AUDIT INDICATES MANY USES OF COMBINATION THERAPY ARE UNLABELED

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In this second of two articles, an audit of patient records reveals that most of the combination chemotherapy regimens prescribed by oncologists in a private practice setting include at least one unlabeled drug.

Many of the chemotherapy agents used in standard combination therapy, which constitutes a substantial percentage of total antineoplastic drug administration, do not fall within the package insert guidelines approved by the Food and Drug Administration (FDA). That conclusion is based on data drawn from a 1986 audit of the medical records of cancer patients who received chemotherapy in a private-practice setting during the first six months of that year.

First, the audit was used to determine the percentage of patients' receiving two or more agents in comparison to single drug therapy for six disease sites, including head, neck and oral cancers; digestive tract cancers; breast cancers; small-cell lung cancers; melanomas; and non-Hodgkin's lymphomas (see table 1).

Second, oncologists were asked what were the most common concomitant therapies for these disease sites. Finally, the eight common chemotherapy agents audited in part I of this study (see "Audit Indicates Half of Current Chemotheerapy Uses Lack FDA Approval," by Lee Mortenson, in the Winter 1988 issue of the *Journal*), and identified as unlabeled uses for those disease sites were identified (see table 2).

Clearly, the majority of combination chemotherapy regimens, considered to be standard medical practice, include unlabeled usages of at least one agent. If, as Part I of this series of articles pointed out, insurers begin to enforce payment policies that deny reimbursement for such usages, not only will almost half of accepted single drug therapy be excluded from coverage, but a large percentage of combination chemotherapy treatments will be effectively denied payment. Of course, none of the combinations have ever been approved as a combination, and some carriers are now apparently denying payment for drugs used in combination. ■

Table 1: CONCOMITANT USE OF ANTINEOPLASTIC AGENTS 1986

Disease Site	Total # Patients	Percentage Single Drug	Percentage Two-Drug	Percentage Three Drug	Percentage Four Drug
Head/Neck/Oral	23,825	61%	27%	10%	2%
Digestive Tract	419,185	70	20	8	1
Breast	654,336	23	18	36	17
Small-Cell Lung	382,868	24	17	37	20
Melanomas	18,445	35	14	22	29
Non-Hodgkin's Lymphoma	39,634	15	26	26	26

*Projected number of patients and percentages for 1986.

Table 2: STANDARD COMBINATION CHEMOTHERAPY REGIMENS

Disease Site	Monotherapy	Two-Drug	Three-Drug	Four-Drug
Head/Neck/Oral	Methotrexate Bleomycin Platinol*	Platinol* Fluorouracil	Platinol* Fluorouracil Methotrexate	N/A
Digestive Tract	Fluorouracil	N/A	Fluorouracil Adriamycin* Mutamycin*	
Breast	Mutamycin*	Adriamycin Oncovin*	Cytoxan Adriamycin Fluorouracil	
Small-Cell Lung	N/A	N/A Adriamycin Oncovin*	Cytoxan* Adriamycin Cytoxan*	Platinol* Vepesid*
Melanoma	DTIC	N/A	DTIC	N/A Platinol* BCNU
Non-Hodkin's Lymphoma	N/A	N/A	Cytoxan Adriamycin Oncovin*	Cytoxan Adriamycin Oncovin* Prednisone

* Unlabeled indication for this drug.