

FROM THE EDITOR...

TACKLING ONCOLOGY'S ISSUES



About a decade ago, R. Lee Clarke, M.D., said that if the Association of Community Cancer Centers didn't exist, the country's cancer leadership would have to invent it. Clarke contended that the concepts first pioneered in university centers needed to be organized and expanded to all of the patients being managed in U.S. communities.

ACCC was a young and ugly duckling in those days, because it was talking about issues that others wanted to ignore. ACCC's leadership was raising a ruckus about wanting to do clinical research in the community.

ACCC's community oncologists, trained in research during medical school, actually claimed that they had not lost their minds or their desire to be active participants in solving oncology's challenges when they left for private practice. Of course, these very same folks were causing trouble in local hospitals by pressing for separate oncology units and specially trained oncology nurses and social workers.

The trouble making has continued. First, community oncologists wanted someone on the National Cancer Advisory Board. Then they pushed for patterns-of-care evaluations through the CHOP program. Next, there was the push for the Community Clinical Oncology Program (CCOP).

Finally, ACCC started talking about product line management, marketing, reimbursement, and quality of care assessment. To add fuel to the fire, in 1982, the organization had the gaul to say that the new competition and changing reimbursement policies were going to severely damage our clinical research system. DHHS, NCI, ASCO, AAMC, and HCFA all assured us that there was no problem. Then, in 1985, we provided to ProPac data that was key in the decision that DRG 403 needed to be recalibrated. Last week, we provided key Congressional staffers with data that led to an important change in the Medicare Catastrophic Coverage Act.

When the *Journal of Cancer Program Management* was launched two years ago, the ACCC board once again decided to target the issues that impact quality cancer care. In the ACCC tradition, the *Journal* has not hesitated to tackle what may be considered avant-garde issues. For instance, the first series on the Joint Commission on Accreditation of Healthcare Organization's (JCAHO's) clinical indicator initiative appeared in the *Journal* more than a year and a half ago—a subject that we revisit in this first edition of *Oncology Issues*. There have also been original articles on cancer Ambulatory Visit Groups (AVGs) and the impact of severity of illness on fixed price cancer reimbursement. More recently, unique, indepth articles have been published on the viability of freestanding cancer centers, the role of oncology medical directors, attempts to restrict care by limiting reimbursement to only those drugs that are currently labeled by the FDA for a specific indication, current reimbursement levels for cancer DRGs, and ACCC's development of standards for cancer programs.

There are many more issues yet to be explored: the use of clinical indicators in oncology; comparing and rating insurance plans' cancer benefits; the role of data management, marketing and research in cancer care; and ways in which cancer programs that are dedicated to quality care can survive and yet bring new innovations to patient care as rapidly as possible. *Oncology Issues* will continue ACCC's tradition of delving into controversies. It will continue to explore the economics of quality cancer care and the realities of survival, while campaigning for health care policies that promote cost-effective, quality care. The new name of the *Journal*, *Oncology Issues*, is our way of emphasizing that ongoing commitment.

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WELLCOVORIN[®] TABLETS =====(leucovorin calcium)==== *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 overdosage 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 10⁻⁴M.^{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}

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