Important Notice

This is one of a series of ethical dilemmas published in the *Texas Dental Journal* between 1993 and 2005. The lead author of these dilemmas, Dr. Thomas K. Hasegawa, died tragically in 2005. The dilemmas remain an important legacy for dentistry.

Format

Each ethical dilemma was originally introduced in one issue of the *Texas Dental Journal* with the question, "What would you do?" The more expansive analysis of the dilemma was presented in a subsequent issue. The second page of this file depicts the cover of the issue containing the analysis of the dilemma, not the issue containing the briefer introduction to the dilemma. The ethical dilemmas were compiled for digital use by the American College of Dentists in 2008.

Purpose

This ethical dilemma and the other dilemmas in the series are only meant to further your knowledge and understanding of dental ethics by presenting, discussing, and analyzing hypothetical ethical dilemmas that may occur in dental settings. The dilemmas are not intended to: a) provide legal advice; b) provide advice or assistance in the diagnosis or treatment of dental diseases or conditions; or c) provide advice or assistance in the management of dental patients, practices, or personnel.

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Support

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American College of Dentists
839J Quince Orchard Boulevard
Gaithersburg, MD 20878-1614

301-977-3223
fax 301-977-3330
office@acd.org

Version 1
2008

April 2005

TEXAS DENTAL Journal

Implants

What Would You Do?

Ethical Dilemma #51

Dr. Sharon Stanford has been in solo general practice in a small town for 10 years. The community is growing and Dr. Stanford's practice is thriving. Her practice includes all phases of dentistry except for endodontics which she refers to a specialist in her building. She enjoys oral surgery and continues to improve her skills through continuing education courses. The only oral surgeon in the community has a part-time practice in the building and Dr. Stanford is covering his emergencies this weekend.

Mr. Ralph Osborne is in town visiting his sister and family during the holidays. Saturday afternoon he slipped on the icy pavement and hit his face. He did not feel like it was much of a fall although an upper left tooth felt loose and "ached a bit." Dr. Stanford was covering emergencies for the group and since Mr. Osborne's sister was a long time member of the practice, she agreed to see him that night.

Mr. Osborne completed the medical history form that indicated that he is a 42-year-old white male with a history of good health until a diagnosis of multiple myeloma 15 months ago. Since that diagnosis he has been under the care of an oncologist, Dr. Norman Reed.

Mr. Osborne has successfully completed an autologous bone marrow transplant and is currently taking Zometa, a bisphosphonate. His other medications include an over-the-counter antihistamine and a thiazide diuretic. His dental examination and periapical radiograph reveals a fractured root for tooth #13. The lingual cusp is sheared off by about 1/3, exposing dentin but not the pulp. The tooth has minimal mobility but the extraction will require the elevation of a mucoperiosteal flap and removal of bone to access and remove the fractured root fragment. It is apparent that without timely treatment Mr. Osborne may suffer from more significant pain and possible infection.

Dr. Stanford recalls that in her last continuing education course, questions were raised about an emerging concern for serious complications from dental infections and healing for patients on this drug regimen (bisphosphonates).

Should Dr. Stanford proceed with the extraction?

Dr. Stanford is now faced with an ethical dilemma. Check the following course(s) of action she should take in this case and mail, fax this page, e-mail, or send a note indicating your recommendations. What would you do if you were Dr. Stanford? Some options (check one or write your own) include:

____1. Dr. Stanford should extract the tooth;

____2. Dr. Stanford should advise Mr. Osborne to tough it out and wait until he returns home;

____3. Dr. Stanford should consult with Dr. Reed before proceeding;

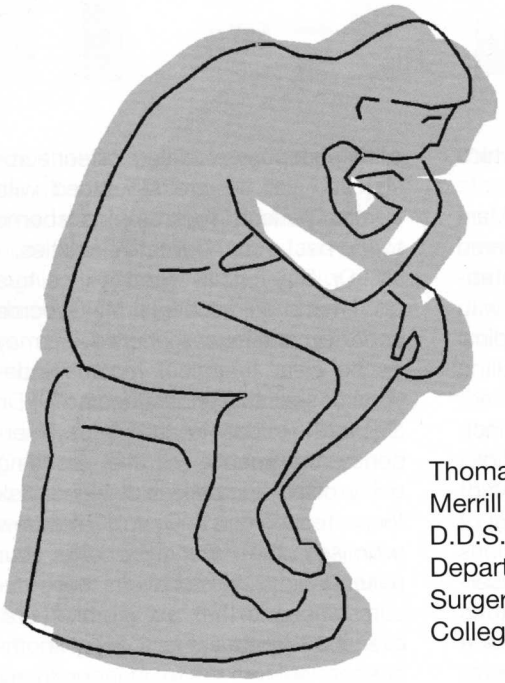
____4. Dr. Stanford should refer Mr. Osborne to an oral surgeon in another town for treatment;

____5. Other alternative (please describe):_____

_____

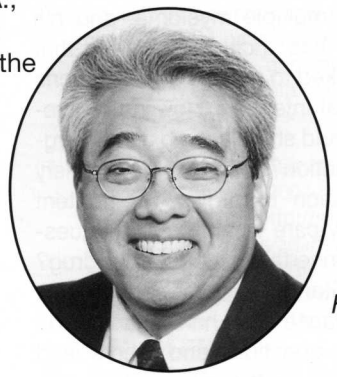
_____

SEND YOUR RESPONSE BY February 1, 2005
ATTENTION: Dr. Thomas K. Hasegawa, Jr.,
Associate Dean for Clinical Services Baylor College of Dentistry,
P.O. Box 660677 Dallas, TX 75266-0677.
Fax to (214) 828-8958 or E-mail to thasegawa@tambcd.edu



Ethical Dilemma

Thomas K. Hasegawa, Jr., D.D.S., M.A., Merrill Matthews, Ph.D., David Grogan D.D.S., M.S.D. Associate Professor in the Department of Oral and Maxillofacial Surgery and Pharmacology Baylor College of Dentistry



Hasegawa

Ethical Dilemma #51
"Dealing with Uncertainty: Bisphosphonate-related Osteonecrosis"

Dr. Sharon Stanford has been in solo general practice in a small town for 10 years. The community is growing and Dr. Stanford's practice is thriving. Her practice includes all phases of dentistry except for endodontics, which she refers to a specialist in her building. She enjoys oral surgery and continues to improve her skills through continuing education courses. The only oral surgeon in the community has a part-time practice in the building, and Dr. Stanford is covering his emergencies this weekend.

Mr. Ralph Osborne is in town visiting his sister and family during the holidays. Saturday afternoon he slipped on the icy pavement and hit his face. He did not feel like it was much of a fall, although an upper left tooth felt loose and "ached a bit." Dr. Stanford was covering emergencies for the group, and since Mr. Osborne's sister was a longtime member of the practice, she agreed to see the patient that night.

Mr. Osborne completed the medical history form, indicating that he is a 42-year-old white male with a history of good health until a diagnosis of multiple myeloma 15 months ago. Since that diagnosis, he has been under the care of an oncologist, Dr. Norman Reed.

Mr. Osborne has successfully completed an autologous bone marrow transplant and is currently taking Zometa, a bisphosphonate. His other medications include an over-the-counter antihistamine and a thiazide diuretic. His dental examination and periapical radiograph reveals a fractured root for tooth #13. The lingual cusp is sheared off by about one-third, exposing dentin but not the pulp. The tooth has minimal mobility, but the extraction will require the elevation of a mucoperiosteal flap and removal of bone to access and remove the fractured root fragment. It is apparent that without timely treatment Mr. Osborne may suffer from more significant pain and possible infection.

Dr. Stanford recalls that in her last continuing education course, questions were raised about an emerging concern for serious complications from dental infections and healing for patients on this drug regimen (bisphosphonates).

Should Dr. Stanford proceed with the extraction?

* * *

Dentists who responded to the case chose the following options: 1) Dr. Stanford should advise Mr. Osborne to tough it out and wait until he returns home; 2) Dr. Stanford should consult with Dr. Reed before proceeding; and 3) Dr. Stanford should refer Mr. Osborne to an oral surgeon in another town for treatment. Other respondents offered their own alternatives with one having Dr. Stanford provide palliative treatment

and then refer the patient to an oral surgeon. Another recommended that she reduce the tooth out of occlusion, open, broach, medicate and close with a temporary. None of the respondents chose to have Dr. Stanford just proceed with an extraction.

Dr. Stanford has agreed to see Mr. Osborne for a dental emergency as a favor to a longtime patient. Now Dr. Stanford learns that Mr. Osborne has a history of multiple myeloma, and his treatment has included a drug that may be linked to serious complications from dental infection. How much credence should she place on this emerging information? How can she satisfy her obligation to provide competent emergency care when there are questions of uncertainty about this drug? Will Dr. Stanford's treatment of Mr. Osborne cause more harm than good?

These questions and others lead us to reflect on the ethics of: 1) bisphosphonate-related osteonecrosis; 2) uncertainty and clinical practice; and 3) dealing with uncertainty.

BISPHOSPHONATE-RELATED OSTEONECROSIS

Bisphosphonates are used in the management of Paget's disease, osteoporosis, and the hypercalcemia associated with metastatic osteolytic lesions associated with breast cancer and multiple myeloma (1–3). The major pharmacologic action of the bisphosphonates is the inhibition of normal and abnormal bone resorption though the inhibition of osteoclastic activity (4).

There are two major classes of bisphosphonates: the non-nitrogen containing (residronate, tiludrinate, etidronate), and the nitrogen containing pamidronate (Aredia) and zoledronate (Zometa). The non-nitrogen containing bisphosphonates are rapidly metabolized, but the nitrogen containing agents are not metabolized and are much more potent. Therefore, the nitrogen containing agents accumulate in bone and have an ongoing affect (5). The nitrogen containing agents are administered intravenously, typically on a monthly cycle, which may continue over years.

Since the original citation by Marx in 2003, more papers have appeared in the literature describing osteonecrosis of the jaws associated with Aredia and Zometa (6–8). The typical lesions were either a non-healing extraction socket or an exposed section of jawbone, with a greater incidence of occurrence in the mandible. In the vast majority of cases, symptoms started following the removal of a tooth. The treatment of these lesions was found to be refractory to conservative debridement and antibiotic therapy. At present, there is no known resolution for this drug-related necrosis of bone.

These findings by Marx and others has prompted the pharmaceutical companies and the FDA to issue product safety alerts regarding bisphosphonates and dental treatment (9). In December 2004, the ADA published the following alert based on the FDA advisory: "While receiving these drugs, high-risk patients should avoid invasive dental procedures if possible. If patients do develop osteonecrosis of the jaw while receiving bisphosphonate therapy, they should avoid dental surgery" (10, 11).

UNCERTAINTY AND CLINICAL PRACTICE

One of the inevitable challenges that doctors face in clinical practice is uncertainty. The psychologist Katz, reflecting on the gap between theory and practice, said, "Medical knowledge is engulfed and infiltrated by uncertainty" (12).

The controversy over Aredia and Zometa reminds us of the vulnerabilities of our knowledge and how our patients bear the burden of our education as clinicians. It brings into focus both the art and science of medicine, and reemphasizes that while the science may seem sound, it is in the treatment of our patients that we learn about the efficacy, risks, complications and side effects. It may take years to understand the mechanisms of bisphosponate-related osteonecrosis, and yet we are still faced with treating patients such as Mr. Osborne to the best of our collective abilities.

Dr. Stanford is faced with a true dilemma: should she treat Mr. Osborne under circumstances where there may be no clear treatment recommendations or scientific understanding? If Dr. Stanford decides not to provide emergency treatment, will the resulting delay place her patient at higher risk for osteonecrosis? One of the few promises that we may offer our patients as professionals in these circumstances is that we will be there, even if the treatment fails, to try another treatment and not to abandon them.

What is the best care for Mr. Osborne? There are no simple answers here.

DEALING WITH UNCERTAINTY

The first step for Dr. Stanford, whether she chooses to treat Mr. Osborne or not, may be an attempt to reach his oncologist, Dr. Norman Reed. A very thorough preoperative consultation needs to be performed to advise Mr. Osborne of the potential outcomes following the extraction. The exact incidence of osteonecrosis of the jaws is not known but it appears to be relatively small compared to the vast number of patients currently taking either drug. Also there appears to be no benefit in stopping the drugs prior to performing the extraction although this point is not without controversy (8, 10, 13). A conversation with the oncologist may provide a clearer picture of the course of Mr. Osborne's malignancy, his chemotherapy, and regimen of Zometa and its effects to date. Dr. Stanford may also learn about the extent of Dr. Reed's experience and understanding of bisphosphonate-related osteonecrosis in the same or similar circumstances as Mr. Osborne.

A second step for Dr. Stanford may be a candid dialogue with Mr. Osborne to acknowledge the limitations and vulnerabilities of our knowledge and therapies, and the material

risk that he may develop osteonecrosis after the extraction. This dialogue may include helping Mr. Osborne understand that a drug that may have significantly improved his quality of life during his malignancy may be related to a debilitating condition after an extraction.

Dr. Stanford would be ethically justified at this point to refer Mr. Osborne to a more experienced and knowledgeable oral surgeon, if one is available. However, if one is not available and delaying care may risk more infection, she would be ethically justified in providing the extraction after consultation and in collaboration with Dr. Reed, including proper assessment on his return home.

Due to the potential for osteonecrosis in this patient population, dentists should carefully screen medical histories to identify those who are currently on these medications or who have taken them in the past. It would be prudent for dentists to learn about bisphosphonate-related osteonecrosis and have a plan for the patient who has taken, is taking, or may be taking these drugs. The plan could include providing proper preventive dental care for those patients who have been diagnosed with a condition that requires the use of Aredia and Zometa (13). This would be an excellent opportunity for dentists to coordinate treatment with the oncologist to attempt to minimize the risk of bisphosphonate-related osteonecrosis or to refer these patients to someone with more experience. As in the case of Mr. Osborne, the FDA advisory recommends that the "clinical judgment of the physician should guide each patient's management, based on an assessment of the benefits and risks (10)."

CONCLUSION

The emerging concern for bisphosphonate-related osteonecrosis reminds us of the uncertainty of practice and that our knowledge may be imperfect or incomplete. The purpose of this review is to offer an overview of these concerns, promote the understanding of the vulnerabilities of practice, and provide some constructive views on dealing with uncertainty. It is not the intent of this case review to discount the improved quality of life that these drugs offer certain seriously ill patients. It is more of a reminder that patients have a right to know about emerging potential adverse reactions and whether there are ways that we, as professionals, can attempt to prevent them.

Dr. Stanford would be ethically justified to refer Mr. Osborne, her emergency patient, to a more experienced and knowledgeable oral surgeon, if one is available. However if one is not available and delaying care may risk more infection, she would be ethically justified in providing the extraction after consultation and collaboration with the patient's oncologist, including proper assessment on his return home, and securing Mr. Osborne's informed consent.

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EDITOR'S COMMENT:

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NOTE: Readers are invited to submit topics to be considered in the Ethical Dilemma column. Contact the editor with suggestions or for further information. Recommendations in these cases are not intended to be legal advice. If you need legal advice, seek consultation from an attorney.