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Cultural CONSIDERATION

Faith, heritage, even sexual orientation can play an important role in hospital care

By Gina Gotsill

Sharnjit Grewal, MD, a hospitalist at Mercy Medical Group in Sacramento, Calif., is familiar with what he calls "the double-take." A Sikh born and raised in California, Dr. Grewal wears a traditional turban and full beard. When he walks into the room, some patient's simply don't know what to make of him, he admits.

"It's confusing—even to my Hindu and Sikh patients," Dr. Grewal says. "They sometimes say, 'You talk like an American, you're obviously from the West, but you follow a faith from the East. The line between religion and culture is obscured."

Although the medical community stresses cultural awareness and sensitivity, Dr. Grewal's experience highlights the fine line between religion and culture, and the barriers standing stand in the way of cultural awareness.

Today, hospitals experience shifting patient demographics and a growing number of languages and dialects observed in the United States today. Between 1990-2000, the foreign-born population in the U.S. increased by 57%, compared with a 9.3% increase for the native population and a 13% increase for the total U.S. population, according to the U.S. Census Bureau.

Break Down Walls

When hospitalists and patients share a culture or language, the result can be extremely positive. In fact, the Joint Commission report states some hospitals in the United States are working to increase racial and ethnic similarities between staff and patient populations.

Joseph Li, MD, a hospitalist at Beth Israel Deaconess Medical Center in Boston, frequently works with Cantonese-speaking patients referred to the hospital by the healthcare clinic in Boston's Chinatown section. When he greets patients in their native tongue, Dr. Li says he can feel their comfort level rise; even though he speaks what he calls "5-year-old Cantonese."

"There is an improved therapeutic relationship when doctors and patients share a language, culture, or belief," Dr. Li says. "There's a level of comfort that you are going to be understood and nothing will be lost in translation."

A patient's culture may drive decisions contradictory to traditional Western medicine, and hospitalists need to make the time to listen and respond. Recently, Dr. Grewal treated a dying, elderly Asian patient whose family insisted on administering an unknown, water-like fluid to cure the loved one. First, the family requested giving the fluid to the patient by mouth. Dr. Grewal denied the request, and told them the water would end up in the patient's lungs because he was comatose and could not swallow. Then, the family asked if they could add it to the intra-

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venous line. Again, Dr. Grewal denied the request, and told them water in an unbuffered solution could be harmful to red blood cells.

"It was frustrating for them," Dr. Grewal says. "I told them, 'It's not that I don't believe the water will cure him. Maybe it will or maybe it won't. But from a medical standpoint, I know there will be complications and I just cannot do this.' "

Eventually, the family asked if a tube could be inserted into the patient's stomach. When the request was denied, the family decided on comfort care for their loved one. Eventually, he passed away. The family, Dr. Grewal says, was grateful for the hospital staff's care and effort, even though their requests to administer the fluid were denied.

Difficult Cases

Firm cultural beliefs may lead patients to resist treatment. Manish Patel, MD, a hospitalist and assistant professor with the division of General Internal Medicine at the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School in New Brunswick, N.J., recalls working with an elderly member of the Indian community who refused to be transferred to a rehabilitation facility. Dr. Patel took time to speak to the patient and learned she came from a tradition that encouraged younger generations to care for the elderly. The patient interpreted her transfer to a rehabilitation facility as a sign her family was abandoning her, Dr. Patel says.

"Sometimes you have to probe to learn more," Dr. Patel says. "Once we understood her fears, we were able to convey to her that this was a temporary situation and that her family could not provide her with the services that she needed at that point in time."

Dr. Patel also interacts with Hispanic and Indian patients—many of whom revere doctors and defer to them for treatment decisions. In these situations, he uses the same approach as he does with patients who question his treatment rec-

DIFFERENCES COME IN ALL SHAPES, SIZES, LANGUAGES

The healthcare industry is addressing cultural competency and encouraging practices and policies aimed at increasing understanding. Sensitivity regarding patients' sexual orientation is a component of cultural competency. Often, gay, lesbian, bisexual, and transgender individuals avoid "even routine medical visits after negative healthcare experiences due to providers' lack of cultural competency," according to the Gay & Lesbian Medical Association's 2008 Healthcare Equality Index.

"One of the challenges of promoting cultural competence is that it is often believed to be aimed solely at individuals from minority backgrounds who may have unique beliefs," says Amy Wilson-Stronks, Project Director for Health Disparities with the Joint Commission and principal investigator of the 2008 Joint Commission report *One Size Does Not Fit All: Meeting the Health Care Needs of a Diverse Population*. "The point is that we are all unique and cultural competency is important for everyone—not just 'minority' populations."

Language barriers are an everyday occurrence for most hospitalists. The limited English proficient population grew from 14 million to 21.3 million between 1990 and 2000, according to U.S. Census figures.

The healthcare system also is dealing with multilingual populations in cities where language has not been a challenge in the past, according Cynthia Roat, MPH, a consultant and trainer on language access in healthcare. For example, limited English proficient populations in Georgia and North Carolina each grew by more than 240 percent from 1990-2000.

More hospitals are turning to professional healthcare interpreters for assistance with medical interviews and communications, Roat says. The most widely interpreted language is Spanish, she says, but more than 300 languages are spoken in the United States. Interpreters in Cantonese, Mandarin, Vietnamese, Korean, and many other languages, are in high demand, she says.

Location makes a difference: Hmong is a high-demand language in Minneapolis and California's Central Valley, while Haitian Creole is in demand in Florida and Boston, she says. As new refugee groups enter the country, new languages are added to the list.—*GG*

ommendations.

"The patient may defer to you, but it's important to empower the patient and give them all the information they need to make major choices in their healthcare."

Information Pipeline

Hospitalists may prefer to be upfront about a patient's condition and treatment, however, cultural norms sometimes dictate who receives information—and how much. For example, Scott Enderby, DO, a hospitalist at Alta Bates Summit Medical Center in Berkeley, Calif., says some Asian families prefer medical staff deliver bad news about the patient to them first. The family then decides what they will tell the patient, he says.

These situations create challenges and opportunities, Enderby says. Medical staff tries to establish a patient-centric care system, so it is important to continue appropriate communication with the patient. It also is important for healthcare providers to avoid putting the family in the middle and marginalizing the patient, he says. Healthcare teams can become frustrated when family members are at odds about decisions and options, and the patient is not involved at the family's request, he says. In these cases, Dr. Enderby sees an opportunity to further engage the family, and, therefore, the patient.

"Often, when there are cultural and language barriers, a disengaged family can make caring for the patient very challenging," Dr. Enderby says. "Having the family involved can help everyone feel more aligned with a treatment plan or strategy."

For Alpesh Amin, MD, associate professor of medicine and vice chair for Clinical Affairs and Quality in the Department of Medicine at the University of California Irvine School of Medicine, being aware of a patient's cultural values is critical to quality care. As executive director of the hospitalist program at the UCI Medical Center in Orange, Calif., Dr. Amin helped develop curriculum to train students on how to collect "values history" from patients, which includes asking questions about religion and culture. Students document their own values history, and then ask the same questions of a patient. Students discuss patient care and the importance of these histories during small group sessions.

"Knowing a patient's cultural information is just as important as knowing their sexual history or drug history," Dr. Amin says. "It's another piece of information that helps you get to know them as a whole. Their overall care is more comprehensive, if you have this knowledge." TH

Gina Gotsill is a journalist based in California.

Reference: 1. Van Wyck DB, Roppolo M, Martinez CO, Mazey RM, McMurray S, for the United States Iron Sucrose (Venofer®) Clinical Trials Group. A randomized, controlled trial comparing IV iron sucrose to oral iron in anemic patients with nondialysis-dependent CKD. *Kidney Int.* 2005;68:2846-2856. **2.** Data on file. American Regent, Inc., Shirley, NY.

Venofer®
iron sucrose injection, USP

Brief Summary (See Package Insert For Full Prescribing Information)

Therapeutic Class: Hematinic

CLINICAL INDICATIONS AND USAGE

Venofer® (iron sucrose injection, USP) is indicated in the treatment of iron deficiency anemia in the following patients:

- non-dialysis dependent-chronic kidney disease (NDD-CKD) patients receiving an erythropoietin
- non-dialysis dependent-chronic kidney disease (NDD-CKD) patients not receiving an erythropoietin

CONTRAINDICATIONS

The use of Venofer® is contraindicated in patients with evidence of iron overload, in patients with known hypersensitivity to Venofer® or any of its inactive components, and in patients with anemia not caused by iron deficiency.

WARNINGS

Hypersensitivity reactions have been reported with injectable iron products. See **PRECAUTIONS** and **ADVERSE REACTIONS.**

PRECAUTIONS

General: Because body iron excretion is limited and excess tissue iron can be hazardous, caution should be exercised to withhold iron administration in the presence of evidence of tissue iron overload. Patients receiving Venofer® require periodic monitoring of hematologic and hematinic parameters (hemoglobin, hematocrit, serum ferritin and transferrin saturation). Iron therapy should be withheld in patients with evidence of iron overload. Transferrin saturation values increase rapidly after IV administration of iron sucrose; thus, serum iron values may be reliably obtained 48 hours after IV dosing. See **DOSAGE AND ADMINISTRATION** and **OVERDOSAGE.**

Hypersensitivity Reactions: Serious hypersensitivity reactions have been reported in patients receiving Venofer®. No life-threatening hypersensitivity reactions were observed in the clinical studies. Several cases of mild or moderate hypersensitivity reactions were observed in these studies. There are post-marketing spontaneous reports of life-threatening hypersensitivity reactions in patients receiving Venofer. See **ADVERSE REACTIONS.**

Hypotension: Hypotension has been reported frequently in hemodialysis dependent chronic kidney disease patients receiving intravenous iron. Hypotension also has been reported in non-dialysis dependent and peritoneal dialysis dependent-chronic kidney disease patients receiving intravenous iron. Hypotension following administration of Venofer® may be related to rate of administration and total dose administered. Caution should be taken to administer Venofer® according to recommended guidelines. See **DOSAGE AND ADMINISTRATION.**

Carcinogenesis, Mutagenesis, and Impairment of Fertility:

No long-term studies in animals have been performed to evaluate the carcinogenic potential of Venofer®.

Venofer® was not genotoxic in the Ames test, the mouse lymphoma cell (L5178Y/TK+/-) forward mutation test, the human lymphocyte chromosome aberration test, or the mouse micronucleus test.

Venofer® at IV doses up to 15 mg iron/kg/day (about 1.2 times the recommended maximum human dose on a body surface area basis) was found to have no effect on fertility and reproductive performance of male and female rats.

Pregnancy Category B: Teratology studies have been performed in rats at IV doses up to 13 mg iron/kg/day (about 0.5 times the recommended maximum human dose on a body surface area basis) and rabbits at IV doses up to 13 mg iron/kg/day (about 1 times the recommended maximum human dose on a body surface area basis) and have revealed no evidence of impaired fertility or harm to the fetus due to Venofer®. 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: Venofer® is excreted in milk of rats. 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 Venofer® is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of Venofer® in pediatric patients have not been established. In a country where Venofer® is available for use in children, at a single site, five premature infants (weight less than 1,250 g) developed necrotizing enterocolitis and two of the five expired during or following a period when they received Venofer®, several other medications and erythropoietin. Necrotizing enterocolitis may be a complication of prematurity in very low birth weight infants. No causal relationship to Venofer® or any other drugs could be established.

Geriatric Use: The five pivotal clinical trials did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently from younger subjects. No overall differences in safety were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

Adverse Events observed in all treated populations

The frequency of adverse events associated with the use of Venofer® has been documented in six randomized clinical trials involving 231 hemodialysis dependent, 139 non-dialysis dependent and 75 peritoneal dialysis dependent-CKD patients; and in two post-marketing safety studies involving 1,051 hemodialysis dependent-CKD patients for a total of 1,496 patients. In addition, over 2,000 patients treated with Venofer® have been reported in the medical literature.

Treatment-emergent adverse events reported by ≥ 2% of treated patients with NDD-CKD in the randomized clinical trials, whether or not related to Venofer® administration, are listed by indication in Table 2.

Treatment-emergent adverse events reported in ≥ 2% of patients by dose group are shown in Table 3.

Table 2. Most Common Treatment-Emergent Adverse Events Reported in ≥ 2% of Patients with NDD-CKD by Clinical Indication (Multidose Safety Population)

Adverse Events (Preferred Term)	NDD-CKD Venofer® (N=139) %	NDD-CKD Oral Iron (N=139) %
Subjects with any adverse event	76.3	73.4
Ear and Labyrinth Disorders		
Ear Pain	2.2	0.7
Eye Disorders		
Conjunctivitis	0	0
Gastrointestinal Disorders		
Abdominal pain NOS*	1.4	2.9
Constipation	4.3	12.9
Diarrhea NOS	7.2	10.1
Dysgeusia	7.9	0
Nausea	8.6	12.2
Vomiting NOS	5.0	8.6
General Disorders and Administration Site Conditions		
Asthenia	0.7	2.2
Chest pain	1.4	0
Edema NOS	6.5	6.5
Fatigue	3.6	5.8
Feeling abnormal	0	0
Infusion site burning	3.6	0
Injection site extravasation	2.2	0
Injection site pain	2.2	0
Peripheral edema	7.2	5.0
Pyrexia	0.7	0.7
Infections and Infestations		
Catheter site infection	0	0
Nasopharyngitis	0.7	2.2
Peritoneal infection	0	0
Sinusitis NOS	0.7	0.7
Upper respiratory tract infection NOS	0.7	1.4
Urinary tract infection NOS	0.7	5.0
Injury, Poisoning and Procedural Complications		
Graft complication	1.4	0
Investigations		
Cardiac murmur NOS	2.2	2.2
Fecal occult blood positive	1.4	3.6
Metabolism and Nutrition Disorders		
Fluid overload	1.4	0.7
Gout	2.9	1.4
Hyperglycemia NOS	2.9	0
Hypoglycemia NOS	0.7	0.7
Musculoskeletal and Connective Tissue Disorders		
Arthralgia	1.4	2.2
Arthritis NOS	0	0

Table 3. Most Common Treatment-Emergent Adverse Events Reported in ≥ 2% of Patients with NDD-CKD by Dose Group (Multidose Safety Population)

Adverse Events (Preferred Term)	NDD-CKD 200 mg (N=109) %	NDD-CKD 500 mg (N=30) %
Subjects with any adverse event	75.2	80.0
Ear and Labyrinth Disorders		
Ear Pain	0.9	6.7
Eye Disorders		
Conjunctivitis	0	0
Gastrointestinal Disorders		
Abdominal pain NOS*	1.8	0
Constipation	3.7	6.7
Diarrhea NOS	6.4	10.0
Dysgeusia	9.2	3.3
Nausea	9.2	6.7
Vomiting NOS	5.5	3.3
General Disorders and Administration Site Conditions		
Asthenia	0.9	0
Chest pain	0.9	3.3
Edema NOS	7.3	3.3
Fatigue	4.6	0
Feeling abnormal	0	0
Infusion site burning	3.7	3.3
Injection site pain	2.8	0
Peripheral edema	5.5	13.3
Pyrexia	0.9	0
Infections and Infestations		
Catheter site infection	0	0
Nasopharyngitis	0.9	0
Peritoneal infection	0	0
Sinusitis NOS	0	3.3
Upper respiratory tract infection NOS	0.9	0
Injury, Poisoning and Procedural Complications		
Graft complication	1.8	0
Investigations		
Cardiac murmur NOS	2.8	0
Fecal occult blood positive	1.8	0
Metabolism and Nutrition Disorders		
Fluid overload	1.8	0
Gout	1.8	6.7
Hyperglycemia NOS	3.7	0
Hypoglycemia NOS	0.9	0
Musculoskeletal and Connective Tissue Disorders		
Arthralgia	0.9	3.3
Back pain	1.8	3.3
Muscle cramp	0	3.3
Myalgia	2.8	6.7

(Table 2 continued)

Adverse Events (Preferred Term)	NDD-CKD Venofer® (N=139) %	NDD-CKD Oral Iron (N=139) %
Musculoskeletal and Connective Tissue Disorders		
Back pain	2.2	3.6
Muscle cramp	0.7	0.7
Myalgia	3.6	0
Pain in extremity	4.3	0
Nervous System Disorders		
Dizziness	6.5	1.4
Headache	2.9	0.7
Hypoesthesia	0.7	0.7
Respiratory, Thoracic and Mediastinal Disorders		
Cough	2.2	0.7
Dyspnea	3.6	0.7
Dyspnea exacerbated	2.2	0.7
Nasal congestion	1.4	2.2
Pharyngitis	0	0
Rhinitis allergic NOS	0.7	2.2
Skin and Subcutaneous Tissue Disorders		
Pruritus	2.2	4.3
Rash NOS	1.4	2.2
Vascular Disorders		
Hypertension NOS	6.5	4.3
Hypotension NOS	2.2	0.7

*NOS=Not otherwise specified

(Table 3 continued)

Adverse Events (Preferred Term)	NDD-CKD 200 mg (N=109) %	NDD-CKD 500 mg (N=30) %
Musculoskeletal and Connective Tissue Disorders		
Pain in extremity	4.6	3.3
Nervous System Disorders		
Dizziness	5.5	10.0
Headache	3.7	0
Respiratory, Thoracic and Mediastinal Disorders		
Cough	0.9	6.7
Dyspnea	1.8	10.0
Pharyngitis	0	0
Skin and Subcutaneous Tissue Disorders		
Pruritus	0.9	6.7
Vascular Disorders		
Hypertension NOS	6.4	6.7
Hypotension NOS	0.9	6.7

*NOS=Not otherwise specified

Drug related adverse events reported by ≥ 2% of Venofer® (iron sucrose injection, USP) treated patients are shown by dose group in Table 4.

Table 4. Most Common Adverse Events Related to Study Drug Reported in ≥ 2% of Patients with NDD-CKD by Dose Group (Multidose Safety Population)

Adverse Events (Preferred Term)	NDD-CKD 200 mg (N=109) %	NDD-CKD 500 mg (N=30) %
Subjects with any adverse event	23.9	20.0
Gastrointestinal Disorders		
Diarrhea NOS*	0	0
Dysgeusia	7.3	3.3
Nausea	2.8	0
General Disorders and Administration Site Conditions		
Infusion site burning	3.7	0
Injection site pain	2.8	0
Peripheral edema	1.8	6.7
Nervous System Disorders		
Dizziness	2.8	6.7
Headache	2.8	0
Vascular Disorders		
Hypotension NOS	0	6.7

*NOS=Not otherwise specified

Adverse Events Observed in Non-Dialysis Dependent Chronic Kidney Disease (NDD-CKD) Patients

In the pivotal study of 182 NDD-CKD patients, 91 were exposed to Venofer®. Adverse events, whether or not related to Venofer®, reported by ≥ 5% of the Venofer® exposed patients were as follows: dysgeusia (7.7%), peripheral edema (7.7%), diarrhea (5.5%), constipation (5.5%), nausea (5.5%), dizziness (5.5%), and hypertension (5.5%). One serious related adverse reaction was reported (hypotension and shortness of breath not requiring hospitalization in a Venofer® patient). Two patients experienced possible hypersensitivity/allergic reactions (local edema/hypotension) during the study. Of the 5 patients who prematurely discontinued the treatment phase of the study due to adverse events (2 oral iron group and 3 Venofer® group), three Venofer® patients had events that were considered drug-related (hypotension, dyspnea and nausea).

Hypersensitivity Reactions: See **WARNINGS** and **PRECAUTIONS.**

In clinical studies, several patients experienced hypersensitivity reactions presenting with wheezing, dyspnea, hypotension, rashes, or pruritus. Serious episodes of hypotension occurred in 2 patients treated with Venofer® at a dose of 500 mg.

The post-marketing spontaneous reporting system includes reports of patients who experienced serious or life-threatening reactions (anaphylactic shock, loss of consciousness or collapse, bronchospasm with dyspnea, or convulsion) associated with Venofer® administration.

OVERDOSAGE

Dosages of Venofer® (iron sucrose injection, USP) in excess of iron needs may lead to accumulation of iron in storage sites leading to hemosiderosis. Periodic monitoring of iron parameters such as serum ferritin and transferrin saturation may assist in recognizing iron accumulation. Venofer® should not be administered to patients with iron overload and should be discontinued when serum ferritin levels equal or exceed established guidelines [1]. Particular caution should be exercised to avoid iron overload where anemia unresponsive to treatment has been incorrectly diagnosed as iron deficiency anemia.

Symptoms associated with overdosage or infusing Venofer® too rapidly included hypotension, dyspnea, headache, vomiting, nausea, dizziness, joint aches, paresthesia, abdominal and muscle pain, edema, and cardiovascular collapse. Most symptoms have been successfully treated with IV fluids, hydrocortisone, and/or antihistamines. Infusing the solution as recommended or at a slower rate may also alleviate symptoms.

Preclinical Data:

Single IV doses of Venofer® at 150 mg iron/kg in mice (about 3 times the recommended maximum human dose on a body surface area basis) and 100 mg iron/kg in rats (about 8 times the recommended maximum human dose on a body surface area basis) were lethal.

The symptoms of acute toxicity were sedation, hypoactivity, pale eyes, and bleeding in the gastrointestinal tract and lungs.

DOSAGE AND ADMINISTRATION

The dosage of Venofer® is expressed in terms of mg of elemental iron. Each mL contains 20 mg of elemental iron.

Most CKD patients will require a minimum cumulative repletion dose of 1,000 mg of elemental iron, administered over sequential sessions, to achieve a favorable hemoglobin response and to replenish iron stores (ferritin, TSAT).

Administration: Venofer® must only be administered intravenously either by slow injection or by infusion.

Recommended Adult Dosage:

Non-Dialysis Dependent-Chronic Kidney Disease Patients (NDD-CKD): Venofer® is administered as a total cumulative dose of 1,000 mg over a 14 day period as a 200 mg slow IV injection undiluted over 2 to 5 minutes on 5 different occasions within the 14 day period. There is limited experience with administration of an infusion of 500 mg of Venofer®, diluted in a maximum of 250 mL of 0.9% NaCl, over a period of 3.5-4 hours on day 1 and day 14; hypotension occurred in 2 of 30 patients treated. (See **CLINICAL TRIALS, Study D: Non-Dialysis Dependent-Chronic Kidney Disease (NDD-CKD) Patients** and **ADVERSE REACTIONS, Adverse Events Observed in Non-Dialysis Dependent-Chronic Kidney Disease (NDD-CKD) Patients sections.**)

HOW SUPPLIED

Venofer® is supplied in 5 mL and 10 mL single dose vials. Each 5 mL vial contains 100 mg elemental iron (20 mg/mL) and each 10 mL vial contains 200 mg elemental iron (20 mg/mL). Contains no preservatives. Store in original carton at 25°C (77°F). Excursions permitted to 15°-30°C (59°-86°F). [See the USP controlled room temperature]. Do not freeze.

Sterile

NDC-0517-2340-01	100 mg/5 mL Single Dose Vial	Individually Boxed	NDC-0517-2310-01	200 mg/10 mL Single Dose Vial	Individually Boxed
NDC-0517-2340-10	100 mg/5 mL Single Dose Vial	Packages of 10	NDC-0517-2310-05	200 mg/10 mL Single Dose Vial	Packages of 5
NDC-0517-2340-25	100 mg/5 mL Single Dose Vial	Packages of 25	NDC-0517-2310-10	200 mg/10 mL Single Dose Vial	Packages of 10

Rx Only

REFERENCE: [1] National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease, 2000. *Am J Kidney Dis.* 37: S182-S238, (suppl 1) 2001.

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