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## Evaluating CCOPs — The First Three Years

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## WELLCOVORIN TABLETS (leucovorin calcium)

Leucovorin in convenient  
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 B<sub>12</sub>. 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/m<sup>2</sup> orally or parenterally followed by 10 mg/m<sup>2</sup> 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/m<sup>2</sup> every three hours until the serum methotrexate level is below  $5 \times 10^{-8} M$ .<sup>1,2</sup>

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.<sup>3,4,5</sup>

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## EVALUATING CCOPs — THE FIRST THREE YEARS

David K. King, M.D.

Secretary, Association of Community Cancer Centers

The first three years of the Community Clinical Oncology Program (CCOP) is coming to a close as the National Cancer Institute (NCI) prepares for a second round of funding. During the ACCC annual meeting, speakers from the NCI, from cooperative groups, and community investigators appraised the first years of the program and looked forward to the next round.



David K. King, M.D., addresses a "standing room only" crowd during the General Session on CCOPs.

In the following articles, Dr. Charles Coltman, Dr. Charles Moertel, and Dr. Peter Deckers discuss their views of the CCOP program, what they learned from it, and describe their view of the future of clinical research based upon the success of the program.

For the most part, the news is good. In some cases, it is extraordinarily good. Community investigators praised the impact of the program and cooperative group chairmen praised the high quality of the data collection and patient accrual by community-based investigators. In some cases, the news delivered at the ACCC Spring meeting was less heartening as NCI Director Vincent DeVita noted that funding constraints may force him to fund as few as 50 programs in the second round (62 are now funded), a signifi-

cant reduction in a program that he calls an "unqualified success." Yet, there is no doubt that DeVita supports the program and hopes to fund more.

One final observation from the session deserves close scrutiny: The remarks by Dr. Charles Coltman on his findings that for two cancer sites the mortality and length of survival for cancer patients has been found to be better in community hospital contributors to protocol than in university contributors, even after you factor out demographics like age, sex, race, socioeconomic factors, and patient status on admission. Clearly, community investigators are doing as rigorous a job of admitting patients to protocol as their university colleagues and living up to the highest standards of quality care. ■