/m² every three hours until the serum methotrexate level is below 5 x 10⁻⁴ M.^{1,2}

The recommended dose of leucovorin to counteract hematologic toxicity from folic acid antagonists with less affinity for mammalian dihydrofolate reductase than methotrexate (i.e. trimethoprim, pyrimethamine) is substantially less and 5 to 15 mg of leucovorin per day has been recommended by some investigators.^{3,4,5}

REFERENCES:

1. Bleyer WA. The Clinical Pharmacology of Methotrexate. *Cancer*. 4(1):36-51. 1978
2. Frei E, Blum RH, Pitman SW, et al. High Dose Methotrexate with Leucovorin Rescue: Rationale and Spectrum of Antitumor Activity. *Am J Med*. 68:370-376. 1980
3. Golde DW, Bersch N, Quan SG. Trimethoprim and Sulphamethoxazole Inhibition of Haematopoiesis in Vitro. *Br J Haematol*. 40(3):363-367. 1978
4. Steinberg SE, Campbell CL, Rabinovitch PS, et al. The Effect of Trimethoprim/Sulfamethoxazole on Friend Erythroleukemia Cells. *Blood*. 55(3):501-504. 1980
5. Mahmoud AAF and Warren KS. Algorithms in the Diagnosis and Management of Exotic Disease. XX. Toxoplasmosis. *J Infect Dis*. 133(3):493-496. 1977

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JCAHO REPORTS FIRST RESULTS OF CLINICAL INDICATOR FIELD TESTING

To date, the data burden involved in the collection of obstetrics/gynecology and anesthesiology clinical indicators is minimal, according to Betty Fuchs, project manager for field activities at the Joint Commission for Accreditation of HealthCare Organizations (JCAHO).

Three different sets of data have been obtained from hospitals participating in the field testing of 30 obstetrics/gynecology clinical indicators and 45 anesthesiology indicators. JCAHO is finding that the time needed to collect the necessary data ranges from 5 to 25 minutes, "depending on the complexity of the medical record," Fuchs explains.

Participating hospitals have also been supplying JCAHO with resource assessment information. Fuchs says that hospitals' reported resource requirements to collect the data have ranged from \$254 to \$8,000. However, Fuchs points out that only one hospital's resource needs totaled \$8,000—a figure which she says is "far out of line with the needs reported by other institutions." In fact, the next highest reported data collection cost was \$1,900. Cost variations, according to Fuchs, are primarily due to the "type of personnel" used to collect data. For instance, at hospitals where nursing staff are collecting data, the costs are higher than in hospitals that are using medical record staff.

Furthermore, because data have been collected manually, the expected switch to an automated system of collection should "easily cut costs in half," Fuchs predicts.

Future possible revisions to collection procedures may include "dropping some of the elements currently being collected, especially in the area of anesthesiology," Fuchs notes. Other possible revisions to the data collection process could include a switch to random collection procedures or, instead of collecting 100 percent of the data, the JCAHO may elect to collect summary information.

Right now, however, JCAHO is concerned with validating current indicators and determining the data capacities within field test hospitals. JCAHO expects to be ready to institute the ongoing collection of data in the areas of obstetrics/gynecology and anesthesiology by the beginning of next year.

The development of oncology clinical

indicators will begin in November, when the oncology task force, chaired by John Yarbrow, M.D., Ph.D., meets for the first time. Field testing of those indicators should begin next June, Fuchs says. Moreover, because many hospitals have "highly developed cancer registries, the collection of oncology indicators may be automated immediately, bypassing the initial, manual collection method employed in other areas."

In addition to oncology, the development of clinical indicators for cardiology and trauma will proceed this year. The next areas targeted for action are long-term care, psychiatric care, and general surgery.

RABSON APPOINTED NCI ACTING DIRECTOR

Alan Rabson, director of the Division of Cancer Biology & Diagnosis, has been appointed acting director of the National Cancer Institute, effective September 1. Dr. Vincent DeVita's 25 years of service at NCI ended on August 31.

The Reagan Administration plans to appoint a replacement for DeVita before a new Administration is in office. White House staff have drawn up a list of candidates for review, none of whom are currently employed by NCI.

ACCC'S YARBRO TO CHAIR JCAHO TASK FORCE

John Yarbrow, M.D., Ph.D., professor of Medicine, University of Missouri School of Medicine, and a founder and past president of the ACCC, has been appointed by the Joint Commission on Accreditation of HealthCare Organizations (JCAHO) to serve as chairman of its Oncology Clinical Indicator Task Force.

The task force is charged with the responsibility for developing oncology clinical indicators to be field tested by June 1989.

CALL FOR PROPOSED BYLAWS AMENDMENTS

The ACCC Bylaws, adopted by the House of Delegates in March 1984, state: "These Bylaws may be amended by the vote or written assent of two-thirds of the Delegate Representatives voting. Written notice of proposed Bylaws amendments must be sent to voting members at least 30

days prior to the meeting at which they are to be acted on."

Any delegate representative may submit a proposed Bylaws amendment. Submissions should be in writing and addressed to Susan Dimpfel, Bylaws Chairman, ACCC, 11600 Nebel St., Suite 201, Rockville, MD 20852.

All suggestions for amendments must be received at the ACCC Executive by December 1, 1988, for consideration by the House of Delegates in March 1989.

NOMINATIONS FOR ACCC OFFICERS AND TRUSTEES

The ACCC Nominating Committee is soliciting nominations for the following 1989-90 board positions:

- President-Elect
- Secretary
- Four Trustees

The term of President-Elect is one year. The Secretary and Trustee positions are two-year terms. While nominees are not required to be the voting representative from their institution, they must represent an ACCC Delegate Institution. ■

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planned for the rest of you is going to be paid for, now that the Blues have decided to only pay for whatever is listed on PDQ."

So folks, chaos reigns. It's supposed to be good for innovation, but lousy for things we know how to do. It's a damn shame that it's being introduced to areas that need stability, like payments for patient care that we know has a positive effect, and payment for research, which guarantees reductions in innovation. Chaos can be okay, but sometimes we've got it backward.



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