

physician.

- While healthcare professionals appear to use current guidelines, "polypharmacy" [use of more than one medication from the same class to achieve the same result] exists.
- Multiple routes of administration are common in acute care settings. These tend to reduce the patients' understanding of their pain medications and to increase costs.

Patient identified barriers to effective pain relief are:

1. Failure of caregivers to believe complaints of pain.
2. Fear of addiction.
3. Undesirable side effects.
5. High costs of opiates.
5. Delay in response to requests to nurses for medication.

There is also a perception that many physicians, who have the greatest responsibility for pain management, have a less than optimal understanding of pain control. They have unreasonable concerns regarding the activities of the Drug Enforcement Administration [DEA], fear of lethal side effects and often underestimate the impact of pain on the lives of their patients.

Several health care institutions in the State of Hawaii have instituted pain management programs that have improved pain management in those institutions. This suggests that requiring pain management programs in health care institutions would have a major impact on the lives of patients receiving care in those institutions.

Including pain management as an educational requirement in all health care professional training and continuing education programs would also be of significant benefit.

We Recommend

1. That the Agency for Healthcare Policy and Research [AHCPR] guidelines for the treatment of pain be accepted as the community standard of care for all health care providers.²
2. That a right to skilled pain management be included in a "Patients Bill of Rights" at all Department of Health certified and/or licensed facilities.³
3. That pain management programs be instituted in each of those facilities.
4. That the AHCPR guidelines be accepted as practice standards in each of those facilities.
5. That educational course work in pain management be a required part of continuing education programs of licensed facilities.
6. That the Department of Health licensing and certification teams specifically include pain management when reviewing records, observing patient/client care, interviewing staff and clients, etc., in their overall review of patient care plans/management.
7. That the Department of Health cite any institution that it finds deficient in the areas noted above.
8. That pain management be part of the required curriculum of all medical, nursing and other health care professional schools in the State of Hawaii.
9. That professional organizations be challenged to adopt formally AHCPR standards and incorporate them in their peer review and continuing education programs.

References

1. Levy, M.H. Pharmacologic Treatment of Cancer Pain. *N. Eng. J Med.* 335; 1124-1132.
2. Management of Cancer Pain, Clinical Practice Guideline Number 9, U.S. Department of Health and Human Services, from the Agency for Health Care Policy and Research Publication No. 94-0592, March 1994, 257 pages.
3. Institutions to be monitored: Acute Care Hospitals, Skilled nursing and intermediate care facilities, Hospice programs and home health and home care agencies.

This issue contains two manuscripts related to psychiatry. It is not one of our "Special Issues," but does have information about care of psychiatric patients and should be of interest to all physicians.

Mahalo to Anders and Olson and to Patrick and associates for important data for Hawaii's psychiatric care givers and administrators.

President's Message

Leonard Howard MD
President, Hawaii Medical Association

The Governor's Blue Ribbon Committee on Living and Dying has submitted their report after 18 months of work. The majority of the committee urges the Governor to support any legislation allowing Physician Assisted Suicide (PAS) and/or Physician Assisted Death (PAD). A dissenting minority report was also submitted opposing the same. This, plus the special edition of the Hawaii Medical Journal, which was criticized by many members as indicating that the HMA supported PAS and PAD, has stimulated this personal opinion.

Your Hawaii Medical Association continues to support the AMA policy opposing both PAS and PAD. We support the efforts to improve pain management and end-of-life care to eliminate the horror stories of terminal suffering that we have all heard. The lead article in AMNews of November 15, 1996 said it very well: *"Although for some patients it might appear compassionate to intentionally cause death, institutionalizing physician-assisted suicide as a medical treatment would put many more patients at serious risk for unwanted and unnecessary death," they said. "Rather than recognize a right to physician-assisted suicide, our society instead should recognize the urgent necessity of extending to all patients the palliative care they need and redouble our efforts to provide such care to all."* The AMA also submitted an amicus brief to the US Supreme Court when it was considering the issue of PAS in regard to the Oregon initiative. The AMA brief begins by affirming that: *"The right to control one's medical treatment is among the most important rights that the law affords each person." This includes the right to have unwanted life-prolonging treatment withheld or withdrawn and to have all medication necessary to alleviate physical pain, even where such medication would hasten death. Through these means, patients can avoid entrapment in a prolonged, painful, or overly medicalized dying process.*" The AMA believes firmly that the lower court was wrong in taking the unprecedented step of announcing a right to control the timing and manner of one's death through the use of physician-assisted suicide. The power to assist in intentionally taking the life of a patient is counter to the health care profession's central mission of healing. It is a power that most health



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†Double-blind, comparative clinical studies have not been conducted to evaluate comparative efficacy.

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Debbie Ross, Hawaii Territory Manager, 310 Front Street South, Issaquah, WA 98027, ross_debbie@allergan.com

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A normalization of keratinization leading to an anticomedomal effect of azelaic acid may also contribute to its clinical activity. Electron microscopic and immunohistochemical evaluation of skin biopsies from human subjects treated with AZELEX[®] demonstrated a reduction in the thickness of the stratum corneum, a reduction in number and size of keratohyalin granules, and a reduction in the amount and distribution of filaggrin (a protein component of keratohyalin) in epidermal layers. This is suggestive of the ability to decrease microcomedo formation. **Pharmacokinetics:** Following a single application of AZELEX[®] to human skin *in vitro*, azelaic acid penetrates into the stratum corneum (approximately 3 to 5% of the applied dose) and other viable skin layers (up to 10% of the dose is found in the epidermis and dermis). Negligible cutaneous metabolism occurs after topical application. Approximately 4% of the topically applied azelaic acid is systemically absorbed. Azelaic acid is mainly excreted unchanged in the urine but undergoes some β-oxidation to shorter chain dicarboxylic acids. The observed half-lives in healthy subjects are approximately 45 minutes after oral dosing and 12 hours after topical dosing, indicating percutaneous absorption rate-limited kinetics. Azelaic acid is a dietary constituent (whole grain cereals and animal products), and can be formed endogenously from longer-chain dicarboxylic acids, metabolism of oleic acid, and α-oxidation of monocarboxylic acids. Endogenous plasma concentration (20 to 80 ng/mL) and daily urinary excretion (4 to 28 mg) of azelaic acid are highly dependent on dietary intake. After topical treatment with AZELEX[®] in humans, plasma concentration and urinary excretion of azelaic acid are not significantly different from baseline levels. **INDICATIONS AND USAGE:** AZELEX[®] is indicated for the topical treatment of mild-to-moderate inflammatory acne vulgaris. **CONTRAINDICATIONS:** AZELEX[®] is contraindicated in individuals who have shown hypersensitivity to any of its components. **WARNINGS:** AZELEX[®] is for dermatologic use only and not for ophthalmic use. There have been isolated reports of hypopigmentation after use of azelaic acid. Since azelaic acid has not been well studied in patients with dark complexions, these patients should be monitored for early signs of hypopigmentation. **PRECAUTIONS: General:** If sensitivity or severe irritation develop with the use of AZELEX[®], treatment should be discontinued and appropriate therapy instituted. **Information for patients:** Patients should be told: 1. To use AZELEX[®] for the full prescribed treatment period. 2. To avoid the use of occlusive dressings or wrappings. 3. To keep AZELEX[®] away from the mouth, eyes and other mucous membranes. If it does come in contact with the eyes, they should wash their eyes with large amounts of water and consult a physician if eye irritation persists. 4. If they have dark complexions, to report abnormal changes in skin color to their physician. 5. Due in part to the low pH of azelaic acid, temporary skin irritation (pruritus, burning, or stinging) may occur when AZELEX[®] is applied to broken or inflamed skin, usually at the start of treatment. However, this irritation commonly subsides if treatment is continued. If it continues, AZELEX[®] should be applied only once-a-day, or the treatment should be stopped until these effects have subsided. If troublesome irritation persists, use should be discontinued, and patients should consult their physician. (See ADVERSE REACTIONS.) **Carcinogenesis, mutagenesis, impairment of fertility:** Azelaic acid is a human dietary component of a simple molecular structure that does not suggest carcinogenic potential, and it does not belong to a class of drugs for which there is a concern about carcinogenicity. Therefore, animal studies to evaluate carcinogenic potential with AZELEX[®] Cream were not deemed necessary. In a battery of tests (Ames assay, HGPRT test in Chinese hamster ovary cells, human lymphocyte test, dominant lethal assay in mice), azelaic acid was found to be nonmutagenic. Animal studies have shown no adverse effects on fertility. **Pregnancy: Teratogenic Effects: Pregnancy Category B.** Embryotoxic effects were observed in Segment I and Segment II oral studies with rats receiving 2500 mg/kg/day of azelaic acid. Similar effects were observed in Segment II studies in rabbits given 150 to 500 mg/kg/day and in monkeys given 500 mg/kg/day. The doses at which these effects were noted were all within toxic dose ranges for the dams. No teratogenic effects were observed. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. **Nursing Mothers:** Equilibrium dialysis was used to assess human milk partitioning *in vitro*. At an azelaic acid concentration of 25 µg/mL, the milk/plasma distribution coefficient was 0.7 and the milk/buffer distribution was 1.0, indicating that passage of drug into maternal milk may occur. Since less than 4% of a topically applied dose is systemically absorbed, the uptake of azelaic acid into maternal milk is not expected to cause a significant change from baseline azelaic acid levels in the milk. However, caution should be exercised when AZELEX[®] is administered to a nursing mother. **Pediatric Use:** Safety and effectiveness in pediatric patients under 12 years of age have not been established. **ADVERSE REACTIONS:** During U.S. clinical trials with AZELEX[®], adverse reactions were generally mild and transient in nature. The most common adverse reactions occurring in approximately 1-5% of patients were pruritus, burning, stinging and tingling. Other adverse reactions such as erythema, dryness, rash, peeling, irritation, dermatitis, and contact dermatitis were reported in less than 1% of subjects. There is the potential for experiencing allergic reactions with use of AZELEX[®]. In patients using azelaic acid formulations, the following additional adverse experiences have been reported rarely: worsening of asthma, vitiligo depigmentation, small depigmented spots, hypertrichosis, reddening (signs of keratosis pilaris), and exacerbation of recurrent herpes labialis. **DOSAGE AND ADMINISTRATION:** After the skin is thoroughly washed and patted dry, a thin film of AZELEX[®] should be gently but thoroughly massaged into the affected areas twice daily, in the morning and evening. The hands should be washed following application. The duration of use of AZELEX[®] can vary from person to person and depends on the severity of the acne. Improvement of the condition occurs in the majority of patients with inflammatory lesions within four weeks. **HOW SUPPLIED:** AZELEX[®] is supplied in collapsible tubes in a 30 gm size: 30 g - NDC 0023-8694-30. **Note:** Protect from freezing. Store between 15°-30°C (59°-86°F). **Caution:** Federal (U.S.A.) law prohibits dispensing without a prescription. Distributed under license; U.S. Patent No. 4,386,104.

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care professionals do not want and could not control. The brief concludes that "The sentiment for physician-assisted suicide is not the right answer to the problem of inadequate care. Although for some patients it might appear compassionate to hasten death, institutionalizing physician-assisted suicide as a medical treatment would put many more patients at serious risk for unwanted and unnecessary death." Rather than recognize a right to physician-assisted suicide, the AMA asserts that "we should recognize instead the urgent necessity of extending to all patients the palliative care they need and redouble our efforts to provide such care to all."

At an Intensive Seminar in Bioethics sponsored by the Bioethics Consultation Group, Inc. of Berkeley, California, a full day was spent on Decisions at the End of Life. A message from that day stuck in my mind, and I have quoted it many times since hearing it. "The difference between withholding Nutrition and Lethal Injection is the difference between letting die and killing." To me this is the essence of the debate. Will we overthrow the teachings of the philosophers of the last 2000 years or will we hew to some new idea that physicians are to be the instrument by which an individual chooses to end his or her life? As for me, I will continue to support the concept that physicians preserve life as long as possible, but prevent suffering. If, by giving a dose of MS adequate to relieve pain I cause respiratory failure, then so be it. The patient's disease has been the essential reason for the death, not my action. On the other hand, if I inject a lethal dose of KCl or prescribe a lethal dose of barbiturate for a patient, then I am the primary cause of the death of the patient. It is the *intention* of our actions that determines their ethical nature. If the state wishes to provide a way that people can voluntarily end their own life for whatever reason, do so, but leave medicine out of it.

In closing, I wish to make it perfectly clear that the HMA leadership has NO control over what is or is not printed in the Hawaii Medical Journal. The content is determined by the Editorial Board and no other. This is as it should be and provides an opportunity for both sides of an issue to be heard.

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