Discussion of Code Status With Outpatients

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Recent medical literature reflects a sharply increasing interest in the clinical-ethical management of patient care, particularly in the determination of code status and do-not-resuscitate orders for hospitalized patients.[1–4] Few studies, however, have addressed the process of how and when physicians actually discuss clinical-ethical issues with their patients[5–7]; fewer still have addressed these issues with outpatients.

METHODS

To assess physician attitudes and practices regarding the discussion of code status and advance directives, such as the living will and the durable power of attorney for health care, with outpatients, a questionnaire was developed. Code status was defined as determining what kind of resuscitative measures, if any, a patient should undergo in an otherwise terminal situation. The living will and the California durable power of attorney for health care are documents that have been described previously.[8,9] An initial questionnaire draft was sent to several family physicians for review; after several revisions, the final questionnaire was sent to each of the 145 members of the Fresno-Kings-Madera (California) chapter of the American Academy of Family Physicians.

Demographic information obtained included decade of licensure, history of residency training in family practice, and self-reporting of any previous training in medical ethics.

The physicians were first asked whether they could identify any occasions in their practice when it would be appropriate to discuss code status with patients or their families in an outpatient setting.

Next, seven outpatient case illustrations were presented, and the physicians were asked to indicate whether they would, would not, or were not sure whether they would discuss code status with such patients or their families. Only those physicians who stated that they could identify occasions in their practice when it would be appropriate to discuss code status with outpatients were asked to respond to the case illustrations.

Finally, the physicians were asked whether they had ever discussed the living will or the California durable power of attorney for health care with an outpatient.

RESULTS

Ninety-nine of the 145 surveyed physicians (68 percent) returned completed questionnaires.

Ninety-one of the 99 responding physicians (92 percent) indicated that they could identify occasions in their practice when it would be appropriate to discuss code status with patients or their families in an outpatient setting. Seventy-two physicians (73 percent) indicated that they had previously done so.

The physicians' responses to the seven outpatient case illustrations are displayed in Table 1.

Fifty-four (55 percent) and 31 (31 percent) physicians, respectively, indicated that they had previously discussed the living will or the California durable power of attorney for health care with an outpatient.

There were no differences among responders for any question when analyzed by decade of licensure or history of residency training. There was a significant difference for one question—case illustration 7—when analyzed by self-reporting of previous ethics training: responders who reported some ethics training were more likely to discuss code status with this patient than those who reported no ethics training (39 of 58 vs 12 of 31; $P < .05$).

COMMENT

Discussing code status and other terminal care issues with patients is difficult. The timing of such discussions is critical: too early may be perceived as threatening and too late may be disastrous. Still, the only way to determine an individual's true feelings toward resuscitation and the limits of treatment is to discuss it calmly and deliberately. If a patient is to make an informed, authentic decision

Submitted, revised, December 4, 1987.

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TABLE 1. PHYSICIAN ATTITUDES TOWARD DISCUSSING CODE STATUS WITH SELECTED OUTPATIENT CASES

Cases	Number Responding	Physician Responses: Definitely or Probably Would (%)	Physician Responses: Not Sure (%)	Physician Responses: Definitely or Probably Would Not (%)
1. J.B. is a 63-year-old man with metastatic squamous cell cancer of the lung who is currently at home with his family. He is still functional at home, but complains of pain frequently	91	78	12	10
2. A.M. is a 66-year-old woman with pancreatic cancer very recently diagnosed after complaining of unrelieved abdominal pain for several weeks. Her pain is controlled now, and she is fully functional living at home with her husband	90	66	13	21
3. P.L. is a 46-year-old man with end-stage (NYHA stage IV) congestive heart failure due to a cardiomyopathy. He is on maximal medical therapy and is able to stay at home with his family and with the help of a visiting nurse	90	82	8	10
4. D.F. is an 80-year-old man who is status post-abdominal peritoneal resection for Dukes' CI (local node metastases) adenocarcinoma of the colon. He is quite weak from continued weight loss but is able to live at home with one of his daughters	90	82	7	11
5. G.R. is a 67-year-old woman with end-stage chronic obstructive pulmonary disease who uses oxygen as needed at home quite frequently. She lives with her husband, who with a daily-visiting aide helps the patient dress and bathe. She quit smoking three years ago	90	68	19	13
6. S.T. is a 65-year-old man with prostate cancer with bony metastases that have regressed postorchiectomy leaving the patient now largely pain-free. He lives at home and is quite functional	90	31	19	50
7. C.J. is a 67-year-old woman with adult onset diabetes mellitus, chronic renal failure, and early dementia; she is also a nursing home resident. Results of an organic brain syndrome workup have been negative; she is not on dialysis. Her small family is simply no longer able to give her 24-hour-a-day supervision. She is able to help with her own care and is involved with several nursing home activities	89	57	13	29

about these matters, the process cannot take place in a noisy, threatening location under acute conditions. Indeed, the most authentic and autonomous decisions are those that are made and reviewed over time. Physician familiarity and comfort in raising these issues and assisting in these decisions are essential.

The goal of this study was to document physician attitudes and practices regarding the discussion of code status and related terminal care issues with outpatients. By relying on physician self-reporting, the study has been successful in a limited and qualitative way. Still, it is a beginning. As other work has demonstrated,[10] investigating the primary care physician's outpatient ethical practices can be difficult. Future investigations might include a longitudinal study, including chart reviews, of physician practices as ethics committees and advance directives become more popular, a survey of patient attitudes regarding these issues, and a review of which continuing education techniques are most successful in keeping physicians abreast of new clinical-ethical developments.

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What starts off as a small lesion on the mouth of an immunocompromised patient can develop into a serious and even life-threatening herpes simplex virus infection.[1] In the compromised host, oral infection may extend opportunistically to involve the esophagus or lungs or may disseminate to the liver, brain, and other organs.[2] Before a limited nonlife-threatening HSV infection has a chance to spread, prompt recognition and treatment with ZOVIRAX Ointment 5% can stop viral replication, accelerate healing, and reduce the accompanying pain.[3]

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*The sun can bring out cold sores.**

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INDICATIONS AND USAGE: Zovirax (Acyclovir) Ointment 5% is indicated in the management of initial herpes genitalis and in limited nonlife-threatening cutaneous Herpes simplex virus infections in immunocompromised patients. In clinical trials of initial herpes genitalis, Zovirax Ointment 5% has shown a decrease in healing time and in some cases a decrease in duration of viral shedding and duration of pain. In studies in immunocompromised patients with mainly herpes labialis, there was a decrease in duration of viral shedding and a slight decrease in duration of pain.

By contrast, in studies of recurrent herpes genitalis and of herpes labialis in nonimmunocompromised patients, there was no evidence of clinical benefit; there was some decrease in duration of viral shedding.

Diagnosis: Whereas cutaneous lesions associated with Herpes simplex infections are often characteristic, the finding of multinucleated giant cells in smears prepared from lesions exudate or scrapings may assist in the diagnosis.[1] Positive cultures for Herpes simplex virus offer a reliable means for confirmation of the diagnosis. In genital herpes, appropriate examinations should be performed to rule out other sexually transmitted diseases.

CONTRAINDICATIONS: Zovirax Ointment 5% is contraindicated for patients who develop hypersensitivity or chemical intolerance to the components of the formulation.

WARNINGS: Zovirax Ointment 5% is intended for cutaneous use only and should not be used in the eye.

PRECAUTIONS:

General: The recommended dosage, frequency of applications, and length of treatment should not be exceeded (see DOSAGE AND ADMINISTRATION). There exist no data which demonstrate that the use of Zovirax Ointment 5% will either prevent transmission of infection to other persons or prevent recurrent infections when applied in the absence of signs and symptoms. Zovirax Ointment 5% should not be used for the prevention of recurrent HSV infections. Although clinically significant viral resistance associated with the use of Zovirax Ointment 5% has not been observed, this possibility exists.

Drug Interactions: Clinical experience has identified no interactions resulting from topical or systemic administration of other drugs concomitantly with Zovirax Ointment 5%.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Acyclovir was tested in lifetime bioassays in rats and mice at single daily doses of 50, 150 and 450 mg/kg/day given by gavage. These studies showed no statistically significant difference in the incidence of benign and malignant tumors produced in drug-treated as compared to control animals, nor did acyclovir induce the occurrence of tumors earlier in drug-treated animals as compared to controls. In 2 *in vitro* cell transformation assays, used to provide preliminary assessment of potential oncogenicity in advance of these more definitive lifetime bioassays in rodents, conflicting results were obtained. Acyclovir was positive at the highest dose used in one system and the resulting morphologically transformed cells formed tumors when inoculated into immunosuppressed, syngeneic, weanling mice. Acyclovir was negative in another transformation system.

No chromosome damage was observed at maximum tolerated parenteral doses of 100 mg/kg acyclovir in rats or Chinese hamsters; higher doses of 500 and 1000 mg/kg were clastogenic in Chinese hamsters. In addition, no activity was found in a dominant lethal study in mice. In 9 of 11 microbial and mammalian cell assays, no evidence of mutagenicity was observed. In 2 mammalian cell assays (human lymphocytes and L5178Y mouse lymphoma cells *in vitro*), positive response for mutagenicity and chromosomal damage occurred, but only at concentrations at least 1000 times the plasma levels achieved in man following topical application.

Acyclovir does not impair fertility or reproduction in mice at oral doses up to 450 mg/kg/day or in rats at subcutaneous doses up to 25 mg/kg/day. In rabbits given a high dose of acyclovir (50 mg/kg/day, s.c.), there was a statistically significant decrease in implantation efficiency.

Pregnancy: *Teratogenic Effects. Pregnancy Category C.* Acyclovir has been known to cause a statistically significant decrease in implantation efficiency in rabbits, when given at subcutaneous doses providing mean plasma levels of drug 2.2 times those expected from use in patients with normal renal function.

Reproduction studies were negative for impairment of fertility or harm to the fetus in mice given oral doses, and in rats given subcutaneous doses providing mean plasma levels of drug 84 times and 4 times (respectively) greater than those expected from use in patients with normal renal function.

Acyclovir was not teratogenic after subcutaneous administration of up to 50 mg/kg/day during the period of organogenesis in rats and rabbits; doses up to 450 mg/kg given daily by gavage to mice were not teratogenic. There are, however, no adequate and well-controlled studies in pregnant women. Acyclovir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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 Zovirax is administered to a nursing woman.

ADVERSE REACTIONS: Because ulcerated genital lesions are characteristically tender and sensitive to any contact or manipulation, patients may experience discomfort upon application of ointment. In the controlled clinical trials, mild pain (including transient burning and stinging) was reported by 103 (28.3%) of 364 patients treated with acyclovir and by 115 (31.1%) of 370 patients treated with placebo; treatment was discontinued in 2 of these patients. Other local reactions among acyclovir-treated patients included pruritus in 15 (4.1%), rash in 1 (0.3%) and vulvitis in 1 (0.3%). Among the placebo-treated patients, pruritus was reported by 17 (4.6%) and rash by 1 (0.3%).

In all studies, there was no significant difference between the drug and placebo group in the rate or type of reported adverse reactions nor were there any differences in abnormal clinical laboratory findings.

DOSAGE AND ADMINISTRATION: Apply sufficient quantity to adequately cover all lesions every 3 hours 6 times per day for 7 days. The dose size per application will vary depending upon the total lesion area but should approximate a one-half inch ribbon of ointment per 4 square inches of surface area. A finger cot or rubber glove should be used when applying Zovirax to prevent autoinoculation of other body sites and transmission of infection to other persons. **Therapy should be initiated as early as possible following onset of signs and symptoms.**

HOW SUPPLIED: Zovirax Ointment 5% is supplied in 15 g tubes (NDC 0081-0993-94) and 3 g tubes (NDC 0081-0993-41). Each gram contains 50 mg acyclovir in a polyethylene glycol base. Store at 15°-25°C (59°-77°F) in a dry place.

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U.S. Patent No. 4199574

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