

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 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 × 10⁻⁸M.^{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}

1. Bleyer WA: The Clinical Pharmacology of Methotrexate. *Cancer*, 41(1):36-51, 1978.
2. Frei E, Blum RH, Pitman SW, et al: High Dose Methotrexate with Leucovorin Rescue: Rational and Spectrum of Antitumor Activity. *Am J Med*, 68:370-376, 1980.
3. Golde DW, Bersch N, Quan SG: Trimethoprim and Sulpha-methoxazole 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 Wdrren KS: Algorithms in the Diagnosis and Management of Exotic Disease. XX Toxoplasmosis. *J Infect Dis*, 135(3): 493-496, 1977.



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QUALITY CONTROL CHALLENGES IN THE NEW COMPETITIVE MARKETPLACE

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President

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Quality health care is a fundamental value of the health care professions; yet, despite a substantial investment of time, resources, and effort in quality assurance activities, the yield to date has been modest. We clearly have had real difficulties in evaluating the care that we provide.

In this new era of health care competition, a number of "audiences" are concerned about quality of care. Indeed, the topic is now a major public policy issue. While price and the cost of care remain significant factors in evaluating health care providers, the quality of care delivered is emerging as a major differentiating factor among providers. Simply claiming that you do a quality job will no longer be sufficient. In the very near future, you will have to prove it!

Different Audiences Have Different "Quality" Definitions

A pivotal problem in evaluating care is the lack of a consensus in defining quality of care. In the good old days, the health care providers' definitions were paramount. Quality was technologic sophistication, diagnostic accuracy, therapeutic efficacy, a touch of humanity, and access to care. All of these standard definitions are particularly relevant to the care of cancer patients.

Other audiences have different interpretations. In the past, patients have expressed concern about the amenities of care, for example, whether the food is edible or the linens clean. As the patient's share of the health care payment has increased, they are also demanding that the old paternalism be dropped, and that they be involved in decision-making about their care. Patients are asking that

health care providers consider whether or not a test or a treatment is really necessary. They do not want their care cut short for cost reasons, but they do not want us to be frivolous with their money either.

Another major audience defining the quality of care is the purchaser of care; many believe that they now control the health care market. In their terms, quality is often defined as effectiveness, efficiency, and appropriateness.

Beyond the variance in definitions, some of these definitions are in direct conflict with each other. To complicate matters, most of these dimensions of quality are unmeasurable. Of course the key question is whose definition will prevail? In my personal estimate, it is unlikely to be the purchasers of care. In the long run, I believe that it will be the public. While the pathway is somewhat convoluted, the public still sets public policy in this country.

Admittedly, the public has been a little schizophrenic over the past 10 years, and the result has been a schizophrenic public policy. Collectively, the public demands lower health care costs, but individually, they wish first class care for themselves. However, today the public is expressing a simple and coherent message -- they want value for the dollar expended. This coherent message is beginning to be expressed in public policy.

Other Environmental Factors that Affect the Quality Issue

This message comes at a time when we are living in a new environment that is characterized by resource limitations. Indeed, it is the impact of these limitations on the quality of care that is causing a number of observers to express concern.

However, several of the major players remain focused on cost issues. The strategic preoccupation is with figuring out ways to shift the risk. The Federal government, with its convoluted plans, formulas, and regulations, actually has a simple agenda: The executive branch, at least, wants to capitate the entire health care system and shift the financial risk away from themselves to someone else. That "someone else" is you, the hospitals, the physicians, and the patients. The private sector has exactly the same idea. Working through business coalitions, they are actively pursuing the same goal.

Essentially, in an era where survival is a major factor, the cost squeeze is having an impact. There certainly appear to be providers who are more concerned about the financial bottom line than the patient. This lies at the heart of the quality of care concern. Survival conditions and tight money have real world translations. They translate into an inability to refurbish a building, buy new patient equipment, or hire people to operate the equipment. Controlling the utilization of health services becomes the only pathway to survival.

A major complication for the health care community in controlling service utilization is the liability insurance crisis, which has created a broad swath of defensive medicine in this country. While many physicians claim they do not personally practice defensive medicine, this has been going on for so long now that it has been inculcated into our basic fundamental behaviors. This is not to say that everything we order for the patient must make a difference in the clinical decision-making process; but, we could probably trim some things back to make the health care dollar go a little further. However, this requires that we do some difficult things that some people will portray under the pejorative heading of "cookbook medicine." A word with a

similar meaning, but with totally different implications, is "protocol," a concept with which oncologists are very familiar.

On the horizon is a whole new science of clinical decision-making, which involves artificial intelligence and computers that will not make decisions for you but will provide guidance in this process. Of course, this is going to raise a whole new spectrum of issues. At some point, this approach to clinical care could well become a national standard. If you do not have a computer, you may be in some difficulty. If you do have a computer and do not follow the algorithm and then something bad happens to your patient, you will still be in trouble. Even if you follow the algorithm and the patient has a bad result, someone will be in trouble. Perhaps the computer will be sued, and a new form of product liability will emerge. In this strange new world we are entering, computers may assist with utilization control, and utilization control is the big issue in a resource limited environment.

Another major problem today is the confusion among quality, appropriateness, and efficiency. When you talk to members of the government and business communities or individuals from your local PRO, you will find that a number of them take pleasure in confusing these concepts. While these terms relate to each other, their distinctions must be made clear. Appropriateness and efficiency are relative. They are not

meaningful unless they are looked at against a benchmark, and that benchmark is called quality.

A classic example of the appropriateness issue is the Wennberg study of regional variation in community surgical rates. In one community, if the hysterectomy rate was 17 percent, while in another the rate was 76 percent, people may just assume that the 17 percent rate must be good. Is it really? The "right" rate could be at either end of the spectrum or in between. Only through evaluating quality of care, in this case patient outcomes, can the answer be found. Efficiency, too, cannot stand alone. If you undertake bypass surgery on a patient, you may do a very efficient job, but if the patient did not need the surgery in the first place, efficiency has not made a difference.

The final background issue is the interrelationship of quality assurance and risk management. In many ways, quality assurance is the child of the medical staff while risk management is the child of administrators and governing bodies. Traditionally, risk management has been a "loss control" function, a fiscal issue; but risk management is now dominated by the burgeoning problem of professional liability. Though merely a small slice of the risk management pie fifteen years ago, professional liability in 1986 is a big chunk of risk management. To the extent that patient risk is reduced (and



Dr. O'Leary explains JCAH initiatives in measuring quality health care

safety enhanced), quality of care is improved. The overlap between quality assurance and risk management is apparent. Tomorrow we will need to build our quality of care evaluation mechanisms with this linkage in mind.

Evaluating Quality and Setting Standards

If the Joint Commission is to be relevant in the future, its mission must be to promote quality health care for the American people. It is apparent that evaluating the quality of care is no longer a simple concept. In the past, the JCAH has used standards to assess four areas of structure and function: The facilities, or the bricks and mortar; the equipment (for general operations and for patients); the people; and the "systems." The two main groups of people are the medical staff and the hospital staff, or employees; for both groups, qualifications must be reviewed and performance monitored. The "systems" link the people with the facilities and equipment. These "systems" are usually described in policy and procedure manuals that are dusted off in time for the arrival of the Joint Commission.

However, to promote quality of care we must look beyond the bricks and mortar; we have to be interested in the care delivered to patients across the health care system. The Joint Commission has been

in part because the changing world of health care now includes providers of care that do not have bricks and mortar. Independent Practice Associations (IPAs) are based in physicians' offices. This year, we signed a contract with the State of Ohio to evaluate 11 HMOs (half of which are IPAs) that include Medicaid patients as enrollees. We used an evaluation protocol, which includes a major medical audit in addition to the usual structure and function standards. A 10 percent patient sample was audited using criteria from 13 common clinical areas, such as hypertension management, prenatal care, and vaginitis. We conducted this audit in physicians' offices, and it has been an interesting, instructive experience. However, we maintain our basic philosophy that we accredit organizations, not individual practitioners. The findings of this evaluation are displayed as characteristics of performance of the whole HMO.

Collectively, the findings suggest that provision of care appears quite strong in some areas and weak in others -- not unlike hospitals. After being in physicians' offices, the sky has not fallen. In fact, we conducted a satisfaction survey and found no problems. This has not completely resolved the issue, but it illustrates how our environment is changing.

It is neither possible, nor desirable, for the JCAH to try to evaluate everything that is related to health care; we must focus on core services and try to under-

stand them. We have judgments to make about the unit of measure issue, but the physician's office is one unit of measure I would not dream of tackling. The entity to be reviewed must be large enough so that the evaluation means something.

At the other end of the spectrum, we are facing the problem of evaluating whole systems of care. Although we can and do look at individual units in systems, there is no way to characterize the entire system. Freestandings, as I call them, are also problems because there are few incentives to review ambulatory health care services. It is a boutique industry and organizations

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concerned about more than just hospitals for quite awhile, though the scope of its activities is not well known. The JCAH was interested in psychiatric facilities and long term-care in the '60s, ambulatory care in the '70s, and hospice care in the '80s. The true unit of measure for quality is the patient outcome, not the facility. Did the patient get well? Return to work? Return to optimal function? Despite our efforts and concerns, we are a long way from focusing on the patient as the unit of measure.

Now, we are being forced to move beyond the "bricks and mortar" mentality

The Competition to Define Quality

Those of us in the health professions are under considerable pressure to define and measure quality of care. If we do not do it, plenty of people would be happy to do it for us. First, the government is concerned about the quality of care delivered and has demonstrated this concern through the creation of PSROs and now PROs. Also, Congress is pressured to expand peer review to HMOs, long-term care, home care, and possibly into other areas as well. The Consolidated Omnibus Reconciliation Act (COBRA) of 1986, includes a mandate for PROs to review and take actions, or invoke sanctions based on the quality of care. This mandate is disheartening, particularly in certain respects. The PROs are required to evaluate quality of care but as yet have no uniform standards of measure. If they take an action and are challenged as to their standard of evaluation, they will have no standard to defend. Meanwhile, back in Washington, HCFA appears to expect action.

HCFA, itself, has another answer to the problem: They have a computer full of Medicare claims data. It now appears that the mortality data released in March was just the first shot out of the barrel; more data will be released. Now that data is claims data, its usefulness as an expression of quality of care is quite limited. Although I think HCFA has begun to understand the issue of data quality and is speaking more conservatively, further data release will be an issue for all of us.

Pressure is also exerted by business and insurance groups. The business community, in particular, has had an interest in quality control for a long time. They use an approach called Statistical Process Control (SPC), which reduces all quality measures to numbers. The business people we talk to understand that determining quality of care is more complicated than making widgets and refrigerators, and that patients themselves are major variables; but, the science of SPC has no provisions for the possibility that a patient may receive impeccable care and still die. We in health care need to learn more about this science if we plan to talk meaningfully with the business community about quality of care.

We also feel pressure to define and measure quality from our own providers. Some providers believe they do a great job and would like to define their success and sell it. It seems to me that the real key to defining quality of care, in the foreseeable future, is clinical performance. Not that other issues, such as access, will not be considered, but clinical performance will be the critical factor. There is clearly a pressure-head from multiple sources to move in this direction.

Measuring Quality is Underway

The question frequently posed to us is: "Can quality be measured?" The fact is that in 1986, it can be measured, and we

This inevitably brings up the question of whether we are truly better off with standards. I believe we are. Otherwise, what are we really dealing with in a court of law? Only the opinion of an expert witness.

Of course, there are problems in measuring quality of care, and we need to know what they are before we charge ahead. First, quality assurance programs have clear disincentives. They cost money and do not generate revenues. There is a liability risk from smart lawyers fishing for exposure in your data. Further, if you start basing actions on your findings, you run the risk of being sued by someone who thinks you are unreasonably curtailing his privileges.

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do not serve ourselves well by stating, in various ways, that health care is too ethereal to evaluate. We have assets today that we did not have before, and a number of elegant studies on this subject have been published. An example of such work is Bill Knaus' use of the APACHE II system to compare patient care in intensive care units. After discovering a wide variance in the performance of 13 ICUs, Knaus determined that the critical variable was the leadership function within the units. Others have done solid work as well, and it is evident that at least microsystem methodology is now available. We now must move from micro to macro, and I think we have that capability.

Another important advantage today is the willingness of professionals to talk about and develop standards and criteria for clinical performance. An issue of JAMA this year included an article on the standards developed for anesthesia care in the eight Harvard hospitals. The standards themselves, although excellent, are not the issue. The issue is that publishing those standards was a courageous thing to do, because I can assure you that such standards will be used in professional liability cases. That is a potential risk for all national performance standards and criteria.

I submit there are greater liability risks in not gathering and using appropriate clinical performance data.

Another significant problem is that most hospitals are not well prepared to adopt this new methodologic approach to evaluation. Good data system and quality assurance program support does not exist in many hospitals, but the commitment of resources needs to be made.

Which of the multiple performance measures will we use? We need to select dimensions of care that are measurable, that have a real effect on care, and that can differentiate between good and substandard performance. Ideally, whether we consider generic, procedural, or diagnosis-specific indicators, and I think we are moving towards the latter, I think we must consider a tracer approach. Otherwise, the risk of data overload is too great.

Finally, we must be reminded that there is still a large subjective element to quality assurance. The patient is a major variable, and severity adjustment must be included in any method of evaluation. Although it has been the subject of a number of papers, the methodology, as applied to quality assurance, is still crude, and we may need to participate in further

developmental efforts. Ultimately, the payoff still lies with effective problem analysis and peer review.

The JCAH Initiatives In Measuring Quality

The Joint Commission initiative will begin in 1987, with clinical profiling of the hospitals ready for re-survey. We will seek information, which the hospital should already be concerned about -- high volume services, high risk services, and the problem prone services; especially the multidisciplinary ones that require significant coordination. The clinical indicator initiative will move in parallel. We will start with generic criteria, but by 1990, we will have moved far beyond these crude measures. We will be developing what we talked about: Establishing meaningful differentiators of performance using a tracer approach.

In developing this new approach, it will be critical to have a normative data base to balance against professional criteria to provide a context of reality. We will adapt the best available severity of illness modifier. We will support the development of institutional data reporting capabilities, and we are going to come down very hard on promoting meaningful problem analysis. Finally, we will interact with health care organizations on an ongoing basis. In so doing, the Joint Commission's relationship with the organizations it accredits will change to a more facilitative and supportive role. The basis of the continual interaction will be a national data base against which you can compare your performance on a given measure with that of similar hospitals. If you have a problem area, you will be working on it, and we will be tracking your progress.

There is a parallel initiative to all of this, which the JCAH calls the organizational performance indicator initiative. We believe that the manner in which an organization functions affects patient care -- team function does make a difference. We have believed this for a long time, but tomorrow we will be looking for performance measures of organizations that demonstrably make a difference in the quality of care. All of this means a refocusing of the survey process -- a survey process that will look

at the validity of the data going into your system, the validity of your problem analysis, whether the actions you take to resolve problems are effective, and it will have to look at organizational indicators as well.

On an accelerated timetable, and with lot of luck, all of this might be in place by 1990; but it is not going to be easy. We will be developing an entirely new conceptual model, and we are certain to face some inertia and resistance. We will probably run into some technical barriers, as there is still much we have to learn. Ultimately, tremendous benefits will emerge from this new approach.

You will have the opportunity to compare yourself meaningfully with related programs, and the JCAH will have the ability to obtain a more realistic appraisal of health care in this country. It is not what people think it is. Most hospitals and practitioners do not perform at 100 percent of perfection all of the time or even close to that. This new approach could have a positive effect in adjusting the context of public expectations. While that will not solve the liability crisis, perhaps we may ease it a bit.

So, the brave new world of health care has begat many new issues, not the least of which is the need to measure and evaluate quality of care in a way that is more meaningful to multiple audiences. It may seem like a burden, but I view it as a new challenge -- a tough one -- and an opportunity. This is an opportunity to demonstrate that what we are and what we have is still the best health care system in the world; it is just not perfect. It is an opportunity for the professions, in particular, to develop evaluation systems, which have true potential to improve the quality of care; and that is for what we all stand. ■

Presented at the ACCC's 1986 Fall Leadership Conference, "Oncology Economics and Alternative Delivery Systems," September 26, 1986, New Orleans, LA.

COMMITTEE BRIEFS

Ad Hoc Committee on Standards

Robert E. Enck, M.D.

Chairperson

Recently, the third draft of standards for community cancer programs was sent to each Delegate Representative for review and comment. These standards will be further discussed during two open forums at the ACCC annual meeting in March. The standards will then be presented to the House of Delegates for final approval by vote. (NOTE: See pages 29 - 32 of JCPM for scheduled meeting times.)

Administrator Special Interest Group

Marsha J. Fountain, R.N., M.N.

Chairperson

The Administrator Special Interest Group will meet on Thursday, March 12th, during the ACCC annual meeting. Anyone interested in giving a 10 - 15 minute presentation on reimbursement, product line management, or other topics of interest to cancer program administrators is asked to contact Marsha Fountain at (505) 848-8026.

Currently, the Administrator Special Interest Group, together with the Clinical Practice Committee and the ACCC Executive Office, is developing a survey on reimbursement. This survey will be mailed to each Delegate Representative for completion. The results will be available at the ACCC annual meeting in March.

Communications Committee

Diane Van Ostenberg

Chairperson

At the 1986 Fall Leadership Conference in New Orleans, the Communications Committee re-evaluated its role and responsibilities. The Committee agreed that its goal is to stimulate community cancer program growth; thus, the Committee agreed to assist the Membership Committee in recruiting new members. After some discussion, the Communications Committee presented to the ACCC Board of Trustees a recommendation that the Communications Committee be re-named the "Marketing Committee" to adequately reflect its new responsibilities. A proposal for this name change will be presented to the House of Delegates for approval by vote. ■