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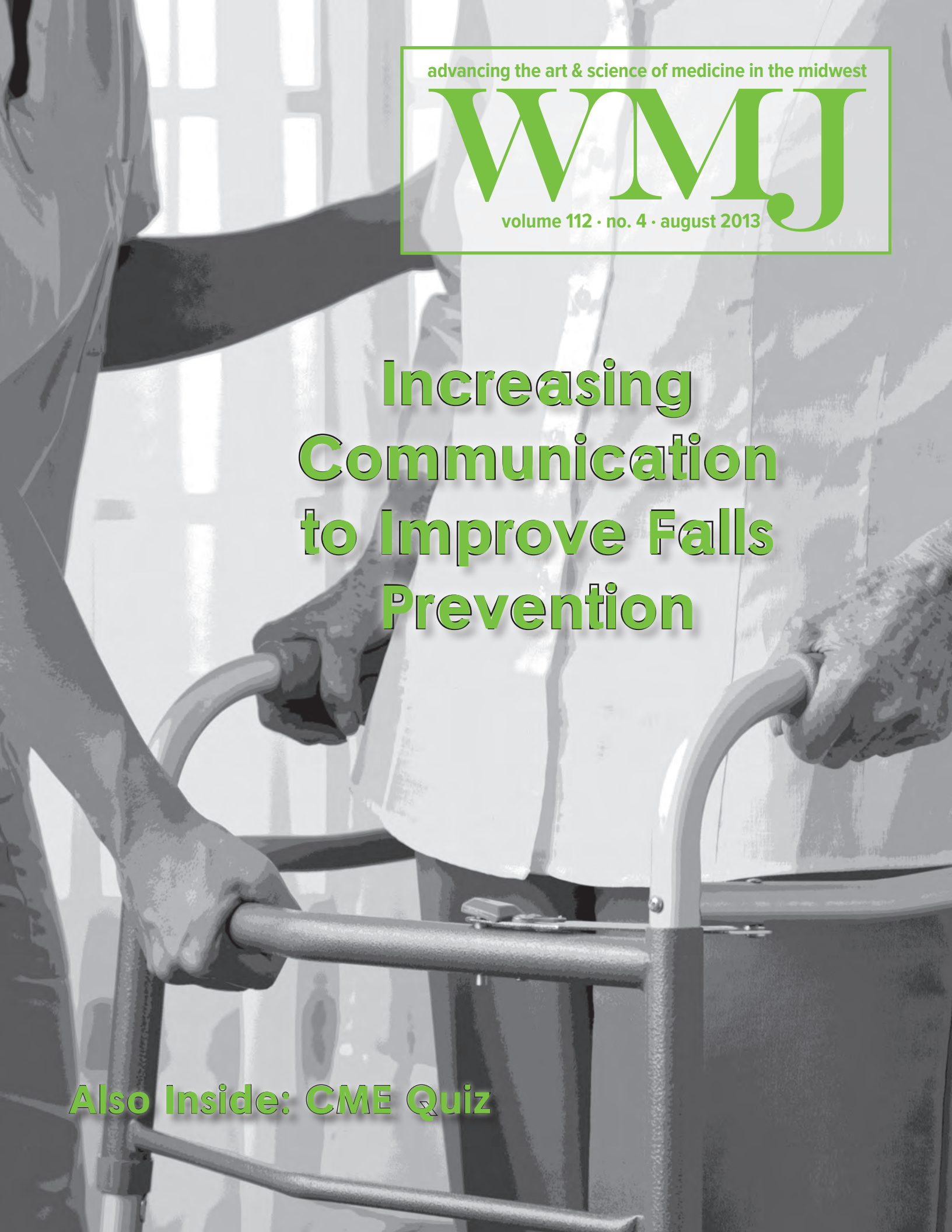

# Increasing Communication to Improve Falls Prevention

Also Inside: CME Quiz


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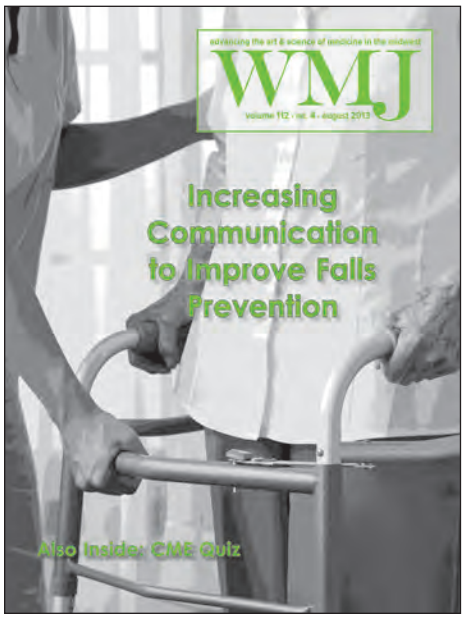
# WMJ




## COVER THEME
## Increasing Communication to Improve Falls Prevention

In this issue of *WMJ,* 3 studies point to communication as a key to prevention. Whether the health issue is falls prevention in nursing homes, teenage pregnancy or completion of advance directives, physicians and others on the health care team are reminded through these studies of the importance of talking both with patients and each other to help drive improved health outcomes.

**Cover design by Mary Kay Adams-Edgette.**



The mission of *WMJ* is to provide a vehicle for professional communication and continuing education for Midwest physicians and other health professionals. *WMJ* is published by the Wisconsin Medical Society.

# advancing the art & science of medicine in the midwest

## CASE REPORT



## YOUR PROFESSION



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VICTOZA®
liraglutide (rDNA origin) injection

## Indications and Usage

Victoza® (liraglutide [rDNA origin] injection) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Because of the uncertain relevance of the rodent thyroid C-cell tumor findings to humans, prescribe Victoza® only to patients for whom the potential benefits are considered to outweigh the potential risk. Victoza® is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise.

Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis has been observed in patients treated with Victoza®. Victoza® has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for pancreatitis while using Victoza®. Other antidiabetic therapies should be considered in patients with a history of pancreatitis.

Victoza® is not a substitute for insulin. Victoza® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.

Victoza® has not been studied in combination with prandial insulin.

## Important Safety Information

**Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Victoza® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be ruled out by clinical or nonclinical studies. Victoza® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Based on the findings in rodents, monitoring with serum calcitonin or thyroid ultrasound was performed during clinical trials, but this may have increased the number of unnecessary thyroid surgeries. It is unknown whether monitoring with serum calcitonin or thyroid ultrasound will mitigate human risk of thyroid C-cell tumors. Patients should be counseled regarding the risk and symptoms of thyroid tumors.**

Do not use in patients with a prior serious hypersensitivity reaction to Victoza® (liraglutide [rDNA origin] injection) or to any of the product components.

Postmarketing reports, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed. Consider other antidiabetic therapies in patients with a history of pancreatitis.

When Victoza® is used with an insulin secretagogue (e.g. a sulfonylurea) or insulin serious hypoglycemia can occur. Consider lowering the dose of the insulin secretagogue or insulin to reduce the risk of hypoglycemia.

Renal impairment has been reported postmarketing, usually in association with nausea, vomiting, diarrhea, or dehydration which may sometimes require hemodialysis. Use caution when initiating or escalating doses of Victoza® in patients with renal impairment.

Serious hypersensitivity reactions (e.g. anaphylaxis and angioedema) have been reported during postmarketing use of Victoza®. If symptoms of hypersensitivity reactions occur, patients must stop taking Victoza® and seek medical advice promptly.

There have been no studies establishing conclusive evidence of macrovascular risk reduction with Victoza® or any other antidiabetic drug.

The most common adverse reactions, reported in ≥5% of patients treated with Victoza® and more commonly than in patients treated with placebo, are headache, nausea, diarrhea, dyspepsia, constipation and anti-liraglutide antibody formation. Immunogenicity-related events, including urticaria, were more common among Victoza®-treated patients (0.8%) than among comparator-treated patients (0.4%) in clinical trials.

Victoza® has not been studied in type 2 diabetes patients below 18 years of age and is not recommended for use in pediatric patients.

There is limited data in patients with renal or hepatic impairment.

**Please see brief summary of Prescribing Information on adjacent page.**


0513-00015590-1 June 2013

**Victoza® (liraglutide [rDNA origin] injection)**
**Rx Only**
**BRIEF SUMMARY. Please consult package insert for full prescribing information.**

**WARNING: RISK OF THYROID C-CELL TUMORS:** Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Victoza® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be ruled out by clinical or nonclinical studies. Victoza® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Based on the findings in rodents, monitoring with serum calcitonin or thyroid ultrasound was performed during clinical trials, but this may have increased the number of unnecessary thyroid surgeries. It is unknown whether monitoring with serum calcitonin or thyroid ultrasound will mitigate human risk of thyroid C-cell tumors. Patients should be counseled regarding the risk and symptoms of thyroid tumors *[see Contraindications and Warnings and Precautions].*

**INDICATIONS AND USAGE:** Victoza® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Important Limitations of Use:** Because of the uncertain relevance of the rodent thyroid C-cell tumor findings to humans, prescribe Victoza® only to patients for whom the potential benefits are considered to outweigh the potential risk. Victoza® is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise. Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis has been observed in patients treated with Victoza®. Victoza® has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for pancreatitis while using Victoza®. Other antidiabetic therapies should be considered in patients with a history of pancreatitis. Victoza® is not a substitute for insulin. Victoza® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. The concurrent use of Victoza® and prandial insulin has not been studied.

**CONTRAINDICATIONS:** Do not use in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Do not use in patients with a prior serious hypersensitivity reaction to Victoza® or to any of the product components.

**WARNINGS AND PRECAUTIONS: Risk of Thyroid C-cell Tumors:** Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors (adenomas and/or carcinomas) at clinically relevant exposures in both genders of rats and mice. Malignant thyroid C-cell carcinomas were detected in rats and mice. A statistically significant increase in cancer was observed in rats receiving liraglutide at 8-times clinical exposure compared to controls. It is unknown whether Victoza® will cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors could not be determined by clinical or nonclinical studies. In the clinical trials, there have been 6 reported cases of thyroid C-cell hyperplasia among Victoza®-treated patients and 2 cases in comparator-treated patients (1.3 vs. 1.0 cases per 1000 patient-years). One comparator-treated patient with MTC had pre-treatment serum calcitonin concentrations >1000 ng/L suggesting pre-existing disease. All of these cases were diagnosed after thyroidectomy, which was prompted by abnormal results on routine, protocol-specified measurements of serum calcitonin. Five of the six Victoza®-treated patients had elevated calcitonin concentrations at baseline and throughout the trial. One Victoza® and one non-Victoza®-treated patient developed elevated calcitonin concentrations while on treatment. Calcitonin, a biological marker of MTC, was measured throughout the clinical development program. The serum calcitonin assay used in the Victoza® clinical trials had a lower limit of quantification (LLOQ) of 0.7 ng/L and the upper limit of the reference range was 5.0 ng/L for women and 8.4 ng/L for men. At Weeks 26 and 52 in the clinical trials, adjusted mean serum calcitonin concentrations were higher in Victoza®-treated patients compared to placebo-treated patients but not compared to patients receiving active comparator. At these timepoints, the adjusted mean serum calcitonin values (~1.0 ng/L) were just above the LLOQ with between-group differences in adjusted mean serum calcitonin values of approximately 0.1 ng/L or less. Among patients with pre-treatment serum calcitonin below the upper limit of the reference range, shifts to above the upper limit of the reference range which persisted in subsequent measurements occurred most frequently among patients treated with Victoza® 1.8 mg/day. In trials with on-treatment serum calcitonin measurements out to 5-6 months, 1.9% of patients treated with Victoza® 1.8 mg/day developed new and persistent calcitonin elevations above the upper limit of the reference range compared to 0.8-1.1% of patients treated with control medication or the 0.6 and 1.2 mg doses of Victoza®. In trials with on-treatment serum calcitonin measurements out to 12 months, 1.3% of patients treated with Victoza® 1.8 mg/day had new and persistent elevations of calcitonin from below or within the reference range to above the upper limit of the reference range, compared to 0.6%, 0% and 1.0% of patients treated with Victoza® 1.2 mg, placebo and active control, respectively. Otherwise, Victoza® did not produce consistent dose-dependent or time-dependent increases in serum calcitonin. Patients with MTC usually have calcitonin values >50 ng/L. In Victoza® clinical trials, among patients with pre-treatment serum calcitonin <50 ng/L, one Victoza®-treated patient and no comparator-treated patients developed serum calcitonin >50 ng/L. The Victoza®-treated patient who developed serum calcitonin >50 ng/L had an elevated pre-treatment serum calcitonin of 10.7 ng/L that increased to 30.7 ng/L at Week 12 and 53.5 ng/L at the end of the 6-month trial. Follow-up serum calcitonin was 22.3 ng/L more than 2.5 years after the last dose of Victoza®. The largest increase in serum calcitonin in a comparator-treated patient was seen with glimepiride in a patient whose serum calcitonin increased from 19.3 ng/L at baseline to 44.8 ng/L at Week 65 and 38.1 ng/L at Week 104. Among patients who began with serum calcitonin <20 ng/L, calcitonin elevations to >20 ng/L occurred in 0.7% of Victoza®-treated patients, 0.3% of placebo-treated patients, and 0.5% of active-comparator-treated patients, with an incidence of 1.1% among patients treated with 1.8 mg/day of Victoza®. The clinical significance of these findings is unknown. Counsel patients regarding the risk for MTC and the symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea or persistent hoarseness). It is unknown whether monitoring with serum calcitonin or thyroid ultrasound will mitigate the potential risk of MTC, and such monitoring may increase the risk of unnecessary procedures, due to low test specificity for serum calcitonin and a high background incidence of thyroid disease. Patients with thyroid nodules noted on physical examination or neck imaging obtained for other reasons should be referred to an endocrinologist for further evaluation. Although routine monitoring of serum calcitonin is of uncertain value in patients treated with Victoza®, if serum calcitonin is measured and found to be elevated, the patient should be referred to an endocrinologist for further evaluation. **Pancreatitis: Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with Victoza®. After initiation of Victoza®, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, Victoza® should promptly be discontinued and appropriate management should be initiated. If pancreatitis is confirmed, Victoza® should not be restarted. Consider antidiabetic therapies other than Victoza® in patients with a history of pancreatitis.** In clinical trials of Victoza®, there have been 13 cases of pancreatitis among Victoza®-treated patients and 1 case in a comparator (glimepiride) treated patient (2.7 vs. 0.5 cases per 1000 patient-years). Nine of the 13 cases with Victoza® were reported as acute pancreatitis and four were reported as chronic pancreatitis. In one case in a Victoza®-treated patient, pancreatitis, with necrosis, was observed and led to death; however clinical causality could not be established. Some patients had other risk factors for pancreatitis, such as a history of cholelithiasis or alcohol abuse. **Use with Medications Known to Cause Hypoglycemia:** Patients receiving Victoza® in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogues) or insulin **Renal Impairment:** Victoza® has not been found to be directly nephrotoxic in animal studies or clinical trials. There have been postmarketing reports of acute renal failure and worsening of chronic renal failure, which may sometimes require hemodialysis in Victoza®-treated patients. Some of these events were reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Some of the reported events occurred in patients receiving one or more medications known to affect renal function or hydration status. Altered renal function has been reversed in many of the reported cases with supportive treatment and discontinuation of potentially causative agents, including Victoza®. Use caution when initiating or escalating doses of Victoza® in patients with renal impairment. **Hypersensitivity Reactions:** There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema) in patients treated with Victoza®. If a hypersensitivity reaction occurs, the patient should discontinue Victoza® and other suspect medications and promptly seek medical advice. Angioedema has also been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of angioedema with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to angioedema with Victoza®. **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Victoza® or any other antidiabetic drug.

**ADVERSE REACTIONS: Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety of Victoza® has been evaluated in 8 clinical trials: A double-blind 52-week monotherapy trial compared Victoza® 1.2 mg daily, Victoza® 1.8 mg daily, and glimepiride 8 mg daily; A double-blind 26 week add-on to metformin trial compared Victoza® 0.6 mg once-daily, Victoza® 1.2 mg once-daily, Victoza® 1.8 mg once-daily, placebo, and glimepiride 4 mg once-daily; A double-blind 26 week add-on to glimepiride trial compared Victoza® 0.6 mg daily, Victoza® 1.2 mg once-daily, Victoza® 1.8 mg once-daily, placebo, and rosiglitazone 4 mg once-daily; A 26 week add-on to metformin + glimepiride trial, compared double-blind Victoza® 1.8 mg once-daily, double-blind placebo, and open-label insulin glargine once-daily; A double-blind 26-week add-on to metformin + rosiglitazone trial compared Victoza® 1.2 mg once-daily, Victoza® 1.8 mg once-daily and placebo; An open-label 26-week add-on to metformin and/or sulfonylurea trial compared Victoza® 1.8 mg once-daily and exenatide 10 mcg twice-daily; An open-label 26-week add-on to metformin trial compared Victoza® 1.2 mg once-daily, Victoza® 1.8 mg once-daily, and sitagliptin 100 mg once-daily; An open-label 26-week trial compared insulin detemir as add-on to Victoza® 1.8 mg + metformin to continued treatment with Victoza® + metformin alone. *Withdrawals:* The incidence of withdrawal due to adverse events was 7.8% for Victoza®-treated patients and 3.4% for comparator-treated patients in the five double-blind controlled trials of 26 weeks duration or longer. This difference was driven by withdrawals due to gastrointestinal adverse reactions, which occurred in 5.0% of Victoza®-treated patients and 0.5% of comparator-treated patients. In these five trials, the most common adverse reactions leading to withdrawal for Victoza®-treated patients were nausea (2.8% versus 0% for comparator) and vomiting (1.5% versus 0.1% for comparator). Withdrawal due to gastrointestinal adverse events mainly occurred during the first 2-3 months of the trials. *Common adverse reactions:* Tables 1, 2, 3 and 4 summarize common adverse reactions (hypoglycemia is discussed separately) reported in seven of the eight controlled trials of 26 weeks duration or longer. Most of these adverse reactions were gastrointestinal in nature. In the five double-blind clinical trials of 26 weeks duration or longer, gastrointestinal adverse reactions were reported in 41% of Victoza®-treated patients and were dose-related. Gastrointestinal adverse reactions occurred in 17% of comparator-treated patients. Common adverse reactions that occurred at a higher incidence among Victoza®-treated patients included nausea, vomiting, diarrhea, dyspepsia and constipation. In the five double-blind and three open-label clinical trials of 26 weeks duration or longer, the percentage of patients who reported nausea declined over time. In the five double-blind trials approximately 13% of Victoza®-treated patients and 2% of comparator-treated patients reported nausea during the first 2 weeks of treatment. In the 26-week open-label trial comparing Victoza® to exenatide, both in combination with metformin and/or sulfonylurea, gastrointestinal adverse reactions were reported at a similar incidence in the Victoza® and exenatide treatment groups (Table 3). In the 26-week open-label trial comparing Victoza® 1.2 mg, Victoza® 1.8 mg and sitagliptin 100 mg, all in combination with metformin, gastrointestinal adverse reactions were reported at a higher incidence with Victoza® than sitagliptin (Table 4). In the remaining 26-week trial, all patients received Victoza® 1.8 mg + metformin during a 12-week run-in period. During the run-in period, 167 patients (17% of enrolled total) withdrew from the trial: 76 (46% of withdrawals) of these patients doing so because of gastrointestinal adverse reactions and 15 (9% of withdrawals) doing so due to other adverse events. Only those patients who completed the run-in period with inadequate glycemic control were randomized to 26 weeks of add-on therapy with insulin detemir or continued, unchanged treatment with Victoza® 1.8 mg + metformin. During this randomized 26-week period, diarrhea was the only adverse reaction reported in ≥5% of patients treated with Victoza® 1.8 mg + metformin + insulin detemir (11.7%) and greater than in patients treated with Victoza® 1.8 mg and metformin alone (6.9%).

**Table 1: Adverse reactions reported in ≥5% of Victoza®-treated patients in a 52-week monotherapy trial**

| | All Victoza® N = 497 | Glimepiride N = 248 |
|---|---|---|
| **Adverse Reaction** | (%) | (%) |
| Nausea | 28.4 | 8.5 |
| Diarrhea | 17.1 | 8.9 |
| Vomiting | 10.9 | 3.6 |
| Constipation | 9.9 | 4.8 |
| Headache | 9.1 | 9.3 |

**Table 2: Adverse reactions reported in ≥5% of Victoza®-treated patients and occurring more frequently with Victoza® compared to placebo: 26-week combination therapy trials**

| **Add-on to Metformin Trial** | | | |
|---|---|---|---|
| | All Victoza® + Metformin N = 724 | Placebo + Metformin N = 121 | Glimepiride + Metformin N = 242 |
| **Adverse Reaction** | (%) | (%) | (%) |
| Nausea | 15.2 | 4.1 | 3.3 |
| Diarrhea | 10.9 | 4.1 | 3.7 |
| Headache | 9.0 | 6.6 | 9.5 |
| Vomiting | 6.5 | 0.8 | 0.4 |
| **Add-on to Glimepiride Trial** | | | |
| | All Victoza® + Glimepiride N = 695 | Placebo + Glimepiride N = 114 | Rosiglitazone + Glimepiride N = 231 |
| **Adverse Reaction** | (%) | (%) | (%) |
| Nausea | 7.5 | 1.8 | 2.6 |
| Diarrhea | 7.2 | 1.8 | 2.2 |

| | | | |
|---|---|---|---|
| Constipation | 5.3 | 0.9 | 1.7 |
| Dyspepsia | 5.2 | 0.9 | 2.6 |
| **Add-on to Metformin + Glimepiride** | | | |
| | Victoza® 1.8 + Metformin + Glimepiride N = 230 | Placebo + Metformin + Glimepiride N = 114 | Glargine + Metformin + Glimepiride N = 232 |
| **Adverse Reaction** | (%) | (%) | (%) |
| Nausea | 13.9 | 3.5 | 1.3 |
| Diarrhea | 10.0 | 5.3 | 1.3 |
| Headache | 9.6 | 7.9 | 5.6 |
| Dyspepsia | 6.5 | 0.9 | 1.7 |
| Vomiting | 6.5 | 3.5 | 0.4 |
| **Add-on to Metformin + Rosiglitazone** | | | |
| | All Victoza® + Metformin + Rosiglitazone N = 355 | Placebo + Metformin + Rosiglitazone N = 175 | |
| **Adverse Reaction** | (%) | (%) | |
| Nausea | 34.6 | 8.6 | |
| Diarrhea | 14.1 | 6.3 | |
| Vomiting | 12.4 | 2.9 | |
| Headache | 8.2 | 4.6 | |
| Constipation | 5.1 | 1.1 | |

**Table 3: Adverse Reactions reported in ≥5% of Victoza®-treated patients in a 26-Week Open-Label Trial versus Exenatide**

| | **Victoza® 1.8 mg once daily + metformin and/or sulfonylurea** N = 235 | **Exenatide 10 mcg twice daily + metformin and/or sulfonylurea** N = 232 |
|---|---|---|
| **Adverse Reaction** | (%) | (%) |
| Nausea | 25.5 | 28.0 |
| Diarrhea | 12.3 | 12.1 |
| Headache | 8.9 | 10.3 |
| Dyspepsia | 8.9 | 4.7 |
| Vomiting | 6.0 | 9.9 |
| Constipation | 5.1 | 2.6 |

**Table 4: Adverse Reactions in ≥5% of Victoza®-treated patients in a 26-Week Open-Label Trial versus Sitagliptin**

| | **All Victoza® + metformin** N = 439 | **Sitagliptin 100 mg/day + metformin** N = 219 |
|---|---|---|
| **Adverse Reaction** | (%) | (%) |
| Nausea | 23.9 | 4.6 |
| Headache | 10.3 | 10.0 |
| Diarrhea | 9.3 | 4.6 |
| Vomiting | 8.7 | 4.1 |

*Immunogenicity:* Consistent with the potentially immunogenic properties of protein and peptide pharmaceuticals, patients treated with Victoza® may develop anti-liraglutide antibodies. Approximately 50-70% of Victoza®-treated patients in the five double-blind clinical trials of 26 weeks duration or longer were tested for the presence of anti-liraglutide antibodies at the end of treatment. Low titers (concentrations not requiring dilution of serum) of anti-liraglutide antibodies were detected in 8.6% of these Victoza®-treated patients. Sampling was not performed uniformly across all patients in the clinical trials, and this may have resulted in an underestimate of the actual percentage of patients who developed antibodies. Cross-reacting anti-liraglutide antibodies to native glucagon-like peptide-1 (GLP-1) occurred in 6.9% of the Victoza®-treated patients in the double-blind 52-week monotherapy trial and in 4.8% of the Victoza®-treated patients in the double-blind 26-week add-on combination therapy trials. These cross-reacting antibodies were not tested for neutralizing effect against native GLP-1, and thus the potential for clinically significant neutralization of native GLP-1 was not assessed. Antibodies that had a neutralizing effect on liraglutide in an *in vitro* assay occurred in 2.3% of the Victoza®-treated patients in the double-blind 52-week monotherapy trial and in 1.0% of the Victoza®-treated patients in the double-blind 26-week add-on combination therapy trials. Among Victoza®-treated patients who developed anti-liraglutide antibodies, the most common category of adverse events was that of infections, which occurred among 40% of these patients compared to 36%, 34% and 35% of antibody-negative Victoza®-treated, placebo-treated and active-control-treated patients, respectively. The specific infections which occurred with greater frequency among Victoza®-treated antibody-positive patients were primarily nonserious upper respiratory tract infections, which occurred among 11% of Victoza®-treated antibody-positive patients; and among 7%, 7% and 5% of antibody-negative Victoza®-treated, placebo-treated and active-control-treated patients, respectively. Among Victoza®-treated antibody-negative patients, the most common category of adverse events was that of gastrointestinal events, which occurred in 43%, 18% and 19% of antibody-negative Victoza®-treated, placebo-treated and active-control-treated patients, respectively. Antibody formation was not associated with reduced efficacy of Victoza® when comparing mean $HbA_{1c}$ of all antibody-positive and all antibody-negative patients. However, the 3 patients with the highest titers of anti-liraglutide antibodies had no reduction in $HbA_{1c}$ with Victoza® treatment. In the five double-blind clinical trials of Victoza®, events from a composite of adverse events potentially related to immunogenicity (e.g. urticaria, angioedema) occurred among 0.8% of Victoza®-treated patients and among 0.4% of comparator-treated patients. Urticaria accounted for approximately one-half of the events in this composite for Victoza®-treated patients. Patients who developed anti-liraglutide antibodies were not more likely to develop events from the immunogenicity events composite than were patients who did not develop anti-liraglutide antibodies. *Injection site reactions:* Injection site reactions (e.g., injection site rash, erythema) were reported in approximately 2% of Victoza®-treated patients in the five double-blind clinical trials of at least 26 weeks duration. Less than 0.2% of Victoza®-treated patients discontinued due to injection site reactions. *Papillary thyroid carcinoma:* In clinical trials of Victoza®, there were 7 reported cases of papillary thyroid carcinoma in patients treated with Victoza® and 1 case in a comparator-treated patient (1.5 vs. 0.5 cases per 1000 patient-years). Most of these papillary thyroid carcinomas were <1 cm in greatest diameter and were diagnosed in surgical pathology specimens after thyroidectomy prompted by findings on protocol-specified screening with serum calcitonin or thyroid ultrasound. *Hypoglycemia:* In the eight clinical trials of at least 26 weeks duration, hypoglycemia requiring the assistance of another person for treatment occurred in 11 Victoza®-treated patients (2.3 cases per 1000 patient-years) and in two exenatide-treated patients. Of these 11 Victoza®-treated patients, six patients were concomitantly using metformin and a sulfonylurea, one was concomitantly using a sulfonylurea, two were concomitantly using metformin (blood glucose values were 65 and 94 mg/dL) and two were using Victoza® as monotherapy (one of these patients was undergoing an intravenous glucose tolerance test and the other was receiving insulin as treatment during a hospital stay). For these two patients on Victoza® monotherapy, the insulin treatment was the likely explanation for the hypoglycemia. In the 26-week open-label trial comparing Victoza® to sitagliptin, the incidence of hypoglycemic events defined as symptoms accompanied by a fingerstick glucose <56 mg/dL was comparable among the treatment groups (approximately 5%).

**Table 5: Incidence (%) and Rate (episodes/patient year) of Hypoglycemia in the 52-Week Monotherapy Trial and in the 26-Week Combination Therapy Trials**

| | **Victoza® Treatment** | **Active Comparator** | **Placebo Comparator** |
|---|---|---|---|
| **Monotherapy** | **Victoza®** (N = 497) | **Glimepiride** (N = 248) | **None** |
| Patient not able to self–treat | 0 | 0 | — |
| Patient able to self–treat | 9.7 (0.24) | 25.0 (1.66) | — |
| Not classified | 1.2 (0.03) | 2.4 (0.04) | — |
| **Add-on to Metformin** | **Victoza® + Metformin** (N = 724) | **Glimepiride + Metformin** (N = 242) | **Placebo + Metformin** (N = 121) |
| Patient not able to self–treat | 0.1 (0.001) | 0 | 0 |
| Patient able to self–treat | 3.6 (0.05) | 22.3 (0.87) | 2.5 (0.06) |
| **Add-on to Victoza® + Metformin** | **Insulin detemir + Victoza® + Metformin** (N = 163) | **Continued Victoza® + Metformin alone** (N = 158*) | **None** |
| Patient not able to self–treat | 0 | 0 | — |
| Patient able to self–treat | 9.2 (0.29) | 1.3 (0.03) | — |
| **Add-on to Glimepiride** | **Victoza® + Glimepiride** (N = 695) | **Rosiglitazone + Glimepiride** (N = 231) | **Placebo + Glimepiride** (N = 114) |
| Patient not able to self–treat | 0.1 (0.003) | 0 | 0 |
| Patient able to self–treat | 7.5 (0.38) | 4.3 (0.12) | 2.6 (0.17) |
| Not classified | 0.9 (0.05) | 0.9 (0.02) | 0 |
| **Add-on to Metformin + Rosiglitazone** | **Victoza® + Metformin + Rosiglitazone** (N = 355) | **None** | **Placebo + Metformin + Rosiglitazone** (N = 175) |
| Patient not able to self–treat | 0 | — | 0 |
| Patient able to self–treat | 7.9 (0.49) | — | 4.6 (0.15) |
| Not classified | 0.6 (0.01) | — | 1.1 (0.03) |
| **Add-on to Metformin + Glimepiride** | **Victoza® + Metformin + Glimepiride** (N = 230) | **Insulin glargine + Metformin + Glimepiride** (N = 232) | **Placebo + Metformin + Glimepiride** (N = 114) |
| Patient not able to self–treat | 2.2 (0.06) | 0 | 0 |
| Patient able to self–treat | 27.4 (1.16) | 28.9 (1.29) | 16.7 (0.95) |
| Not classified | 0 | 1.7 (0.04) | 0 |

*One patient is an outlier and was excluded due to 25 hypoglycemic episodes that the patient was able to self-treat. This patient had a history of frequent hypoglycemia prior to the study.

In a pooled analysis of clinical trials, the incidence rate (per 1,000 patient-years) for malignant neoplasms (based on investigator-reported events, medical history, pathology reports, and surgical reports from both blinded and open-label study periods) was 10.9 for Victoza®, 6.3 for placebo, and 7.2 for active comparator. After excluding papillary thyroid carcinoma events *[see Adverse Reactions]*, no particular cancer cell type predominated. Seven malignant neoplasm events were reported beyond 1 year of exposure to study medication, six events among Victoza®-treated patients (4 colon, 1 prostate and 1 nasopharyngeal), no events with placebo and one event with active comparator (colon). Causality has not been established. **Laboratory Tests:** In the five clinical trials of at least 26 weeks duration, mildly elevated serum bilirubin concentrations (elevations to no more than twice the upper limit of the reference range) occurred in 4.0% of Victoza®-treated patients, 2.1% of placebo-treated patients and 3.5% of active-comparator-treated patients. This finding was not accompanied by abnormalities in other liver tests. The significance of this isolated finding is unknown. **Vital signs:** Victoza® did not have adverse effects on blood pressure. Mean increases from baseline in heart rate of 2 to 3 beats per minute have been observed with Victoza® compared to placebo. The long-term clinical effects of the increase in pulse rate have not been established. **Post-Marketing Experience:** The following additional adverse reactions have been reported during post-approval use of Victoza®. Because these events are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure: Dehydration resulting from nausea, vomiting and diarrhea; Increased serum creatinine, acute renal failure or worsening of chronic renal failure, sometimes requiring hemodialysis; Angioedema and anaphylactic reactions; Allergic reactions: rash and pruritus; Acute pancreatitis, hemorrhagic and necrotizing pancreatitis sometimes resulting in death.

**OVERDOSAGE:** Overdoses have been reported in clinical trials and post-marketing use of Victoza®. Effects have included severe nausea and severe vomiting. In the event of overdosage, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms.

**More detailed information is available upon request.**

For information about Victoza® contact: Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, NJ 08536, 1–877-484-2869

Date of Issue: April 16, 2013

**Version: 6**

Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark



novo nordisk®

VICTOZA®

liraglutide (rDNA origin) injection

# Physicians as Patients in Advance Care Planning

When Honoring Choices Wisconsin (HCW) launched in September 2012, Tim Bartholow, MD, the Wisconsin Medical Society's (Society) chief medical officer, acknowledged that "starting a conversation about the end of life is difficult for all of us, whether we are physicians, patients, family members, religious and community leaders or health care professionals."

Since then, more than 300 patients at 6 health care organizations have discussed their future medical decisions, including end-of-life preferences, with facilitators trained through a pilot program with HCW. Much of the early success of HCW—the Society's advance care planning project—can be attributed to physician leaders at the Society and participating organizations in southern Wisconsin. They have committed staff time and resources to HCW to help ensure that their patients understand treatment options and receive the care they want.

An article in this issue of *WMJ*—"An Exploratory Study of the Use of Advance Directives by US Oncologists"[1]—provides evidence of this. In their survey of almost 7600 physician members of the American Society of Clinical Oncology (ASCO), the authors found that only a slight majority (58.8%) of oncologists who responded had completed a living will or a power of attorney for health care – two of the most common types of advance directives.

Although one might expect more physicians to have completed an advance directive, previous studies have shown that health care workers have completion rates similar to the general population. The good news is that respondents with an advance directive reported being more likely to routinely discuss advance directives with their patients and being more comfortable helping patients complete one. In addition, three-fourths of all oncologists who responded said they already had end-of-life discussions with their loved ones, and all respondents with an advance directive reported that the documents were in their medical records.

Having a conversation with loved ones about future health care wishes is a critical first step, but equally important is formalizing those wishes in an advance directive that is shared with a patient's physician—even if the patient is a physician. That's exactly what hundreds of patients in southern Wisconsin have experienced with the help of trained facilitators through HCW pilot projects.

Patient participation has been higher than expected, with overwhelmingly positive feedback. All patients surveyed found the advance care planning discussion either "helpful" or "very helpful," and 100% of health care agents said they "now feel better prepared to make health care decisions for their loved ones."

Society leaders were confident that's what they would hear from participants. Physicians want to provide the most appropriate care and respect patient's wishes at every stage of life; Honoring Choices Wisconsin allows them to do so.

Because of the early success of the pilot projects, the Society is recruiting additional organizations to participate. To learn more, visit www.wisconsinmedicalsociety.org/professional/hcw.

*John Maycroft, MPP, Director of Policy Development and Initiatives, Wisconsin Medical Society*

## Reference

**1.** Sharma UM, Schroeder JE, Al-Hamadani M, et al. An Exploratory Study of the Use of Advance Directives by US Oncologists. *WMJ.* 2013;112(4):158-161.

**The name "Honoring Choices Wisconsin" is used under license from East Metro Medical Society Foundation.*

# The State of Telemedicine in Wisconsin

Recent coverage of telemedicine by the popular media has increased public awareness of its potential;[1] however, barriers to telemedicine expansion are numerous. For example, a recent survey identified the following as principal human barriers to adoption of robotic telemedicine in emergency and critical care medicine: (1) regulatory barriers for physician privileges; (2) financial barriers related to the inability to bill for services while needing to pay for additional technology; and (3) cultural barriers resulting from a lack of desire or unwillingness to change clinical paradigms through the use of telemedicine.[2] Nonetheless, with the adoption of the Affordable Care Act, the impact of the regulatory and financial barriers mentioned may be lessened. In addition, other inventive solutions to these problems such as special telemedicine licenses and credentialing agreements have been described and are being implemented.[3]

Informed planning, including an understanding of resources available at present and the resources that ultimately will be needed, is important for the successful expansion of telemedicine. The state of telemedicine within Wisconsin, that is to say the number of programs currently in place, the way these programs are being used, and the perceived need for access to health care that telemedicine might provide, is largely unknown. The most recent summary of telemedicine activity in Wisconsin was published in 2009 when the Rural Wisconsin Health Cooperative released a report that included information gathered via a survey of "a broad range of health care providers," informant interviews, and a literature search.[4] It identified 98 sites utilizing telemedicine applications. Those successful in establishing telemedicine programs cited good strategic planning and the ability to secure funding as keys to success. This project did not aim to identify any perceived need for access to telemedicine that might exist within the state. Characterizing any existing gap between currently available programs and perceived needs might allow for better allocation of resources as well as guide development of future telemedicine programs. As such, we recently developed a survey that aimed to characterize such a gap between current resources and perceived need.

A short survey of medical providers was created using the online software SurveyMonkey (www.surveymonkey.com) as a platform. Sample questions from the survey are provided in Figure 1. In May 2011, the survey was distributed electronically to 3095 Wisconsin physicians using the Med-E-Mail physician e-mail address database (Medical Marketing Services Inc., Wood Dale, Illinois). This is a proprietary database sourced from multiple contributors. The response rate was low (4%), precluding accurate quantification of existing telemedicine resources within the state; however, perceived need for access to telemedicine was identified. Fifty percent of respondents (n = 57) do not currently have access to telemedicine resources. Of these, 65% (n = 37) report interest in gaining access to additional services via telemedicine and only 18% (n = 10) are aware of plans to establish telemedicine services at their institution. When asked about the subspecialty services they anticipate they would most likely consult, responses were highly variable and differed greatly from the reported subspecialty utilization by those currently using telemedicine for consultation purposes (Figure 2). The discrepancy between anticipated consultation and reported consultation was greatest for the pediatric subspecialty. Only 9% of respondents report consultation of a pediatric service. However, 46% of those without access to telemedicine report that they would likely consult pediatricians, possibly an indication of a lack of comfort with this age group. Also notable was that the anticipated frequency of consultation exceeded the reported frequency of consultation in all but 3 subspecialties (psychiatry, general surgery, radiology), which could speak to general

enthusiasm for access to telemedicine resources by those who currently operate without them. While the sample size of this survey does not allow for proper statistical analysis, the survey does demonstrate a perceived need for access to telemedicine and suggests a favorable environment for development of telemedicine programs.

The development of broad-based telemedicine programs and technology platforms offers opportunities to manage a patient population across the continuum of care, from home-based monitoring systems to improving local subspecialty care by remote presence of outreach providers. In Wisconsin, the growth of the telemedicine field likely will involve the creation of new telemedicine programs to address specific medical conditions but also will include the optimization of existing resources. Efficiency of resource allocation will require more than a market-based approach but also a collaborative approach between the state and regional health care networks to identify resources, needs, and gaps to appropriately implement telemedicine programs and state and national health care reforms. As the authors of this letter continue to consider methods to better describe the state of telemedicine within the state of Wisconsin, we urge others to do the same as informed planning will increase the likelihood of successful expansion of this promising field.

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**Funding/Support:** This project was funded by a grant from the Laura P. and Leland K. Whittier Virtual PICU Fellowship (Russell, Rice).

**Figure 1.** Telemedicine Survey Sample Questions

Instructions: If you practice at more than one institution, please answer such that responses are reflective of the institution where you practice primarily.

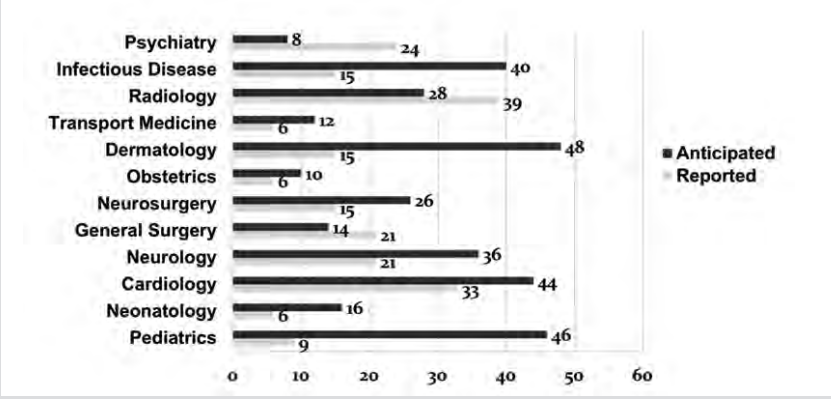
**1. Which of the following best describes telemedicine resources within your institution? (Please select one.)**
- ❑ My institution uses telemedicine to access services provided by remote consultants.
- ❑ My institution uses telemedicine to access services not available onsite AND also provides services to others via telemedicine.
- ❑ My institution provides services to others via telemedicine.
- ❑ My institution does not use telemedicine to access services from remote consultants nor does it provide services to others via telemedicine.

**2. Which of the following describes the services that you access via telemedicine? (Check all that apply.)**
- ❑ Consultation with a remote consultant using two-way video and audio (provider requesting consultation and remote consultant are able to view and hear one another).
- ❑ Consultation with a remote consultant using one-way video and two-way audio (video is transmitted to the remote consultant with audio available to both parties).
- ❑ Consultation with a remote consultant other than a radiologist using store-and-forward technology (audio, video, or imaging that is stored and then forwarded to the remote consultant).
- ❑ Consultation with a remote radiologist for review and interpretation of imaging studies, eg radiographs, CT scans, etc.
- ❑ Other (please specify)_____

**3. From which of the following specialty services do you most commonly request a consultation? (Check all that apply.)**
- ❑ Pediatrics
- ❑ Neonatology
- ❑ Cardiology
- ❑ Neurology
- ❑ General Surgery
- ❑ Neurosurgery
- ❑ Obstetrics
- ❑ Dermatology
- ❑ Transport Medicine
- ❑ Radiology
- ❑ Infectious Disease
- ❑ Other (please specify) _____

**4. If a remote provider is consulted, which of the following are the most common reasons for consultation? (Check all that apply.)**
- ❑ Emergent/urgent management of a critical patient.
- ❑ Nonemergent management of a patient requiring specialty services not available onsite, eg pediatrics, neonatology, cardiology, dermatology.
- ❑ Interpretation of imaging studies by remote radiologist.
- ❑ Other (please specify)_____

**Figure 2.** Anticipated Frequency (%) of Consultation vs Reported Service Use (% Reporting Consultation) Among Non-users of Telemedicine.

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# Wisconsin Medical Society

**Physicians and their health care teams face two significant transitions in the near future—a new Medicare Administrative Contractor (MAC) and ICD-10 implementation. Look no further than the Wisconsin Medical Society for the information you need to navigate these and many other changes now and in the months ahead.**


The Society's 14th annual Symposium features top-notch speakers sharing their wealth of knowledge about practice management, coding, billing, quality and compliance, and ICD-10. The Symposium also offers participants opportunities to meet and network with peers and colleagues to share ideas and discuss innovative solutions.

**September 22-24, 2013 • Kalahari Resort, Wisconsin Dells**

Participants are eligible for up to 16 continuing education units (CEUs) from the American Academy of Professional Coders (AAPC) and Practice Management Institute (PMI).

• • •

The Society is pleased to welcome National Government Services (NGS)—the new MAC for Jurisdiction 6—to its fall Medicare seminar. Christine Obergfell of NGS and Sandy Stehli of SVA will join the Society's Jen Cohrs for this full-day, information-packed learning opportunity. The morning session will focus on the Medicare Physician Fee Schedule and other hot topics, and the afternoon session will give participants the opportunity to learn about NGS.

**October 29:** Madison • **October 30:** Brookfield • **October 31:** Green Bay

• • •


ICD-10 will affect all aspects of health care in 2014, and the Society is partnering with the Wisconsin Hospital Association and Wisconsin Medical Group Management Association to make sure physicians and their staffs are ready. The ICD-10 Summit will set practice managers, coding and billing specialists, and health information professionals on the path to a successful implementation. Participants will have the tools and confidence for the go-live date of October 1, 2014.

**March 17-19, 2014** • Location: Kalahari Resort, Wisconsin Dells
Details and registration coming soon!

• • •

**For more information about these and many other learning opportunities, visit www.wisconsinmedicalsociety.org/resources/education.**
**To register, go to http://wismed.increachce.com**

# The National Anguish

D.N. Goldstein, MD, Editorial Director

*Editor's note: The following is an editorial published in* WMJ, *Volume 62, p. 358, August 1963.*

The racial demonstrations of 1963 may, in time, be recognized as events of great importance to the perfection of American democracy. The progress toward human equality before the law proclaimed by the Constitution of the United States and its amendments, and pragmatically confirmed by the Emancipation Proclamation, is measured now by the demonstrations. Our country is being asked by a group of citizens whether it is only masquerading to the world as an exponent of human rights. The mettle of our social structure stands tested in a way that may determine the ultimate destiny of our nation and the principles on which it was founded.

These are stirring times in which we live. The demonstrations for racial equality expose such critical issues in our democracy that we stand as much at a crossroad of destiny as Americans did in the summer of 1861. Because the Negro community of Wisconsin is relatively small and concentrated in the industrial counties, the issue of racial equality may seem remote to many of our citizens. But the issue is not industrial or metropolitan or Southern. It is a national issue. It is a human issue. Above all, it is a moral issue, and that is why it is an important issue to discuss in the editorial pages of a medical journal. For we are human beings as well as doctors.

Racial inequality has cost America dearly. The thousands of lives in the Civil War to establish, among other things, that slavery was not part of American culture must ever remind us that no man bears a heritage of servitude because of an accident of birth. In the century since the legal end of slavery in this country we have taxed ourselves heavily by depriving ourselves of the human resources that might have been available to us if all of our citizens had, in fact, equal opportunity. We have imposed a burden of bigotry on our national character that has made our posture in the family of nations hypocritical.

If they succeed in no other respect, the demonstrations will have forcefully shown that the problems on the Negro minority are national problems. They will have shown that discrimination because of race is wrong—economically, socially and morally. It is to be hoped that the demonstrations proceed peacefully, without the hoodlumism and impatience that could alienate the public opinion so necessary to the Negro cause. But no matter how the events of this summer transpire, nobody—no bigot, no politician, no backwater demagogue—will ever again be able to use the tired wheezes of "state rights" or "inalienable right of the majority to oppress a minority" as an excuse to support a stance of racial superiority. Respectability and morality go hand in hand, and respectable America can no longer afford the immorality of racial discrimination.

As doctors, and respectable members of our community, we will take the lead in sympathizing the goals of the peaceful, responsible demonstrators, and we will use our position to explain their methods and their purposes.

—DNG

# Communication as Prevention: The Value of Talking With Each Other

John J. Frey, III, MD, Medical Editor

This issue of the journal has 3 articles that emphasize the value of communication in preventing adverse outcomes for patients and communities. As physicians, we have to talk both with our patients about future issues that will affect their health and with each other about the patients we share. Sadly, these articles also remind us of the potential consequences from a lack of communication.

I remember a patient who, in response to my question about why he had come, said, "I turned 40 this month and I guess there are some things I should get checked." While there are few differences in the recommendations from the US Preventive Services Task Force at 40 than for the decade before and the decade after, I took the opportunity to ask my patient whether he and his wife had a will, and if they had talked about and made decisions about advance directives. His belief was that such things were for old people. I responded that he was older now than a month ago, that the burden of a sudden devastating illness in a young person fell on his family, and that it was the responsible person who would have something in place to guide them. The next time I saw him, he had it done.

The exploratory study by Sharma and colleagues bravely looks at whether we physicians practice what we preach and sadly, to no one's surprise, we don't.[1] Even at Gundersen Health System, which with Mayo Health System has helped La Crosse become a national model for end-of-life care, less than half of the faculty at their community cancer center had advance directives. Even with its low response rate, their survey of US oncologists raises issues that must be addressed. While the respondents who were older had the documents, less than 40% of those who had them had discussed them with their personal physicians. No data were gathered about whether they had a primary care clinician and, if they did, whether that physician inquired about end-of-life documents. If we as doctors don't ask our patients, we have to take a great deal of responsibility for the low prevalence of such documents in our communities. When we are sitting with families and patients deciding such issues after they arise—as they always do—"don't ask, don't tell" is a strategy that will lead to the kind of tragedies all of us have experienced. Both Wisconsin and Minnesota have taken strides toward supporting work in end-of-life care, both our patients' and our own, with the Wisconsin Medical Society building on previous programs through its Honoring Choices Wisconsin program,[2] but there is much work to be done in this area.

As physicians, we have to talk both with our patients about future issues that will affect their health and with each other about the patients we share.

It is redundant to say that falls are an increasing source of morbidity and mortality in this country as we see larger numbers of us age into the balance- and strength-challenged generation.[3] And larger numbers of us will end up spending part of our lives in nursing homes. So decreasing the potential for falling in nursing homes is a very big deal. Chapman and Newenhouse's survey of nursing home staff and administrators in largely rural institutions found that communication among staff about changes in a patient's condition was the largest modifiable variable that could influence the rate of falls.[4] Doctors who care for nursing home patients must sit with lead nurses and staff to talk about patients, with a particular attention to falls potential. And nursing home staff should talk with each other for the same reason. While physicians and patient care staff huddling together prior to a clinic session or hospital rounds seems to be a logical way to plan the day, it rarely happened until recent increased emphasis on medical home and patient-centered care prescribed it as one of the essential components for the process. Chapman and Newenhouse also point out what many urban clinicians may not know, which is that falls are a greater risk in a rural population than urban nursing home populations. Their findings should challenge hospital systems that work with rural nursing homes to provide ongoing education, assistance, and support for the in-facility and between-facility challenges for falls prevention.

The encouraging data from the article by

Layde and Remington[5] on the decade long decrease in teen pregnancies in Wisconsin are tempered somewhat by the continued, although narrowing, discrepancies between white and black populations and by the distressing data on increases in the American Indian and Latino populations. While the authors were able to describe only county and state trends, the discussion in this paper highlights a community and public health research agenda that would help identify effective methods for decreasing teen pregnancies. One can hope that the increased conversations at school, social centers, and in families about encouraging teens to use contraceptive methods to avoid pregnancy and take responsibility for themselves and others has had some effect on these trends. Physicians can offer guidance and advice and birth control—not inconsequential components of a program of prevention. What also is needed however, as the authors point out, is continuity conversations among teens, teachers, parents, and the community at large about attitudes and behaviors that might help young people be parents when they are better able to fulfill that role.

Two case reports highlight the vulnerability of kidneys to unexpected adverse effects. Dabigatran is a popular newer agent for prevention of the thrombotic consequences of surgical and cardiac illnesses but, like many new agents each year, can have unintended serious consequences that are not widely known. Shafi and colleagues[6] do a service for us all through their reporting of a case of acute renal failure that should alert others who prescribe dabigatran. Murphy and colleagues report a case[7] of biopsy proven tubular injury and Fanconi syndrome likely caused by deferasirox, which is an agent primarily used in iron-overload syndromes where phlebotomy is not an option. Although the patient they describe had a number of serious ongoing medical problems relating to cancer care, the case reminds us to think first of medications as a potential cause of deterioration, since this is something we can change and potentially reverse the problem, which it did in this case.

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# An Exploratory Study of the Use of Advance Directives by US Oncologists

Umesh M. Sharma, MD; Jonean E. Schroeder, BS, RN; Mohammed Al-Hamadani, MS; Michelle A. Mathiason, MS; Christine M. Meyer; Kathleen A. Frisby, RN, BSN; Lori A. Meyer, RN; Debbie L. Sieber, BS; Ronald S. Go, MD

## ABSTRACT

**Purpose:** This study sought to determine the rate of advance directive completion among US oncologists and factors influencing such a decision.

**Methods:** We surveyed 7590 members of the American Society of Clinical Oncology using a web-based questionnaire.

**Results:** The response rate was 8.1%. Most respondents (59%) had completed at least 1 document: 9% living will, 9% power of attorney for health care, and 41% both. Respondents who were older, men, married, with children, working in the community setting, radiation oncologists, and practicing general oncology were more likely than their counterparts to have an advance directive. Among those who had one, 95% and 36% had discussed their wishes with their loved ones and health care providers, respectively. Factors including experience at work, spouse, children, family, and religion had the most influence on respondents' decision. The majority of those without an advance directive reported either no reason or lack of time. Those who had them were more likely to report having a comprehensive review of their wishes with those closest to them, being more knowledgeable, having more routine discussions with their patients, and being more comfortable helping their patients complete one.

**Conclusion:** Only about half of US oncologists who responded to our survey have completed an advance directive.

## BACKGROUND

Advance care planning is an important and ongoing process in which people discuss their health care goals and preferences with their loved ones and their health care providers. These discussions are intended to determine the patients' wishes regarding such issues as resuscitation and use of advanced life support at the end of life, and to help them choose appropriate health care agents who will make decisions on their behalf if they should lose the capacity to decide for themselves. To document those decisions, patients often complete an advance directive, a document that includes written instructions regarding their decisions regarding end-of-life health care.[1] The most common types of advance directives are: (1) the living will, which lists instructions for medical care; (2) the power of attorney for health care, which designates another person to make decisions on the patient's behalf; and (3) a combined document that has features of both the living will and the power of attorney for health care.[1] Without an advance directive, patients who have lost decision-making capacity might receive unwanted aggressive care, which can lead to worsened quality of life for patients and a more difficult bereavement adjustment for caregivers.[2,3]

The Patient Self-Determination Act of 1990 requires all medical facilities certified by Medicare and Medicaid to provide patients with advance directive information and to advise them of their right to accept or refuse medical treatments.[4,5] Most people have discussed their advance care planning with their family members at some point, yet less than 25% of patients have a written document that is available to their health care providers.[1] Even when patients have an advance directive, their physicians may be unaware of its existence.[4] This is true even among patients with serious illnesses such as cancer. A recent study showed that less than half of seriously ill admitted oncology patients at an urban academic medical center had an advance directive.[6] The completion rate for health care providers—even those who care for cancer patients—is not different from that of patients.[5,7,8] At our own community cancer center, only 35% of the 134 health care professionals who have face-to-face patient contacts had a written advance directive. Among those with advance directives, 66% had informed their primary care providers. More importantly, just 58% of our 13 oncologists had completed an advance directive.[8]

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Oncologists often care for patients who are near the end of their lives and, as such, it might be assumed that they are also involved with patients' end-of-life care issues and advance directive discussions. Yet neither oncologists' attitudes toward advance directives nor their completion rates have been systematically captured, analyzed, and reported. The aims of this study were to document the rate of advance directive completion among oncology physicians in the United States, to identify the factors that influenced their decision to complete an advance directive, and to find out whether those who had an advance directive had communicated its existence to their health care provider.

## METHODS

The American Society of Clinical Oncology (ASCO) is the largest oncology society in the world, representing over 30,000 oncology professionals from 120 countries and encompassing all subspecialties. Using the ASCO membership book, we identified ASCO members who had an MD or equivalent degree, lived in the United States, and were actively involved in clinical oncology care. The Gundersen Clinic Human Subjects Committee/Institutional Review Board exempted the study because we did not collect any respondent identifiers in our anonymous web-based survey. Between June 2007 and December 2007, the survey (available online at: www.wisconsinmedicalsociety.org/_WMS/publications/wmj/pdf/112/4/sharma_survey.pdf) was sent to these ASCO members via e-mail. For purposes of the study, advance directive was defined as either a living will and/or a power of attorney for health care. In addition to information regarding advance directive, the survey captured demographic data (age, sex, marital status, number of children) and practice data (type, setting, specialty, location, time spent in direct patient care, and year of oncology training completion). Using the Agency for Healthcare Research and Quality survey guideline definitions, we identified incomplete surveys and excluded them from the analyses.[9] Data were analyzed using SAS statistical software, version 9.3 (SAS Institute, Inc., Cary, NC). The $\chi^2$ test was used to compare groups.

## RESULTS

We emailed the survey to 7590 ASCO members who met our inclusion criteria. Of these, 614 (8.1%) responded to the survey. We excluded 37 surveys because less than half of the research questions had been answered. The demographic and clinical practice features of the 614 respondents included in the final analysis are described in Table 1. Most were men, age 50 years or older, married with children, and community oncologists devoting over 75% of their time to caring for adult patients.

A slight majority (58.8%) of the respondents had completed at least 1 of the advance directive documents: 9.0% living will alone, 8.6% power of attorney for health care alone, and 41.2% both documents. Respondents who were older than 50 years (74.9%), were men (64.5%), were married (60.0%), had children (62.1%), worked in the community setting (65.5%), were radiation oncologists (78.1%), and practiced general oncology (62.3%) were more likely than their counterparts to have advance directives (Table 2). Among those with advance directives, 95.3% and 36.3% had discussed their wishes with their loved ones and health care providers, respectively. All (100%) of those with advance directives reported that their documents were in their medical records.

Factors such as experience at work (66.5%), spouse or domestic partner (46.3%), children (21.6%), family or friends (11.4%), and spirituality or religion (10.3%) had the most influence among respondents' decision to have an advance directive. The majority of those without one reported either no reason (52.2%) or lack of time (43.4%). See Table 3. Most (74.3%) of those without advance directives reported having discussed their wishes regarding future life-sustaining medical care with those closest to them. However, those with advance directives were more likely to report having had a comprehensive review of their wishes with those closest to them (54.9% vs 34.6%; $P < .001$), being more knowledgeable about advance directive (93.2% vs 85.0%; $P < .001$), routinely discussing advance directives with their patients (58.3% vs 49.4%; $P = .030$), and being more comfortable helping patients complete advance directives (93.0% vs 87.0%; $P = .013$). See Table 4.

## DISCUSSION

Despite working in oncology or related fields and having to discuss end-of-life issues with patients, nearly half of the ASCO members who responded to the survey do not have a written advance directive. This is not surprising because previous studies have shown that health care workers have advance directive completion rates similar to those of the general population.[5,7,8] This may be a reflection of health care providers' attitudes toward advance care planning—attitudes that likely influence the advance directive completion rate of their patients. As others have suggested, physicians need to address their own fears, concerns, goals for care, and quality-of-life issues before they can address them with patients.[10]

In our study, the typical oncologist who has completed an advance directive is a married man older than 50 years who has children, practices in the community setting, and spends over 75% of the time in direct patient care. In many ways, these qualities are congruent with the most common reasons described by respondents as having a positive influence on having an advance directive—namely, work experience, family, and health concerns. These findings are reinforced by a recent survey among cancer patients and medical staff at an oncology clinic, which showed that although the overall completion rate was low (<20%), respondents who were older, in poor health, or in pain were more likely to have the intention to complete an advance directive if given the opportunity.[7]

Barriers to patients completing advance directives have been studied, but reasons for health care providers not completing them remain largely unknown and under studied.[7,8] A robust debate on the utility of advance directives persists in the medi-

**Table 1.** Demographic and Clinical Practice Descriptions of Survey Respondents

| Characteristic | n (%) |
|---|---|
| **Men** | **428 (72.4)** |
| **Age, Years** | |
| <40 | 120 (20.9) |
| 40-49 | 139 (24.2) |
| 50-60 | 199 (34.7 |
| >60 | 116 (20.2) |
| **Marital Status** | |
| Single | 46 (7.8) |
| Married | 513 (86.8) |
| Separated | 5 (0.8) |
| Divorced | 16 (3.9) |
| Widowed | 4 (0.7) |
| **Number of Children** | |
| 0 | 103 (17.5) |
| 1-2 | 296 (50.3) |
| >3 | 189 (32.1) |
| **Practice Setting** | |
| Academic | 225 (37.5) |
| Community with teaching | 127 (21.2) |
| Community without teaching | 224 (37.3) |
| Government | 10 (1.7) |
| Other | 14 (2.3) |
| **Primary Practice** | |
| Adult hematology-oncology | 494 (82.3) |
| Pediatric hematology-oncology | 16 (2.7) |
| Radiation oncology | 32 (5.3) |
| Surgical oncology | 36 (6.0) |
| Other | 22 (3.7) |
| **Practice Specialty (may choose more than one)** | |
| Brain cancer | 156 (25.4) |
| Breast cancer | 260 (42.3) |
| Gastrointestinal cancer | 222 (36.2) |
| General oncology | 385 (62.7) |
| Genitourinary cancer | 189 (30.8) |
| Gynecological cancer | 147 (23.9) |
| Head and neck cancer | 170 (27.7) |
| Hematologic cancer | 250 (40.7) |
| Lung cancer | 210 (34.2) |
| Melanoma | 185 (30.1) |
| Palliative care | 190 (30.9) |
| Sarcoma | 153 (24.9) |
| Other | 30 (4.9) |
| **Practice Location (states)** | |
| Atlantic (NJ, NY, PA) | 41 (6.9) |
| Great Lakes (IL, IN, MI, OH, WI) | 85 (14.2) |
| Midwest (IA, KS, MN, MO, ND, NE, SD) | 71 (11.9) |
| Mountain (AZ, CO, ID, MT, NM, NV, UT, WY) | 42 (7.0) |
| Northeast (CT, MA, ME, NH, RI, VT) | 29 (4.9) |
| Pacific (AK, CA, HI, OR, WA) | 119 (19.9) |
| Southeast (DC, DE, FL, GA, MD, NC, SC, VA, WV) | 107 (17.9) |
| South (AL, KY, MS, TN) | 34 (5.7) |
| West (AR, LA, OK, TX) | 68 (11.4) |
| **Time Spent in Direct Patient Care, %** | |
| >75 | 378 (63.0) |
| 50-74 | 111 (18.5) |
| 25-49 | 51 (8.5) |
| 1-24 | 48 (8.0) |
| None | 12 (2.0) |
| **Year Completed Oncology Training** | |
| Before 1980 | 125 (21.3) |
| 1980-1999 | 305 (51.9) |
| After 1999 | 133 (22.7) |
| None | 24 (4.1) |

**Table 2.** Characteristics of Respondents and Completion of Written Advance Directive (AD)

| Characteristic | n | No. with AD (%) | *P* Value |
|---|---|---|---|
| **Age, Years** | | | |
| <50 | 299 | 125 (41.8) | <.001 |
| >50 | 315 | 236 (74.9) | |
| **Sex** | | | |
| Women | 163 | 73 (44.8) | <.001 |
| Men | 428 | 276 (64.5) | |
| **Marital Status** | | | |
| Married, divorced, separated, or widowed | 540 | 324 (60.0) | .057 |
| Single | 46 | 21 (45.7) | |
| **Children** | | | |
| 0 | 103 | 46 (44.7) | .001 |
| >1 | 485 | 301 (62.1) | |
| **Completion of Medical Training** | | | |
| Before 1990 | 302 | 231 (76.5) | <.001 |
| On or after 1990 | 235 | 98 (41.7) | |
| **Practice Setting** | | | |
| Academic | 225 | 108 (48.0) | <.001 |
| Community with teaching | 127 | 82 (64.6) | |
| Community without teaching | 224 | 148 (66.1) | |
| Other | 24 | 14 (58.3) | |
| **Primary Practice** | | | |
| Adult hematology/oncology | 494 | 292 (59.1) | .042 |
| Pediatric hematology/oncology | 16 | 7 (43.8) | |
| Radiation oncology | 32 | 25 (78.1) | |
| Surgical oncology | 36 | 19 (52.8) | |
| Other | 22 | 9 (40.9) | |
| **Practice Specialty** | | | |
| General oncology | 385 | 240 (62.3) | .021 |
| Other | 229 | 121 (52.8) | |
| **Practice Location** | | | |
| Midwest (Midwest, Great Lakes) | 299 | 125 (41.8) | .587 |
| Northeast (Northeast, Atlantic) | 70 | 40 (57.1) | |
| South (South, Southeast, West) | 161 | 97 (60.3) | |
| West (Pacific, Mountain) | 163 | 73 (44.8) | |
| **Time Spent in Direct Patient Care, %** | | | |
| >75 | 489 | 288 (53.3) | .050 |
| <75 | 378 | 233 (61.6) | |

**Table 3.** Factors Influencing the Decision to Have an Advance Directive[a] (AD)

| Factor | AD (n=361) | No AD (n=253) |
|---|---|---|
| Experience at work | 66.5 | — |
| Spouse or domestic partner | 46.3 | 4.0 |
| Children | 21.6 | 1.2 |
| Other family members or friends | 11.4 | 0.4 |
| None | 15.5 | 52.2 |
| Religion/spirituality | 10.3 | 0.8 |
| Medical condition or illness | 7.5 | 1.2 |
| Financial advisor/attorney | 5.0 | — |
| Media | 4.4 | 0.0 |
| Old age | 0.4 | — |
| Lack of time required to complete written AD | — | 43.4 |
| Healthy/young | — | 5.5 |
| Lack of discussion by primary care provider | — | 4.3 |
| Lack of value | — | 1.6 |
| Non-US citizen | — | 0.4 |

[a]All data are presented as percentage of respondents with or without an AD who indicated the factor.

cal literature, with evidence suggesting that patient-designated and next-of-kin surrogates incorrectly predict patients' end-of-life preferences in one-third of the cases.[10-13] Another potential explanation is the influence of culture and society on patient attitudes toward advance directives. In one study, 80% of the patients in the United States had negative feelings toward end-of-life care, compared with only 45% in Japan.[14] Workplace-based interventions, such as electronic reminders or designating a department meeting once a year for advance directive completion, may boost completion rates. Our study suggests that cancer care providers might be easily persuaded to complete their advance directives because over three-fourths of respondents reported already having had end-of-life discussions with their loved ones.

Although the response rate was low, our study is the largest survey of US oncologists regarding advance directives to date. Nevertheless, caution is necessary in interpreting the results because they may not be representative of most oncologists in the United States. Because this was a web-based survey that required self-reporting, subjective interpretation of the questions and answer choices could not be avoided. Because of the exploratory nature of our study, we did not perform a multivariate analysis. Many of the variables associated with having an advance directive may also be associated with each other—for example, age, marital status, number of children, and year of completion of medical training (Table 2).

Regrettably, forces beyond the physician-patient relationship may become barriers to efforts to promote end-of-life discussions. A recent *New York Times* editorial aptly described how politics—both secular and religious—can hinder advance directive discussions between physicians and patients.[15] Nevertheless, many health care organizations, including ours—Gundersen Health System in La Crosse, Wisconsin—have been successful in implementing community-wide advance care planning.

**Table 4.** Discussion of Advance Directives (AD) with Family and Patients[a]

| Questions | AD n=361 | No AD n=253 | *P* Value |
|---|---|---|---|
| **Have you discussed your wishes regarding future life-sustaining medical care with those closest to you?** | 95.3 | 74.3 | <.001 |
| **Which of the following best describes the level of discussion you have had with those closest to you?** | | | |
| A few comments about your wishes | 6.4 | 10.6 | |
| A brief conversation about your wishes | 16.0 | 18.1 | |
| A limited exchange of ideas about your wishes | 22.7 | 36.7 | <.001 |
| A comprehensive review of your wishes | 54.9 | 34.6 | |
| **What is your level of knowledge regarding advance directives?** | | | |
| Very knowledgeable | 58.6 | 52.2 | |
| Knowledgeable | 34.7 | 32.8 | <.001 |
| Somewhat knowledgeable | 6.8 | 13.4 | |
| Not knowledgeable | 0.0 | 1.6 | |
| **What percentage of your patients do you discuss an advance directive with?** | | | |
| 0 | 1.7 | 5.1 | |
| 1-24 | 16.6 | 23.7 | |
| 25-49 | 23.4 | 21.7 | .030 |
| 50-74 | 28.2 | 32.4 | |
| 75-100 | 30.1 | 17.0 | |
| **What is your level of comfort in helping patients with an advance directive?** | | | |
| Very comfortable | 60.9 | 45.5 | |
| Comfortable | 32.1 | 41.5 | .013 |
| Somewhat uncomfortable | 6.2 | 10.7 | |
| Not comfortable | 0.9 | 2.4 | |

[a]All data are presented as percentage of respondents with or without an AD indicating the level of discussion, knowledge, or comfort with ADs.

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# Nursing Home Staff Perception of a Falls Management Intervention

Larry J. Chapman, PhD; Astrid C. Newenhouse, PhD


## ABSTRACT

**Background:** Many nursing home fall injuries are believed to be preventable. Little is known about the fall prevention activities nursing homes are using.

**Methods:** We conducted a census of all nursing homes in 6 Wisconsin counties by mailing a needs assessment to administrators and directors of nursing. Later we mailed a report of the results, an information intervention (an annotated list of falls management resources), and a follow-up questionnaire.

**Results:** Respondents believed that the most important barriers to better falls management in typical Wisconsin nursing homes were the fall-prone character of the population (80%), followed by the need for staff to communicate changes in a resident's condition better and more quickly (58%). Most felt that the components they needed to improve in their own nursing home were training for new staff (71%) and communicating any immediate care plan changes (65%). Respondents reported getting useful fall prevention information in the last year from in-house physical and occupational therapists (87%) and conferences, workshops, or meetings (82%). They were most interested in receiving new information about how to train their staff to analyze resident fall data and develop prevention plans (76%) and where to find training videos (68%). Forty-four percent reported becoming personally more aware of falls management resources and 31% reported that their nursing home had adopted changes in falls management activities in the last 7 months at least in part as a result of our intervention.

**Conclusion:** Information dissemination interventions can increase awareness and changes in nursing home falls management activities.


## INTRODUCTION

Many nursing home falls and serious fall injuries are believed to be preventable. Research on nursing facility falls has yielded best practice recommendations and other tools and resources.[1-5] Some nursing homes appear to be gradually adopting and improving falls management programs while others lag behind. When successful, falls management efforts can result in older adults experiencing a higher quality of life, contribute to a greater ease of delivery of care by nursing home staff, and lower the overall cost of care.[6,7]

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As part of a larger effort funded by the US Department of Agriculture, we were interested in learning more about how nursing home staff, especially those in more rural compared to urban counties, viewed fall prevention efforts, what they were currently doing to prevent falls, and how they wanted to improve. Our efforts resulted in an information dissemination intervention to nursing home staff.

## METHODS

### Needs Assessment Questionnaire Development and Administration

We developed a 4-page needs assessment questionnaire that focused on falls management and efforts to reduce fall risks in nursing facilities. We designed the questionnaire as a needs assessment so respondents would be less likely to feel their facility's programming was being evaluated against others. The questions were designed to be easy to complete, with a dozen or more possible responses so that respondents could check them off. Each question included an open-ended response marked "other." A copy of the questionnaire is available online for modification and use by others with the provision that a note identifying the funding source and grant number be included.[8]

We used the methods of the widely recognized Dillman mail survey method to administer the needs assessment questionnaire.[9,10] Our initial mailing to subjects included a stamped, pre-addressed return envelope and a cover letter describing the survey's purpose, funding source, and privacy protections. Cover letter wording encouraged respondents to participate by describing how completing the survey could benefit nursing facility residents and staff. After 10 days, we sent nonrespondents a reminder postcard. After 14 more days, we sent any remaining nonrespondents a complete second mailing. The University of Wisconsin's social and behavioral science human subjects internal review board approved our procedures and our questionnaire.

### Information Intervention Development and Administration

Three months after the needs assessment was mailed out, we developed and mailed a 4-page report of the results to the same list of administrators and directors of nursing we originally mailed to at all the nursing homes. This mailing went to respondents and nonrespondents. In the same mailing, we included a 4-page annotated list of resources we had developed that provided internet links and surface mail addresses for a variety of types of fall prevention training resources and other information that respondents had requested on the needs assessment questionnaire. We ordered the list according to which information the respondents had requested most often on Question 4 (ie, "Are you interested in obtaining any of the following information about falls management programs?"). The resource list we developed emphasized training materials and information that were consistent with evidence-based best practices, peer-reviewed or used in articles published in peer review journals, and were in the public domain. A copy is available online for modification and use by others with the provision that a note identifying the funding source and grant number be included.[11]

### Follow-up Questionnaire Administration

We also developed a short, single-page follow-up questionnaire with 3 questions and yes or no check box responses. We asked whether individuals had personally become more aware about falls management resources at least in part as a result of our mailings, whether their nursing facility had adopted changes in falls management activities in the last 7 months at least in part as a result of our mailings, and whether their nursing facility had begun the process to adopt changes in falls management activities in the next 6 months at least in part as a result of our mailings. Six months after the needs assessment was mailed and 3 months after the report and list of resources were mailed, we administered the follow-up questionnaire to the same group (respondents and nonrespondents), with the same reminder postcard and remailing.

### Subjects

We were interested in getting responses to our questions from individuals working in nursing facilities who could best reflect the totality of their organization's activities and perceptions. Nursing home administrators were chosen because they could provide an overall picture that included their knowledge from the business and regulatory perspective of their nursing facility. Directors of nursing were chosen because they could provide a perspective that was more oriented toward daily experience with actual clinical care aspects. In practice, there was some overlap in perspectives and experience between the 2 groups. We were also interested in comparing nursing homes in largely rural counties with those in more urban counties. We selected 5 largely rural counties in Wisconsin, based on the US Department of Agriculture definitions.[12] We mailed our questionnaire to the nursing home administrator and director of nursing at every nursing facility in the 5 counties using a list provided by the Wisconsin Division of Quality Assurance. This comprised a census of 22 nursing facilities in the rural counties.[13] We also mailed surveys to a comparison group made up of a census of all 21 nursing facilities located in a largely urban county in Wisconsin.

**Table 1.** Study Subjects and Return Rates

| Questionnaires | Mailed | Needs assessments returned (rate) | Follow-up returned (rate) |
|---|---|---|---|
| **Type of Respondent** | | | |
| Nursing home administrators | 43 | 16 (37%) | 19 (44%) |
| Directors of nursing | 42[a] | 23 (55%) | 25 (60%) |
| **Type of County** | | | |
| More urban | 42 | 12 (29%) | 12 (29%) |
| More rural | 43 | 27 (63%)[b] | 30 (70%)[c] |
| Total | 85 | 39 (46%) | 45 (53%) |

[a] Two nursing homes shared a single director of nursing
[b] Significant difference for type of county with $P<0.048$ rural vs urban on 2-sided Pearson chi-square.
[c] Significant difference for type of county with $P<0.021$ rural vs urban on 2-sided Pearson chi-square.

### Data Analysis and Statistics

Reasonably complete returned questionnaires (those with more than two-thirds of the questions answered) were coded and entered into a database. All questionnaires were manually checked to verify the accuracy of data entry. IBM SPSS Statistics version 20 (IBM Corporation, Armonk, New York) was used to make comparisons between administrators and directors of nursing and between rural counties and the urban county. The Pearson's chi-square test (2-sided) was used to compare percentages and Student's $t$ test (2-tailed) was used to compare numerical values after Levene's test for equality of variances. No adjustments were made for multiple statistical comparisons.

## RESULTS

### Questionnaire Subjects and Return Rates

Return rates were 46% overall for the needs assessment questionnaire (Table 1). Respondents from nursing homes in the 5 more rural counties were more likely to return their questionnaires than respondents from nursing homes in the more urban county (63% vs 29%; $P<0.048$).

Return rates were 53% overall for the follow-up questionnaire administered 7 months after the needs assessment questionnaire. Again, personnel from the more rural county nursing homes were more likely to return the questionaires than those from the more urban county (70% vs 29%; $P<0.021$).

### Barriers to Better Fall Prevention in Typical Nursing Homes

Respondents were asked what barriers they saw as "extremely important" to improve fall prevention in typical Wisconsin nursing homes that serve older adults. Respondents most often

**Table 2.** Respondent Reports of "Extremely Important"[a] Barriers to Better Fall Prevention in Typical Wisconsin Nursing Facilities (n=38-39)

| Barrier | Extremely Important |
|---|---|
| Nursing facility residents are a fall-prone population. | 80% |
| Need for better and quicker communication of changes in a resident's condition. | 58% |
| Nursing assistants need better training in falls management. | 44% |
| Nursing leadership needs to prioritize falls management. | 44% |
| Nursing leadership needs to listen to and learn more from nursing assistants. | 42% |
| Staff ratio too low to afford better falls management. | 42%[b] |
| Direct patient care takes up nearly all time. | 37% |
| Nursing leadership needs to provide better support to nursing assistants. | 33% |
| Need to identify more affordable materials & training to implement best practices. | 31% |
| Nursing assistants need incentives to become more conscientious about falls. | 23%[c] |
| Too difficult to identify best practices for improving falls management. | 24% |
| Staff turnover rate among nursing assistants is too high. | 16% |
| Other. | 13% |

[a] Survey question: "How important do you believe the following potential barriers are to improving falls management at typical nursing facilities in Wisconsin serving older adults?" (Results reportd indicate percent responding "Extremely Important" on a scale of Extremely Important, Somewhat Important, Not Important.)
[b] Significant difference for type of county ($P<0.014$; urban 1.909 vs rural 2.518 for continuous variable, where Not Important=1, Somewhat Important=2 and Extremely Important=3).
[c] Significant difference for type of respondent ($P<0.05$; administrator 1.533 vs director of nursing 2.043).

checked the response "nursing facility residents are a fall-prone population" (80%) (Table 2). More than half cited the "need for better and quicker communication of changes in a resident's condition" as an extremely important barrier (58%). The third most cited extremely important barrier was that "nursing assistants need better training in falls management" (47%). Significantly more rural than urban respondents rated "staff ratio too low to afford better falls management" as extremely important ($P<0.014$). Significantly more administrators than directors of nursing rated "nursing assistants need incentives to become more conscientious about falls" as extremely important ($P<0.05$).

### Fall Prevention Activities in Need of Improvement

When asked about 17 components of a comprehensive multifactorial fall prevention effort in their own facility, respondents most often cited "training new staff in how falls management fits in" as "needs to improve" (71%) (Table 3). Next most cited as needing improvement was "communicating any immediate care plan changes to nursing assistants and other staff" (65%) after team meetings, followed by "getting nursing assistants and other staff to enact changes quickly and carefully" after investigating a resident's fall (63%), and "getting nursing assistants and other staff to enact changes quickly and carefully" after team meetings to evaluate the response to a resident's fall (63%). Significantly more rural than urban respondents rated "getting the team to quickly decide on any additional changes in each resident's plan" as an area that needs to improve ($P<0.003$) (Table 3).

Nearly all nursing homes were using a multifactorial approach that included evaluating the fall risk of new residents, investigating resident falls, conducting team meetings to evaluate the response to a resident's fall, and taking steps to change their nursing home's organization to manage falls better. On the other hand, 21% reported that they don't "provide support to nursing assistants so they have incentives to achieve fall prevention goals" and 13% reported they "don't use" team meetings to "discuss and evaluate each resident's fall from the day before and any immediate care plan changes in daily team meetings" (Table 3).

### Sources of Useful Fall Prevention Information

When asked where they got useful fall prevention information in the last year, most respondents identified as sources their facility's occupational or physical therapist (87%); conferences, workshops, or meetings (82%); in-house nurses (79%); in-house nursing assistants (76%), and professional journals in their field (66%). Many also reported obtaining information on fall prevention from newsletters of their professional organizations (55%) and during in-house training sessions (58%) (Table 4).

Significantly more administrators than directors of nursing (73% vs 30%) reported getting fall prevention information from professional organization staff ($P<0.019$), while more rural than urban respondents obtained information from occupational or physical therapists outside their own nursing home, journals in their field or other publications and online from the Wisconsin Association of Homes and Services for the Aging ($P\leq0.038$) (Table 4).

### Information of Interest to Respondents

Most respondents were interested in obtaining information about how to improve their staff's ability to analyze resident fall data and develop prevention plans (76%), and where to find video presentations to train staff and educate residents about falls management (68%). Nearly as many were interested in how to better assess and care for new residents in ways that reduce fall risks during their first weeks (65%) and how to get all staff to more quickly and more consistently adopt changes in individual resident care plans (62%). The same percentage wanted to know how to better communicate falls management information between staff (62%) and how to make better detailed assessments and investigations after a resident has fallen (62%) (Table 5).

Significantly more rural than urban respondents were interested in getting information about "how to make better detailed assessments and investigations after a resident has fallen," "where to find protocols, forms or other tools to guide immediate evalu-

**Table 3.** Respondent Reports of Fall Prevention Activities That Need to Improve, Are Working Well or Don't Use in Their Own Nursing Homes (n=37-39)[a]

| Falls Management Component Activity | Needs to Improve | Working Well | Don't Use |
|---|---|---|---|
| **Preventing Falls By New Residents** | | | |
| Communicating the plan to nursing assistants quickly and executing it carefully | 49% | 51% | 0% |
| Developing an individualized falls management plan for each new resident's initial weeks | 36% | 62% | 3% |
| Assessing each new resident for their fall risks guided by a protocol, form or other tool | 13% | 87% | 0% |
| **Investigating a Resident's Fall** | | | |
| Communicating any immediate care plan changes to nursing assistants and other staff | 67% | 33% | 0% |
| Getting nursing assistants and other staff to enact immediate changes quickly and carefully | 63% | 37% | 0% |
| Getting the resident and the resident's nursing assistants to contribute to the investigation and problem solving immediately following the fall | 54% | 46% | 0% |
| Getting nursing staff to immediately evaluate and investigate all falls guided by a protocol, form or tool | 46% | 54% | 0% |
| Making any immediate changes in the resident's care plan that are warranted | 42% | 58% | 0% |
| **Team Meetings to Evaluate the Response to a Resident's Fall** | | | |
| Getting nursing assistants and other staff to enact care plan changes quickly and carefully | 65% | 35% | 0% |
| Communicating any care plan changes quickly and clearly to nursing assistants | 51% | 49% | 0% |
| Discussing and evaluating each resident's falls from the day before and any immediate care plan changes in daily team meetings | 32% | 55% | 13% |
| Getting team to quickly decide on any additional changes in each resident's plan | 21%[b] | 76% | 3% |
| **Changing Your Organization** | | | |
| Training of new staff in how falls management fits in with other policies in our facility | 71% | 26% | 3% |
| Provide better support to nursing assistants so they have incentives to achieve fall prevention goals | 55% | 24% | 21% |
| Semiannual reviews of policies, procedures and documentation standards | 34% | 53% | 13% |
| Periodic, collective review, identification and analysis of trends in resident falls throughout the facility | 24% | 76% | 0% |
| Designating falls management as a Quality Improvement measure for your facility | 13% | 87% | 0% |
| Other (please fill in) _____ | 5% | 0% | 0% |

[a] Survey question: "Which of the following falls management activities don't you use, which are working well at your facility, and which need to improve?" (Percent responding Needs to Improve.)
[b] Significant difference for type of county ($P<0.003$; urban 3.000 vs rural 2.518) for continuous variable where Don't Use=1, Needs to Improve=2 and Working Well=3 (ie, lower is doing worse at having all components in place and working).

ation of falls that residents experience," and "where to find slide presentations with scripts that you can use to train staff and educate residents about falls management." (Table 5).

### Follow-up Questionnaire

Forty-four percent of the staff who responded to the follow-up questionnaire indicated that in the last 7 months they had personally become more aware of falls management resources; 31% reported that in the last 7 months their nursing facility had adopted changes in falls management activities, "at least in part because of ideas inspired by the needs assessment questionnaire and the materials" sent to them, and 31% reported that their nursing facility had begun a process that likely will lead them to adopt changes in falls management activities within the next 6 months. Significantly more rural than urban respondents (42% vs 8%) reported their facility had adopted changes in falls management activities in the last 7 months ($P<0.012$).

## DISCUSSION

Our study's return rates for questionnaires of 46% and 53% nearly matched the average rate obtained from nursing home administrators and directors of nursing (47%) in a recent study of 224 US nursing homes where respondents were offered monetary incentives of $10 to $30.[14]

We found only 1 other study that identified barriers to better falls management in nursing homes. That survey asked a differently worded question and response set and rated the need for "buy-in" from residents, staff, and families as the most important barrier, followed by time constraints, the health of residents, a lack of resources (including staff, space and equipment), and communication problems.[15]

In a North Carolina nursing home study,[16] 86% of facilities assessed fall risks among new residents and 81% conducted an investigation after a resident had fallen. In comparison, 100% of the Wisconsin nursing homes that responded to our study were assessing each new resident for their fall risks and conducting an investigation after a resident had fallen.

### Response to Intervention

The high proportions of administrators and directors of nursing in our study who reported improving their personal awareness and who reported making changes in their nursing homes sug-

**Table 4.** Where Respondents Reported Getting Useful Fall Prevention Information in the Last Year (n=38)[a]

| Source | Percent Yes |
|---|---|
| **People in Your Nursing Facility** | |
| Occupational therapy (OT), physical therapy (PT) or Speech therapy staff | 87% |
| Nursing staff | 79% |
| Nursing assistants | 76% |
| Nursing home residents or family members | 50% |
| Nursing home administrator | 42% |
| Pharmacy staff | 32% |
| Other | 21% |
| **People Outside Your Nursing Facility** | |
| Professional organization staff | 47%[b] |
| Dealers or suppliers of commercial products | 40% |
| State of Wisconsin staff | 34% |
| Nursing staff | 26% |
| OT, PT or Speech therapy staff | 24%[c] |
| Pharmacy staff | 18% |
| Commercial consultant | 11% |
| Nursing home administrator | 8% |
| University of Wisconsin or UW Extension staff | 8% |
| Other | 18% |
| **Information, Media or Events** | |
| Conferences, workshops or meetings you attended | 82% |
| Professional journals in your field or other publications | 66%[d] |
| Training sessions held by your nursing home | 58% |
| On-line webinars or other computer-based education | 53% |
| Training sessions held by other nursing homes | 13% |
| **Online Information** | |
| Professional organization newsletters or online information | 55% |
| Wisconsin Association of Homes and Services for the Aging online information | 47%[e] |
| Pharmacy Newscapsule or online information | 42% |
| CHSRA's Wisconsin Clinical Resource Center online information | 40% |
| State of Wisconsin newsletters or online information | 37% |
| National AHCA or Leading Edge (AAHSA) online information | 13% |
| US Center for Medicare and Medicaid Services online information | 13% |
| Wisconsin Health Care Association's online information | 11% |
| Nursing home resident and family care giver newsletters or online information | 5% |
| University of Wisconsin or UW Extension online information | 3% |
| Other | 8% |

[a] Survey question: "Where did you get useful information about ways to improve falls management in the last year?" (Percent responding "Yes" to list of resources)
[b] Significant difference for type of respondent ($P<0.019$; administrators 73% vs directors of nursing 30%).
[c] Significant difference for type of county ($P<0.038$; rural 33% vs urban 18%).
[d] Significant difference for type of county ($P<0.024$; rural 78% vs urban 36%).
[e] Significant difference for type of county ($P<0.033$; rural 59% vs urban 18%).

gested that relatively simple and low cost information dissemination efforts may be useful in efforts to improve nursing home falls management activities. We found 1 existing study that demonstrated lower rates of serious fall-related injuries across a region in Connecticut after an information dissemination intervention.[17] The researchers mailed out a list of resources as we did, but their project also had a staff of outreach workers, enlisted a working group of local clinicians, conducted face-to-face outreach contacts, and used outreach among older adults. In comparison, our intervention approach relied entirely on mail contact and did not include objective measures such as fall rates. In comparison, our very modest intervention did yield self-reported improvements in falls management understanding and reports of changes in falls management activities by about one-third of the nursing home leaders who responded.

### Rural vs Urban County Nursing Homes

In our study, significantly more respondents from rural vs urban county nursing homes felt that: (1) low staff to patient ratios were a barrier to better falls management in typical Wisconsin nursing homes, and that (2) getting teams to quickly decide on a care plan were situations that needed to improve in their facility. Rural respondents also tended to get more information from professional journals and from nursing staff outside their own facility, as well as from certain online information sources. Respondents from rural counties were significantly more interested in 3 types of falls management information: (1) how to improve investigations after a resident has fallen, (2) where to find resources to guide investigations after a resident has fallen, and (3) where to find slide presentations with scripts to train staff and educate residents. Respondents from rural counties were also significantly more likely to report that their own nursing home had adopted changes in falls management activities after our intervention than urban residents. These results suggest that a simple information dissemination intervention maybe be of greater benefit to rural than urban nursing homes.

The rationale for promoting health and preventing injury to keep older adults healthy and active as they age is especially relevant for those living in more rural areas. In 2004, 16% of all US nursing facilities (2600) were in highly rural areas located outside both metropolitan and micropolitan (suburban) areas.[18] Rural nursing homes may be able to benefit more than urban nursing homes from falls management activities because rural populations have disproportionately higher rates of unintentional fall injuries and related mortality.[19] A study of older adults living in a community in Texas showed that, compared to urban participants, rural participants entered and exited a community fall prevention program with lower falls efficacy scores, higher health interference scores, and higher days limited from usual activity. Nonetheless, the rural partici-

**Table 5.** Information Respondents Said They Were Interested In (n=37)[a]

| Information | Percent Yes |
|---|---|
| How to get your facility's staff better at analyzing resident fall data and developing prevention plans | 76% |
| Where to find video presentations you can use to train staff and educate residents about falls management | 68% |
| How to better assess and care for new residents in ways that reduce fall risks during their first weeks | 65% |
| How to make better detailed assessments and investigations after a resident has fallen | 62%[b] |
| How to get all staff to more quickly and consistently adopt changes in individual resident care plans | 62% |
| How to get all staff to more quickly and consistently adopt changes in individual resident care plans | 62% |
| Where to find best practice guidelines for nursing home falls management | 60% |
| Where to find protocols, forms or other tools to guide evaluation of new resident fall risks | 54% |
| Where to find video presentations and other tools you can use to conduct successful nontraditional strength, balance and mobility improvement programs likely to interest residents (eg, yoga, tai chi, etc.) | 52% |
| Where to find protocols, forms or other tools to guide immediate evaluation of falls that residents experience | 51%[c] |
| How to provide support for front line care staff so they have incentives to achieve fall prevention goals | 49% |
| Where to find video presentations and other tools you can use to conduct successful traditional strength, balance and mobility improvement programs likely to interest residents (eg, walking, exercises, etc.) | 41% |
| Where to find slide presentations with scripts you can use to train staff and educate residents about falls management | 41%[d] |
| How to draw on shared values and other motivational sources in ways that motivate front line staff | 38% |
| How to get more accurate information about a new resident from your referral agencies | 35% |
| Where to find electronic medical records systems and clinical decision support systems that include falls management | 19% |
| Where to find other information (please fill in) | 8% |

[a] Survey question: "Are you interested in obtaining any of the following information about falls management programs?" (Percent responding Yes.)
[b] Significant difference for type of county ($P<0.008$; rural 77% vs urban 27%).
[c] Significant difference for type of county ($P<0.001$; rural 69% vs urban 9%).
[d] Significant difference for type of county ($P<0.014$; rural 54% vs urban 9%).

pants actually benefited more than urban participants from the program because their rates of positive health-related changes achieved after the program were significantly greater than urban participants.[20]

### Limitations

The most obvious limitation of our survey was its small size, just 43 nursing homes in 6 counties. There were a total of 399 nursing homes in all of Wisconsin's 72 counties in 2011.[13] Future research could benefit by undertaking a census of all Wisconsin nursing homes. The associated increase in statistical power could allow a clearer characterization of any differences between more rural and more urban counties, between administrators and directors of nursing, and along other dimensions such as facility size or fall injury rates.

Some new research suggests that even adoption of all of the best practice falls management components may not always produce improvements in fall or fall injury rates when conducted by in-house nursing home staff rather than research teams.[16,21-24] A possible explanation for this difference could be that having evidence-based, best practice content for a nursing home falls management program may be of little value unless that nursing home also has open, inclusive, process features. Another consideration may be that improved staff knowledge alone does not necessarily translate into improved care outcomes, as has been demonstrated during training for staff serving older people with dementia.[25] While knowledge may be important, there are other critical components for successful interventions including problem solving, teamwork, and communication skills.[26-28] Future research should consider a study of what happens after nursing homes receive relevant information about best practice falls management.

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# Geographic and Racial Variation in Teen Pregnancy Rates in Wisconsin

Molly M. Layde; Patrick L. Remington, MD, MPH


## ABSTRACT

**Background:** Despite recent declines in teen birth rates, teenage pregnancy remains an important public health problem in Wisconsin with significant social, economic, and health-related effects.

**Objective:** Compare and contrast teen birth rate trends by race, ethnicity, and county in Wisconsin.

**Methods:** Teen (ages 15-19 years) birth rates (per 1000 teenage females) in Wisconsin from 2001-2010 were compared by race/ethnicity and county of residence using data from the Wisconsin Interactive Statistics on Health.

**Results:** Teen birth rates in Wisconsin have declined by 20% over the past decade, from 35.5/1000 teens in 2001 to 28.3/1000 teens in 2010—a relative decline of 20.3%. However, trends vary by race, with declines among blacks (-33%) and whites (-26%) and increases among American Indians (+21%) and Hispanics (+30%). Minority teen birth rates continue to be 3 to 5 times greater than birth rates among whites. Rates varied even more by county, with an over 14-fold difference between Ozaukee County (7.8/1000) and Menominee County (114.2).

**Conclusion:** Despite recent declines, teen pregnancy continues to be an important public health problem in Wisconsin. Pregnancy prevention programs should be targeted toward the populations and counties with the highest rates.


## INTRODUCTION

Teenage pregnancy is an important public health problem in Wisconsin with significant social, economic, and health-related effects. Researchers have identified risk factors for teen pregnancy, including socioeconomic status, family support, as well as race and ethnicity.[1,2] Teen pregnancy rates also vary substantially among states, from a high of 65.7 per 1000 in Mississippi to a low of 19.8 in New Hampshire,[3] with even greater variation from county to county within states.[4] The geographic differences in teen pregnancy rates may be due to differences in demographic characteristics between communities, but they also are determined by complex social-environmental factors such as peer norms and the availability of public health and health care resources.

Identification of teens at high risk of becoming pregnant is important. Children born to teen mothers are at an increased risk of adverse pregnancy outcomes, including preterm delivery, low birth weight, and neonatal mortality.[5] Effective teen pregnancy prevention programs can be targeted to high-risk teens. Common interventions of such programs include delaying the onset of sexual activity, educating teenagers about how pregnancy can occur, increasing motivation for pregnancy prevention, and encouraging use of higher-effectiveness birth control methods.[6] In addition, identification of high-risk teens can provide an opportunity to reduce adverse outcomes by promoting early prenatal care in those who do become pregnant.

Ashby and colleagues[7] reviewed patterns of teen pregnancy in Wisconsin from 1995 to 2002. This paper updates that earlier analysis with recent data on teen births in Wisconsin and further explores the influence of geographic residence on teen birth rates.

## METHODS

We studied births in Wisconsin from 2001 to 2010. Teen birth rates were calculated by dividing the number of births among teens ages 15 to 19 years by the population of teenage girls ages 15 to 19 years. Data on both births and population were taken from the Wisconsin Interactive Statistics on Health (WISH) database available at: http://www.dhs.wisconsin.gov/wish/. Data were collated for each year by maternal age, county, race, and ethnicity.

We evaluated patterns in teen births by race/ethnicity and county of residence. We analyzed race/ethnicity data using the following groups: non-Hispanic white, non-Hispanic black,

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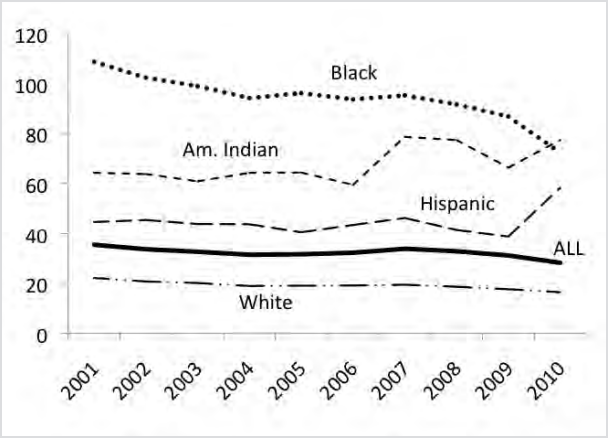
**Table 1.** Birth Rate per 1000 Teens 15 to 19 Years Old by Year, Race, and Ethnicity for Wisconsin, 2001-2010

| Race/Ethnicity | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | All Years | 95% CI Lower | 95% CI Upper |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Non-Hispanic White | 22.2 | 20.8 | 20.2 | 19.0 | 19.1 | 19.2 | 19.5 | 18.7 | 17.7 | 16.5 | 19.3 | 17.3 | 21.4 |
| Non-Hispanic Black | 108.7 | 102.4 | 99 | 94.2 | 96.2 | 93.7 | 95.3 | 91.7 | 86.8 | 72.4 | 93.5 | 90.7 | 96.2 |
| American Indian | 64.3 | 63.8 | 60.9 | 64.3 | 64.4 | 59.5 | 78.7 | 77.4 | 66.4 | 77.4 | 67.5 | 64.0 | 71.0 |
| Hispanic | 44.6 | 45.4 | 43.8 | 43.7 | 40.5 | 43.4 | 46.2 | 41.4 | 38.8 | 58.3 | 44.0 | 41.6 | 46.4 |
| All Selected[a] | 35.5 | 33.7 | 32.7 | 31.5 | 31.7 | 32.3 | 33.9 | 32.9 | 31.2 | 28.3 | 32.4 | 30.3 | 34.5 |

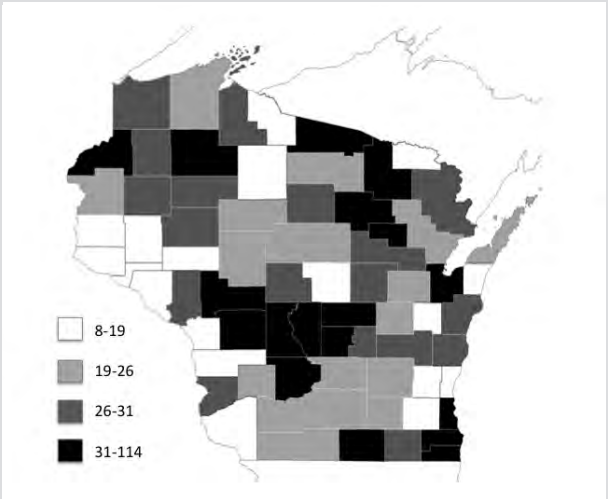
[a] All Selected rates includes only the racial/ethnic groups specified.

**Figure 1.** Trends in Teen Birth Rates in Wisconsin, 2001-2010[a]




[a]Per 1000 females ages 15-19 years by year and race/ethnicity.

**Figure 2.** Variation in Teen Birth Rates in Wisconsin, 2001-2010[a]




[a] Per 1000 females ages 15-19 years, by county. Counties are grouped by quartile (n=18 counties in each group).

Hispanic, and non-Hispanic American Indian (American Indian). We did not include Laotian/Hmong separately because population data were not available. To provide more reliable estimates for counties, birth rates were calculated and compared for the 10-year period from 2001 to 2010. Rate ratios were calculated by dividing the rate of births in different race/ethnicity groups and counties of residence minority teens by the rate in the appropriate referent groups. To estimate the 95% confidence limits (CL) for the rates, we used the following formula: 95% CL = 1.96 * rate/(square root of n), where n = the number of births.[8]

## RESULTS

There were 60,581 births to mothers 15 to 19 years of age in Wisconsin from 2001 to 2010, which corresponds to an annual rate of 32.4 teen births per 1000 girls ages 15 to 19 years. The rate declined steadily, from 35.5 in 2001 to 28.3 in 2010—a relative decline of 20.3%, or about 2.5% per year (Table 1). If the birth rate among teenage girls had not declined during this decade, there would have been more than 1590 additional teen births in 2010 in Wisconsin.

Birth rates varied substantially by race and ethnicity (Table 1). The rate of teen births in non-Hispanic blacks of 93.5 per 1000 per year was almost 5 times the rate of 19.3 in non-Hispanic whites. Among American Indians, the rate was 67.5 per 1000 per year, and among Hispanics the rate was 44.0 per 1000 per year.

The decline in the teen birth rate over the past decade varied by race and ethnicity (Figure 1). The rates declined the most for non-Hispanic blacks (relative decline of 33%) followed by non-Hispanic whites (relative decline of 26%). In contrast, birth rates increased by 20% among American Indian teens and by 31% among Hispanic teens.

While there was considerable variability of rates among racial and ethnic groups, there was even more variability by county of residence. The teen birth rate varied more than 14-fold, ranging from a low of 7.8 per 1000 in Ozaukee County to a high of 114.2 in Menominee County (Table 2). While rates tend to be lowest in suburban areas, there was dramatic variability among rural areas, with rural counties among both the highest and the lowest ranked counties in the state (Figure 2).

## DISCUSSION

Our study shows that progress has been made in reducing rates of teen pregnancy in Wisconsin, dropping over 20% in the decade from 2001 to 2010. The trend in Wisconsin is similar to the trends observed in the United States, where teen birth rates have declined almost continuously since the early 1990s—including

**Table 2.** Number of Births and Rate for Teens 15-19 Years Old by County for Wisconsin, 2001-2010

| County of Residence | Rank (Rate) | No. Births | Rate/ 1,000/year | 95% CI | |
|---|---|---|---|---|---|
| Ozaukee | 1 | 238 | 7.8 | 6.8 | 8.8 |
| Pierce | 2 | 203 | 9.9 | 8.6 | 11.3 |
| Waukesha | 3 | 1,365 | 10.7 | 10.1 | 11.2 |
| Iron | 4 | 23 | 11.4 | 6.8 | 16.1 |
| St Croix | 5 | 384 | 14.8 | 13.4 | 16.3 |
| Florence | 6 | 21 | 14.9 | 8.5 | 21.3 |
| Washington | 7 | 632 | 15.5 | 14.3 | 16.7 |
| Calumet | 8 | 249 | 15.6 | 13.7 | 17.6 |
| Price | 9 | 78 | 15.9 | 12.4 | 19.4 |
| Dunn | 10 | 342 | 16.3 | 14.5 | 18.0 |
| Pepin | 11 | 45 | 16.3 | 11.5 | 21.1 |
| Eau Claire | 12 | 802 | 17.3 | 16.1 | 18.4 |
| Portage | 13 | 550 | 17.3 | 15.9 | 18.8 |
| Kewaunee | 14 | 125 | 17.6 | 14.5 | 20.7 |
| Buffalo | 15 | 86 | 18.4 | 14.5 | 22.3 |
| La Crosse | 16 | 933 | 18.6 | 17.4 | 19.8 |
| Grant | 17 | 408 | 18.9 | 17.1 | 20.8 |
| Vernon | 18 | 206 | 19.4 | 16.7 | 22.0 |
| Dane | 19 | 3,212 | 19.4 | 18.7 | 20.1 |
| Door | 20 | 165 | 20.4 | 17.2 | 23.5 |
| Bayfield | 21 | 98 | 20.5 | 16.4 | 24.6 |
| Iowa | 22 | 166 | 20.5 | 17.4 | 23.6 |
| Lafayette | 23 | 126 | 20.7 | 17.1 | 24.3 |
| Taylor | 24 | 147 | 20.8 | 17.4 | 24.2 |
| Jefferson | 25 | 657 | 21.5 | 19.8 | 23.1 |
| Winnebago | 26 | 1,338 | 21.9 | 20.8 | 23.1 |
| Oneida | 27 | 253 | 22.4 | 19.6 | 25.1 |
| Richland | 28 | 146 | 22.5 | 18.8 | 26.1 |
| Columbia | 29 | 407 | 22.8 | 20.6 | 25.0 |
| Outagamie | 30 | 1,398 | 22.9 | 21.7 | 24.1 |
| Oconto | 31 | 317 | 24.3 | 21.6 | 26.9 |
| Clark | 32 | 326 | 24.6 | 22.0 | 27.3 |
| Dodge | 33 | 692 | 24.6 | 22.8 | 26.5 |
| Marathon | 34 | 1,165 | 25.0 | 23.5 | 26.4 |
| Polk | 35 | 393 | 25.9 | 23.4 | 28.5 |
| Green | 36 | 307 | 26.0 | 23.1 | 29.0 |
| Fond du Lac | 37 | 911 | 26.1 | 24.4 | 27.8 |
| Manitowoc | 38 | 773 | 26.7 | 24.8 | 28.6 |
| Crawford | 39 | 156 | 27.1 | 22.9 | 31.4 |
| Marinette | 40 | 400 | 27.2 | 24.5 | 29.8 |
| Chippewa | 41 | 551 | 27.2 | 25.0 | 29.5 |
| Walworth | 42 | 930 | 27.3 | 25.6 | 29.1 |
| Shawano | 43 | 386 | 28.0 | 25.2 | 30.8 |
| Wood | 44 | 717 | 28.1 | 26.0 | 30.1 |
| Trempealeau | 45 | 256 | 28.1 | 24.6 | 31.5 |
| Waupaca | 46 | 500 | 28.1 | 25.7 | 30.6 |
| Green Lake | 47 | 168 | 28.2 | 23.9 | 32.5 |
| Barron | 48 | 460 | 29.0 | 26.3 | 31.6 |
| Lincoln | 49 | 281 | 29.4 | 26.0 | 32.8 |
| Washburn | 50 | 153 | 30.0 | 25.3 | 34.8 |
| Douglas | 51 | 442 | 30.3 | 27.5 | 33.1 |
| Sheboygan | 52 | 1,179 | 30.6 | 28.8 | 32.3 |
| Rusk | 53 | 161 | 30.6 | 25.9 | 35.4 |
| Ashland | 54 | 191 | 31.3 | 26.8 | 35.7 |
| Vilas | 55 | 191 | 31.8 | 27.3 | 36.4 |
| Brown | 56 | 2,839 | 33.3 | 32.1 | 34.5 |
| Sauk | 57 | 652 | 33.7 | 31.1 | 36.3 |
| Marquette | 58 | 171 | 35.6 | 30.2 | 40.9 |
| Langlade | 59 | 248 | 35.8 | 31.4 | 40.3 |
| Monroe | 60 | 561 | 36.3 | 33.3 | 39.4 |
| Burnett | 61 | 180 | 36.7 | 31.4 | 42.1 |
| Jackson | 62 | 232 | 37.8 | 32.9 | 42.7 |
| Juneau | 63 | 315 | 37.9 | 33.7 | 42.1 |
| Waushara | 64 | 286 | 38.0 | 33.6 | 42.4 |
| Kenosha | 65 | 2,183 | 38.1 | 36.5 | 39.7 |
| Rock | 66 | 2,306 | 42.3 | 40.6 | 44.0 |
| Forest | 67 | 153 | 43.0 | 36.1 | 49.8 |
| Racine | 68 | 2,888 | 44.1 | 42.5 | 45.7 |
| Sawyer | 69 | 247 | 45.7 | 40.0 | 51.4 |
| Adams | 70 | 261 | 51.4 | 45.2 | 57.6 |
| Milwaukee | 71 | 20,009 | 60.5 | 59.6 | 61.3 |
| Menominee | 72 | 241 | 114.2 | 99.8 | 128.6 |
| **Total** | | **60,581** | **30.6** | **30.4** | **30.9** |

an 8% drop from 2010 to 2011—and as of 2011 were at historic lows. This decline was not experienced by all groups, however, and substantial variability remains in the risk for teenage births in different racial and ethnic groups and in different counties of residence within the state.

We found large racial and ethnic disparities in the teen birth rates in Wisconsin. The rate of births to black teenagers was over 4 times that of white teenagers. While both black and white teenagers experienced substantial reductions in their risk for teen birth over the past decade, the risk actually increased in American Indian and Hispanic populations. The racial and ethnic disparities may be accounted for by differences in the underlying causes of teen births, such as poverty, sexual abuse, and having a pregnant or parenting older teenage sister.[9] Studies also indicate that low contraceptive use rates[10] and a social norm stressing the desirability of giving birth as a teen[11] may contribute to high rates of teen births in certain groups. High-risk groups may particularly benefit from programs designed to prevent teen pregnancy.

Although the variability in teen birth rates was substantial among different racial and ethnic groups, there was even wider variability based on a teenager's county of residence. Compared to Ozaukee County, which had the lowest teen birth rate, the rate in Menominee County was over 14 times greater. While that difference was extreme, there was also major variability among rural counties in the state, some of which had among the lowest teen birth rates in the state and some among the highest. This suggests that there may be differences in social norms, prevention programs, and the availability of family planning and reproductive services, such as contraceptive services. If all counties could achieve the teen pregnancy rate observed in the counties with the lowest rates, thousands of births to teenagers could be prevented in Wisconsin each year.

Several limitations need to be considered when interpreting the results of this study. First, these data include only live births

to teenage girls. No information is available on differences in teenage sexual activities, use of contraception, pregnancy rates, or rates of pregnancy termination. In addition, we did not consider differences in availability of prevention services across the state. Differences in these factors could account for the observed differences in teen birth rates, and would have important implications on future program and policy considerations. In addition, differences in the teen birth rates for some smaller counties may be due to chance due to the smaller population of teenage girls with fewer observed births.

## CONCLUSION

Given the results from this study and the important impact of teen births, greater attention needs to be given to evidence-based programs to prevent teen pregnancy. The Guide to Community Preventive Services website recommends comprehensive risk reduction interventions for adolescents and states that there is insufficient evidence to support abstinence education interventions alone.[12] Some work suggests that promoting condom use for protection against sexually transmitted infections (STIs), including human immunodeficiency virus, may be a useful way to increase contraceptive use and reduce teen birth rates in addition to STIs.[6] Given the significant variability among teen birth rates by race, ethnicity, and place of residence in Wisconsin, physicians and other health care professionals should engage with community partners to assess their own community needs and resources and develop community health improvement plans that include preventing teen pregnancies.

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# A Case of Dabigatran-associated Acute Renal Failure

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## ABSTRACT

Dabigatran is a direct thrombin inhibitor that reduces the risk of systemic embolism in patients with nonvalvular atrial fibrillation. We report a case of an elderly man who developed unexplained rapid decline in renal function 6 weeks after starting dabigatran. A renal biopsy was planned to find out the etiology of acute renal failure, but the patient has significantly prolonged coagulation parameters despite holding medication for 5 days per manufacturer's recommendation. He was started on hemodialysis due to worsening renal function and to ensure dabigatran clearance before renal biopsy. Renal biopsy showed renal atheroembolic disease, which was possibly induced by dabigatran. Although renal atheroembolic disease is a known rare complication following treatment with warfarin, heparin, and thrombolytic agents, this is the first reported case of renal atheroembolic disease potentially caused by dabigatran. This case also highlights the extended duration of prolonged coagulation parameters after holding dabigatran and its implication for timing of nonemergent invasive procedures.


## INTRODUCTION

Dabigatran, a direct thrombin inhibitor, is the first available oral anticoagulant alternative to warfarin for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.[1] We report a case of an elderly patient who developed unexplained acute renal failure 6 weeks after he started dabigatran. A renal biopsy was planned to determine the cause of renal failure. However, the patient had significantly abnormal coagulation parameters, and we were faced with the clinical dilemma of the need for an urgent renal biopsy vs uncertainty regarding how much time should be allowed to pass before performing a renal biopsy after stopping the medication. Eventually, renal biopsy showed renal atheroembolic disease, which was possibly precipitated by dabigatran. Though rare, renal atheroembolic disease has been described following treatment with warfarin, heparin and thrombolytic agents.[2-5] To our knowledge, this is the first reported case of renal atheroembolic disease possibly induced by dabigatran.

## CASE

A 79-year-old African American man was referred to an outpatient nephrology clinic for evaluation of renal dysfunction discovered incidentally during a routine follow-up the week before. His blood urea nitrogen (BUN) was 52 mg/dL (Ref: 9-23 mg/dL), serum creatinine (Cr) was 2.9 mg/dL (Ref: 0.7-1.3 mg/dL), and estimated glomerular filtration rate (eGFR) was 27.2 ml/min/1.73 (Ref: > 60 ml/min/1.73). He had fatigue but no other symptoms. Three months previously, his Cr was 1.3 mg/dL, eGFR was 69 ml/min/1.73 and hemoglobin was 11.0 g/dL (Ref: 12.5-16.5 g/dL) with normal white blood cell differential. His past medical history included hypertension, hyperlipidemia, and a recent diagnosis of atrial fibrillation. His medications included amlodipine 5 mg daily, valsartan 320 mg daily, rosuvastatin 10 mg daily, vitamin D 2000 units daily, and dabigatran 150 mg twice a day, started 6 weeks earlier for atrial fibrillation by his cardiologist. He had undergone no interventional procedures. On physical examination, his blood pressure was elevated at 179/79 mm Hg. Laboratory tests revealed normal white blood cell count and differential, as well as normal platelet count and electrolytes. Hemoglobin was low at 10.0 g/dL. Urinalysis showed 1+ protein and > 20 red blood cells/high power field (hpf) (Ref: < 2/hpf). Urine protein to creatinine ratio was 0.5 (Ref: 0.0-0.2). Repeat BUN was 50 mg/dL, Cr was 3.3 mg/dL, and eGFR was 22 ml/min/1.73.

Urgent renal ultrasound with Doppler was ordered. However, on the day of the renal ultrasound, the patient's blood pressure was severely elevated at 243/109 mm Hg, prompting hospital admission. His hospitalization occurred 5 days after he was first

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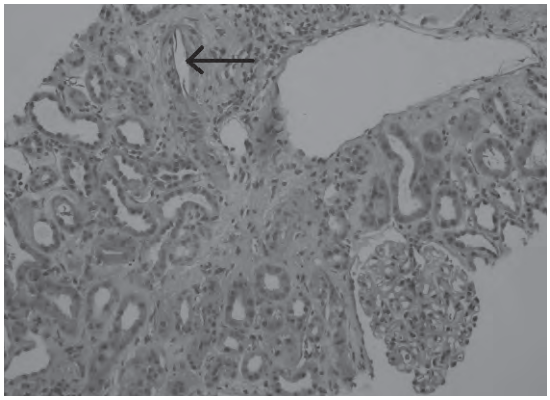
**CME available. See page 176 for more information.**

**Table 1.** Coagulation Parameters, Serum Creatinine, and Timing of Hemodialysis and Renal Biopsy in Patient after Hospitalization

| | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 | Day 8 | Day 9 | Day 10 | Day 11 | Day 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PT/INR (0.8-1.2) | 2.9 | | 3.7 | 3.2 | 2.5 | 2.1 | 1.8 | 1.7 | 1.5 | 1.4 | 1.4 | |
| aPTT (23-32s) | 66.1 | | 71.2 | 65.7 | 55.2 | 47.7 | 43.5 | 40.6 | 33.7 | 28.7 | 26.8 | 25.7 |
| TT (11.8-17.6s) | | | | | | | >120 | >120 | >120 | | | 89 |
| SCr (mg/dL) | 3.2 | 3.1 | 3.2 | 3.4 | 3.7 | 4.1 | 4.3 | 4.8 | 4.2 | 4.3 | 5.1 | 4.1 |
| Procedure | | | | | | | | HD | HD | | HD | Biopsy |

Abbreviations = PT/INR, prothrombin time/international normalized ratio; aPTT, activated partial thromboplastin time; TT, thrombin time; SCr, serum creatinine; HD, hemodialysis.

**Figure 1.** Renal Biopsy (200 X)



Irregular outline of occlusive atheroembolus within artery/arteriole (arrow). Formalin fixation removes the lipid but the jagged outline remains.

seen in the renal clinic and nearly 7 weeks after he was first started on dabigatran. Renal ultrasound with Doppler was suspicious for left renal artery stenosis. Repeat blood work showed hemoglobin at 10.8 g/dL and peripheral eosinophil% at 10 (Ref: 0-6%); erythrocyte sedimentation rate was 39 mm/hr (Ref: 0-15 mm/hr), BUN was 47 mg/dL, creatinine was 3.2 mg/dL, and eGFR was 22 ml/min/1.73. He had no eosinophiluria. Complete serological workup, including antinuclear antibody, antineutrophilic cytoplasmic antibody, complement 3 and 4, hepatitis B surface antigen, hepatitis C antibody, antiglomerular basement membrane antibody, cryoglobulins, serum, and urine protein electrophoresis were found to be normal over subsequent days. Due to unexplained renal failure, we opted for renal biopsy. The patient was empirically started on intravenous (IV) methylprednisolone to cover for possible acute interstitial nephritis or rapidly progressive glomerulonephritis. Dabigatran was stopped on the day of admission. All coagulation parameters, including prothrombin time/international normalized ratio (PT/INR), activated partial thromboplastin time (aPTT), and thrombin time (TT) were significantly abnormal. These results are shown in Table 1. Fibrinogen was normal. Mixing studies suggested the presence of inhibitor or anticoagulation effect. The patient was started on hemodialysis on day 8 of hospitalization due to worsening renal function and abnormal coagulation parameters. Placement of a temporary femoral hemodialysis catheter was uneventful despite prolonged aPTT, PT/INR and TT. A renal biopsy was performed on day 12 of hospital admission. There was no major post-procedure bleeding. Renal biopsy showed cholesterol emboli, ischemic glomerular changes, and hypertensive glomerulosclerosis (Figure 1). Dabigatran was permanently discontinued. The patient continued on hemodialysis, but renal function did not recover.

## DISCUSSION

Renal atheroembolic disease, also known as cholesterol embolization, causes a decline in renal function due to occlusion of renal arteries, arterioles, and glomerular capillaries by cholesterol crystals, which dislodge from atherosclerotic plaques.[2] In clinical practice, 3% to 10% of all cases of acute renal failure may be attributed to renal atheroembolic disease.[2] Renal atheroembolic disease is usually found in adults older than 60 years with diffuse atherosclerosis.[2] The most common etiology is an interventional or surgical procedure involving manipulation of the aorta or other major blood vessels.[2] Renal atheroembolism is also a rare complication in patients on anticoagulants (including warfarin, heparin, low molecular weight heparin) and thrombolytic agents.[2-5] In studies of biopsy-proven renal atheroembolic diseases, anticoagulation could be implicated in only 7% of cases without preceding vascular interventional procedures.[2] Among patients taking warfarin, the incidence of systemic cholesterol embolism is low (0.7% to 1.0%).[6,7] The exact mechanism underlying anticoagulant- or thrombolytic-induced atheroembolic renal disease is not clear. One proposed explanation is that anticoagulants and thrombolytics may disrupt or dissolve protective thrombi that cover ulcerated atherosclerotic plaques, exposing the lipid core to the systemic circulation.[2] Spontaneous atheroembolic disease is rare with reported incidence of 1.9% to 13%.[2]

The patient in this case report has risk factors for atherosclerosis including advanced age, history of hypertension, and hyperlipidemia. Though spontaneous atherombolic disease is a possibility in our patient, the temporal relationship between starting dabigatran and onset of renal failure in the absence of any vascular interventional procedure makes it likely that dabigatran was the predisposing factor in this patient. To our knowledge, this is the first reported case of renal atheroembolic disease potentially induced by dabigatran.

The most common extra-renal manifestation of atheroembolic renal disease is skin involvement in the form of livedo reticularis, blue toe syndrome, ulceration, gangrene, and purpura, with recent studies reporting a frequency of 75% to 96%.[2] Other organs, including the retina, gastrointestinal tract, central nervous system, and heart also may be affected.[2] Our patient exhibited no extra-renal manifestations but had eosinophilia, which was suggestive but not specific for renal atheroembolic disease. Overall, the patient's clinical presentation was not suggestive of renal atheroembolic disease. But comprehensive evaluation for other causes of renal failure was unremarkable and renal biopsy was conclusive, which is the definite test to diagnose atheroembolic disease.[2]

An additional highlight of our case is the patient's abnormal coagulation profile and its impact on our decision to delay renal biopsy and initiate dialysis prior to renal biopsy. Dabigatran is primarily cleared by the kidneys (85%).[1] The manufacturer recommends holding dabigatran for 1 to 2 days (if creatinine clearance > 50 ml/min) and 3 to 5 days (if creatinine clearance < 50 ml/min) before any interventional or surgical procedure.[8] However, in our patient, coagulation parameters, including PT/INR, PTT, and TT were prolonged well beyond 5 days, which made us hesitant to perform renal biopsy on day 5.

Routine monitoring of the coagulation profile in patients taking dabigatran is not indicated,[1] but it may be essential in special circumstances like this case. The effect of dabigatran on coagulation parameters has been the subject of several recent studies and reviews.[9-12] In the latest study,[12] aPTT and hemoclot thrombin inhibitor assay were found to be the most useful monitoring tests, with the latter regarded as the gold standard. Ecarin clotting time was found to be reliable, while TT was considered too sensitive and was not recommended. However, a normal TT rules out any dabigatran effect.[9] Of all these tests, only aPTT and TT are readily available in most institutions. The correlation between aPTT, TT, and clinical bleeding has not been determined in patients on dabigatran, which limits interpretation of these coagulation tests in assessing clinical safety.[10] In addition, PT/INR is not considered a sensitive indicator of dabigatran activity, except perhaps at supratherapeutic concentrations.[10-12] But patient had significantly prolonged PT/INR, and this has been found in other case reports of elderly patients who developed gastrointestinal hemorrhage in the context of renal failure while on dabigatran.[13,14]

Since there is no effective antidote for dabigatran[1] and hemodialysis is effective in removing 62% to 68% of the drug,[15] we performed 3 hemodialysis sessions before proceeding with renal biopsy. It was only after holding dabigatran for 10 days and after 2 hemodialysis sessions that PT/INR and aPTT returned to normal. TT was improved but still prolonged on day 12, perhaps due to residual dabigatran activity although, as mentioned above, the test has been found to be too sensitive. In addition, the patient did not exhibit significant bleeding on placement of the dialysis catheter on day 8. We felt it was probably safe to perform renal biopsy after holding dabigatran for 12 days and after 3 hemodialysis sessions. There were no post-procedure complications.

## CONCLUSION

Dabigatran may induce renal atheroembolic disease in elderly patients with appropriate risk factors for atherosclerosis. This diagnosis should be considered in patients who develop unexplained renal failure while taking dabigatran. Additional case reports of renal atheroembolic disease in setting of dabigatran may confirm that this disease can be induced by dabigatran like other anticoagulants and thrombolytics.

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# Quiz: A Case of Dabigatran-associated Acute Renal Failure

## EDUCATIONAL OBJECTIVES

Upon completion of this activity, participants will be able to:

1. Understand some of the pharmacology of dabigatran and how its activity can be monitored.
2. Understand the etiology and pathophysiology of renal atheroembolic disease.

**PUBLICATION DATE:** August 15, 2013

**EXPIRATION DATE:** August 15, 2014

## QUESTIONS

1. Dabigatran is a direct thrombin inhibitor.
   ❑ True ❑ False
2. Dabigatran is indicated to reduce the risk of systemic embolism in patients with atrial fibrillation due to valvular heart disease.
   ❑ True ❑ False
3. Renal atheroembolic disease, also known as cholesterol embolization, causes a decline in renal function due to occlusion of renal arteries, arterioles, and glomerular capillaries by cholesterol crystals, which dislodge from atherosclerotic plaques.
   ❑ True ❑ False
4. In clinical practice, almost half of all cases of acute renal failure may be attributed to renal atheroembolic disease.
   ❑ True ❑ False
5. The most common extra-renal manifestation of atheroembolic renal disease is skin involvement in the form of livedo reticularis, blue toe syndrome, ulceration, gangrene, and purpura.
   ❑ True ❑ False

• • •

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6. The most common cause of renal atheroembolic disease is a result of an interventional or surgical procedure involving manipulation of the aorta or other major blood vessels.
   ❑ True ❑ False
7. Renal atheroembolic disease is a not uncommon complication following treatment with warfarin, heparin and thrombolytic agents and can be implicated in more than 20% of cases without preceding vascular interventional procedures.
   ❑ True ❑ False
8. Spontaneous atheroembolic disease is rare with reported incidence of 1.9% to 13%.
   ❑ True ❑ False
9. The exact mechanism underlying anticoagulant- or thrombolytic-induced atheroembolic renal disease is not clear; however, one proposed explanation is that anticoagulants and thrombolytics may disrupt or dissolve protective thrombi that cover ulcerated atherosclerotic plaques, exposing the lipid core to the systemic circulation.
   ❑ True ❑ False
10. Renal atheroembolic disease is usually found in adults older than 60 years with diffuse atherosclerosis.
    ❑ True ❑ False
11. Dabigatran is primarily cleared by the liver.
    ❑ True ❑ False
12. The prothrombin time/international normalised ratio (PT/INR) is recommended for use in monitoring dabigatran activity in clinical practice.
    ❑ True ❑ False
13. The thrombin time (TT) is considered too sensitive to monitor dabigatran activity; however, a normal TT rules out any dabigatran effect.
    ❑ True ❑ False
14. Hemodialysis is not effective in removing dabigatran.
    ❑ True ❑ False
15. The authors of this case report suggest that dabigatran may induce renal atheroembolic disease in elderly patients with appropriate risk factors for atherosclerosis.
    ❑ True ❑ False

# A Case Report of Deferasirox-induced Kidney Injury and Fanconi Syndrome

Noreen Murphy, MD; Mohsen Elramah, MD; Hemender Vats, MD; Weixong Zhong, MD, PhD; Micah R. Chan, MD MPH


## ABSTRACT

Cases of kidney injury associated with the use of deferasirox chelation therapy during the course of treatment for iron overload have been reported infrequently. We present the case of a patient treated with deferasirox who had biopsy-proven tubular injury in the setting of clinical Fanconi syndrome. The patient required hospitalization for metabolic acidosis, electrolyte abnormalities, and associated symptoms. With supportive care and cessation of chelation therapy he improved, but has yet to fully recover. This is the first known case reporting biopsy-proven tubular damage in the setting of deferasirox use.


## INTRODUCTION

High iron stores in the body can result from primary or secondary processes. Several genetic mutations have been identified as causing primary or hereditary hemochromotosis. Patients with these mutations are typically of Northern European descent and develop complications from iron deposition in various organs. The classic triad of bronze skin, diabetes, and liver failure highlights some of the complications of the disease, which can also include arthritis, hypogonadism, cardiomyopathy, and hepatocellular carcinoma. The cornerstone of treatment in these patients is routine phlebotomy.[1]

Secondary iron overload usually results from multiple blood transfusions or a severe hemolytic anemia.[1] Patients with hemoglobinopathies such as thalassemia or sickle cell disease and patients with bone marrow pathology such as myelodysplasia or myelofibrosis often become dependent on routine blood transfusions.[2] Others who develop this acquired form of iron overload may have required a significant number of blood transfusions for a defined period of time—such as during or after treatment of a malignancy. Iron overload syndromes can result in the same complications described above as a result of iron deposition in various tissues.[3] Patients with secondary iron overload cannot tolerate phlebotomy as a treatment option because their primary disease is anemia. Instead, these patients are treated with chelating agents that specifically target iron removal or prevent iron overload from occurring without affecting hemoglobin levels.[3,4]

Chelation therapy has long been considered an inconvenience to both patient and clinician.[4,5] Until 2005, for patients in the United States with iron overload syndromes, chelation therapy meant daily subcutaneous injections and thus frequent medication noncompliance and therapy failure.[4,5] In 2005, the US Food and Drug Administration approved deferasirox (Exjade), an oral chelating agent, intended for use in patients age 2 years and older suffering from iron overload syndromes.[6]

Deferasirox binds iron with high affinity, facilitating iron excretion primarily through the feces. Approximately 8% of the drug and its metabolites are excreted by the kidney. A starting dose of 20 mg/kg/day is recommended with a recommended maximum daily dose of 40 mg/kg. The prescribing package insert recommends reduction of the daily dose of deferasirox by 10 mg/kg if a rise in serum creatinine to >33% above the average pretreatment measurements is seen at 2 consecutive visits, and cannot be attributed to other causes.[6]

Warnings and precautions in the package insert identify the possibility of sometimes-fatal acute renal failure in patients taking deferasirox. Without describing the specific case fatalities, they report that patients at greatest risk are those with advanced age, advanced hematologic disease, or previous renal disease. During clinical trials, 113 out of 296 patients (38%) developed >33% increase in creatinine on 2 consecutive visits. Fanconi syndrome is listed as a rare complication occurring in 0.1% to 1% of patients treated with deferasirox. We found case reports documenting 6 patients who developed Fanconi syndrome in the setting of deferasirox therapy.[6]

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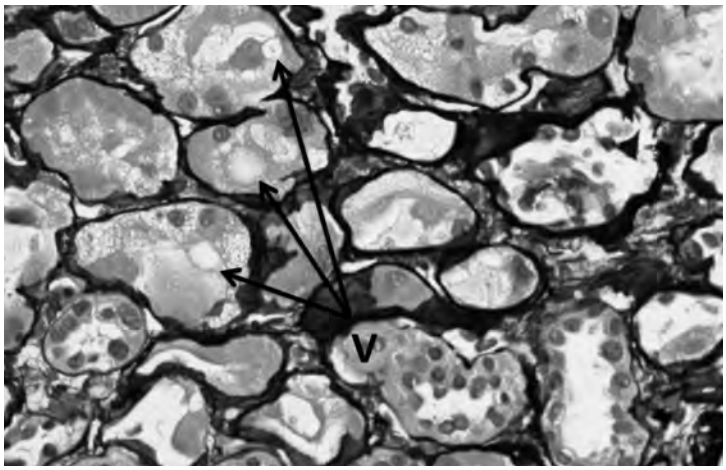
**Table 1.** Patient's Laboratory Results Prior to, During and After Deferasirox Therapy

| | March 2011 | August 2011 | December 2011 | March 2012 | May 2012 |
|---|---|---|---|---|---|
| Serum Potassium | 5.7 | 4 | 3.3 | 2.7 | 3.5 |
| Serum Phosphorus | 2.6 | 2.2 | 2.6 | 1.6 | 2 |
| Serum Creatinine | 1.0 | 1.26 | 1.5 | 2.5 | 1.52 |
| Urine Glucose | trace | 2+ | 3+ | 3+ | 2+ |
| Urine Potassium | | | | 39 | |
| Urine Phosphorus | | | | | 36 |

**Figure 1.** Kidney Biopsy




Silver-stained section from patient's biopsy at 400X magnification. The tubular epithelial cells have marked cytoplasmic vacuolization consistent with drug toxicity—similar to that reported in the animal studies on marmosets and rats administered oral deferasirox.

## CASE DESCRIPTION

Our patient is a 21-year-old male survivor of Ewing sarcoma who developed progressive decline in renal function and Fanconi syndrome after being prescribed deferasirox for treatment of iron overload.

Three years into remission of his Ewing sarcoma, the patient had a ferritin level of 1502 ng/mL (range 20-300 ng/mL) and magnetic resonance imaging (MRI) revealed T2 hypointensities consistent with iron deposition in the liver and spleen. Hemochromotosis gene mutation tests were negative, so iron overload was thought to be secondary to the over 35 blood transfusions he received during the course of treatment for Ewing sarcoma.

The patient was started on deferasirox 1125 mg daily in June 2011, at which time his serum creatinine was 1.1 mg/dL (range 0.7-1.2 mg/dL). His renal function declined progressively while on chelation therapy, with serum creatinine increases to 1.25 mg/dL in August 2011; 1.5 mg/dL in December 2011; 1.84 mg/dL in January 2012; and 2.03 in February 2012. Throughout the months he received chelation therapy, the patient's urinalyses were significant for 1-3+ proteinuria and 2-3+ glycosuria. In early March of 2012, he was admitted to the hospital with abdominal pain, nausea, vomiting, body aches, and anorexia. He was found to have a creatinine of 2.5 mg/dL, bicarbonate of 16 mmol/L (range 22-32 mmol/L), potassium of 2.7 mmol/L (range 3.5-4.8 mmol/L), phosphorous of 2.4 mg/dL (range 2.5-4.5 mg/dL), 1+ proteinuria, and 2+ glycosuria. His random urine potassium was 39 mmol/dL and his transtubular potassium gradient (TTKG) was 11, confirming inappropriate urinary excretion of potassium (Table 1). The patient's urine sediment was bland and urine eosinophils negative. His kidney biopsy revealed severe tubular injury with tubular epithelial cells demonstrating isometric vacuolization consistent with drug toxicity. There was no glomerular injury, arteriolar or interstitial inflammation (Figure 1). Deferasirox was stopped. He was treated with bicarbonate drip and potassium and phosphate repletion. Eleven days after admission, the patient's creatinine improved to 1.5 mg/dL and bicarbonate returned to 24 mmol/L. However, 4 months after deferasirox was stopped, the patient continues to have hypokalemia, hypophosphatemia, proteinuria, and glycosuria and requires daily potassium and phosphate supplementation (Table 1).

## DISCUSSION

Our patient presented with renal insufficiency, proteinuria, glycosuria, hypophosphatemia, hypokalemia, and metabolic acidosis. This constellation of symptoms strongly suggested renal pathology and specifically Fanconi syndrome. A healthy kidney will conserve potassium in the setting of hypokalemia. In a healthy patient with hypokalemia, the random urine potassium level should be no greater than 20-30 mmol/L. Our patient's random potassium level was 39 mmol/L. The TTKG is a calculation that helps to differentiate renal potassium losses from gastrointestinal potassium losses. In the setting of hypokalemia, the TTKG should be less than 3. Our patient's TTKG while hypokalemic was 11. Both the urine potassium and the TTKG measurements confirmed inappropriate potassium losses in the kidney, and at the time, strengthened our suspicion for proximal tubular damage and Fanconi syndrome.

Fanconi syndrome is a disorder of kidney tubules that causes

**Table 2.** Effects on Renal Function During Deferasirox Therapy as per Case Reports [2, 7-13]

| Case Report | Patient | Dose | Finding | Outcome |
|---|---|---|---|---|
| Rafat, et al. 2009[2] | 78 y/o M w/ chronic lymphocytic leukemia, sideroblastic anemia, and transfusion dependence. | 24mg/kg/d | Increase in Cr from 0.9 to 1.4 to 2.0, hypophosphatemia, metabolic acidosis, glycosuria. Diagnosis: Fanconi syndrome. | Drug was stopped and creatinine fell to 1.2. All features of proximal tubule dysfunction resolved. |
| Brosnahan, et al. 2008[7] | 62 y/o M w/ myelodysplastic syndrome and myeloproliferative disorder. | 2g/d | Increase in Cr from 1.6 to 2.2 to 3.0 and proteinuria. Biopsy showed acute interstitial nephritis. | Drug was stopped. Cr level returned to 1.3. |
| Yusuf, et al. 2008[8] | 43 y/o F w/ sickle cell disease, ESRD on peritoneal dialysis, and transfusion dependence. | 1.5g/d | Decrease in serum calcium from 8.0 to 5.9. Diagnosis: symptomatic hypocalcemia. | Drug was stopped and calcium normalized. Drug was then restarted; calcium again fell from 8.0 to 6.5. |
| Even-Or, et al. 2010[9] | 18 y/o M w/ pure red cell aplasia and transfusion dependence. | 20mg/kg/d | Increase in Cr from 0.6 to 1.07, glycosuria, hypokalemia, hypophosphatemia, phosphaturia, and aminoaciduria. Diagnosis: Fanconi syndrome. | Drug was stopped and electrolyte abnormalities resolved. Drug was then restarted and abnormalities reoccurred. |
| | 11 y/o F w/ B-thalassemia major and transfusion dependence. | 20mg/kg/d | Developed glycosuria, hypophosphatemia, proteinuria, phosphaturia, and amino-aciduria. Diagnosis: Fanconi syndrome. | Drug was stopped and both serum and urine labs normalized. |
| Grange, et al. 2010[10] | 77 y/o M w/ nonhereditary hemochromatosis | 1.5g/d | Developed increased Cr, hypokalemia, glycosuria, asthenia, anorexia, constipation, and epigastralgia. Diagnosis: Fanconi syndrome. | Drug was stopped and patient had complete resolution of symptoms and recovery of renal function. |
| Yew, et al. 2010[11] | 70 y/o M w/ porphyria cutanea tarda and multiple myeloma. | Not reported | Developed acute renal failure requiring dialysis. Biopsy showed tubulointerstitial nephritis. | Drug was stopped. Patient was started on dialysis and steroids. Creatinine returned to baseline. |
| Wei, et al. 2011[12] | 18 y/o M w/ B- thalassemia major and transfusion dependence. | 1375mg/d | Developed coma, hepatic dysfunction, thrombocytopenia, metabolic acidosis, elevated Cr, proteinuria and glycosuria. Diagnosis: Fanconi syndrome. | Drug was stopped and patient had full recovery. |
| Rheault, et al. 2011[13] | 7 y/o M w/ B-thalassemia major and transfusion dependence. | 0.5g/d | Developed nausea, anorexia, phosphaturia, aminoaciduria, glycosuria, hypokalemia, metabolic acidosis. Diagnosis: Fanconi syndrome. | Drug was stopped. Labs normalized. Drug was then restarted at lower dose. Labs again showed evidence of proximal tubule dysfunction. |
| | 8 y/o F adopted sibling of patient 1 also with B thalassemia major. | 0.5g/d | Developed elevated B2-microglobulin, microscopic hematuria, and proteinuria. | No treatment intervention. Continued to monitor. |

Abbreviations: y/o = year old; M = male; F = female; Cr = creatine

urinary loss of glucose, protein, potassium, phosphate, bicarbonate, and amino acids. Patients often present with generalized weakness, bone pain, and hypovolemia secondary to large volume urine loss. This is a rare disease with a limited number of etiologies. In children, cases are typically inherited; the most commonly associated diseases are cystinosis and Wilson's disease. In adults, etiologies include light chain disease such as multiple myeloma or amyloidosis, use of carbonic anhydrase inhibitors, heavy metal toxicity such as lead poisoning, and nephrotoxic drugs.[1] Our patient's ceruloplasmin was normal and he had no evidence of heavy metal toxicity. Upon review of his medications, ifosfamide and deferasirox were 2 drugs he had taken with links to proximal tubule injury. The patient did have trace glycosuria on his initial urinalysis in March 2011, which suggests a residual mild tubulopathy from ifosfamide as well. However, the progressive decline in renal function and full constellation of Fanconi syndrome suggests acute damage from deferasirox.

A review of the literature revealed less than a dozen case reports documenting significant renal dysfunction in the setting of deferasirox use. Injuries described include Fanconi syndrome, acute interstitial nephritis, calcium wasting, and acute renal failure (Table 2). Though the mechanism of kidney injury is unknown, a letter to the *American Journal of Kidney Diseases* in March 2010 from Dr Robert Hider suggests the nephrotoxicity of deferasirox is associated with the deferasirox-iron compound triple negative charge.[14] The negative charge traps the compound intracellularly, thus damaging the cell.

The history of ifosphamide and deferasirox use provided a good explanation for the patient's Fanconi syndrome. However, this did not explain the patient's progressive renal failure, so a biopsy was performed. Figure 1 is a silver stained section from our patient's biopsy at 400X magnification. The tubular epithelial cells have marked cytoplasmic vacuolization consistent with drug toxicity—similar to that reported in the animal studies in marmosets and rats that were administered oral deferasirox.[15]

Because the biopsies showed vacuolization and no evidence

of light chain deposition, no evidence of glomerular injury and no evidence of interstitial inflammation, and because evidence of renal injury coincided with the initiation of iron chelation therapy, deferasirox was left as the as the most likely explanation for both Fanconi syndrome and progressive renal failure. This is the first known case of Fanconi syndrome with biopsy-documented proximal tubulopathy in the setting of deferasirox use.

## CONCLUSION

This case report highlights the possibility of deferasirox-associated Fanconi syndrome and renal failure. The convenience of taking an oral medication is a great breakthrough in chelation therapy; however, it carries the risk of these rare side effects. Thus, we recommend monitoring of renal function with serial urinalyses, electrolyte levels, and creatinine levels during treatment.

Fanconi syndrome should be suspected in patients who present with low serum bicarbonate, potassium, and phosphorous levels in addition to glycosuria. All case reports thus far have demonstrated complete recovery of Fanconi syndrome and improvement in creatinine levels with cessation of deferasirox. Unfortunately, though our patient's renal function improved with cessation of therapy, he continues to require a significant amount of potassium and phosphorous supplementation daily.

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Robert N. Golden, MD

Karen Timberlake, JD

# Population Health Improvement: Moving Beyond the Clinic and Into the Community

Robert N. Golden, MD; Karen Timberlake, JD

Why should physicians and health care provider organizations move beyond caring for patients toward the more ambitious goal of identifying and addressing the community conditions that affect their patients' health?

The answer to this question is straightforward: because such an expanded focus is essential to the growing expectations that we accept greater accountability not just for high quality health care services, but increasingly for improved health outcomes.

The premise that health care delivery influences only 10% to 20% of life expectancy and quality of life is now well documented, although it is still surprising to many.[1] While it is difficult to enjoy a healthy life without adequate access to affordable, high-quality health care, we know from decades of research that simply investing more resources in health care delivery does not, by itself, produce better health for individuals or populations.

Take, for example, the recently released report from the Institute of Medicine of the National Academy of Sciences. The title itself is a wake-up call: *US Health in International Perspective: Shorter Lives, Poorer Health*.[2] Although our country invests a substantially greater share of its gross domestic product in health care delivery when compared to countries like Germany, England, and Japan, we simply do not live longer, healthier lives. This report highlights the many factors contributing to Americans' shorter lives and poorer health. We have the highest rate of obesity of the 17 industrialized nations studied. We have a higher death rate from injuries and accidents. We lose more years of life to the abuse of alcohol and prescription and illicit drugs. We have the highest rate of teen pregnancy. Our rates of infant mortality, mortality of children up to age 5, and child poverty are among the worst. Simply put, a baby born in the United States today runs a serious risk of living a shorter, less healthy life than a baby born in most of the other industrialized nations. Perhaps most surprising, this finding holds true across the socioeconomic spectrum.

No one sector of society is responsible for the root causes or controls the potential solutions to any of these complex challenges. Thus, we must find ways to work together toward the goal of longer healthier lives for all. At the University of Wisconsin (UW) Population Health Institute, we have worked for a decade to provide communities with insights into their current health status and the drivers of health by ranking health across a wide array of indicators at the county level. Four years ago, this work was expanded to a national level through a partnership with the Robert Wood Johnson Foundation. Released every spring, the *County Health Rankings & Roadmaps* now provides people living in virtually every county in all 50 states with information on how healthy their communities are, and what contributes to longer healthier lives (see www.countyhealthrankings.org).

What does all of this mean for physicians and other health care professionals? How can the prevailing trends in health care transformation—accountable care organizations, patient-centered medical homes, payment for value rather than volume—translate into not only better-managed, error-free health care services, but also meaningful improvements in health for individuals and communities? The short (and not simple) answer is this: health care organizations must expand their engagement in health promotion beyond the clinic and into the community.

Consider patients with chronic diseases like asthma, hypertension, and diabetes. More than 75% of our current health care expenditures are now directed to treating these and other chronic conditions, which in many instances could be prevented, or their severity reduced, by improving access to affordable, healthy food, safe places to exercise, and evidence-based techniques for reducing smoking and excessive alcohol consumption. Good clinical care always will be important, but realizing optimal clinical outcomes also requires environmental interventions, such as the remediation of contaminants in the apartment of a patient with asthma. The prevention and management of Type 2 diabetes relies on ready access to affordable, healthy food at convenient distances from the homes or workplaces of the people under our care.

Individual physicians and provider organi-

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zations have long been important partners in community-based health improvement activities. These activities fit with the mission of health care provider organizations and are consistent with the traditional ideals and values of the practice of medicine. This engagement needs to be substantially expanded. Employers purchasing private health care coverage and the Centers for Medicare and Medicaid Services alike need to control their financial investment in health care and obtain better health outcomes for their employees and beneficiaries. Success in this brave new world of health care financing requires not just the reduction of waste and variation in health care delivery; it also requires health care professionals to seek partnership opportunities with the public health sector, civic and philanthropic organizations, faith communities, schools, and private- and public-sector employers, which will enhance the environmental determinants of health and disease prevention.

These are just some of the questions that need to be addressed at the population level:

- How healthy are our residents? What does the health status of our community look like?
- What is occurring or might occur in the future that affects the health of our community?
- What assets do we have that can be used to improve community health?
- What are the components, activities, competencies, and capacities of those in a position to influence health (health care, public health, schools, businesses, transportation, etc)?

Within a physician's practice or health system, providers need to ask and answer questions like these:

- Who is leading the thinking for our organization on improving clinical outcomes by improving health in the community? Is this work taking place within a silo, or is it integrated into our strategic thinking?
- Who are our important local partners? Are we engaged with the right people and organizations?
- How can we move beyond a "safe" focus on health behaviors to working on the major drivers of longer, healthier lives: educational attainment, income, and a focus on reducing inequities in health status? How can we bring about policy, systems, and environmental changes?
- How can health care organizations within a community collaborate to advance health, even as they compete for patients?

Please take advantage of the resources available through the *County Health Rankings & Roadmaps* and other aspects of the UW Population Health Institute. Tell us what you are doing, how it is working, and what tools, resources, and data you need. Working together, we can realize better health for the people of Wisconsin, as we broaden our thinking beyond earlier concepts of health care delivery to a new integrated perspective of health promotion.

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# MetaStar: Celebrating 40 Years of Improving Health Care

Jay A. Gold, MD, JD, MPH

The year was 1973 and the top song on the Billboard charts was "Tie a Yellow Ribbon Round the Ole Oak Tree" by Tony Orlando and Dawn. President Nixon released the Watergate tapes and withdrew the last troops from Vietnam. Billie Jean King defeated Bobby Riggs in tennis. The Sears Tower was completed in Chicago, measuring 1454 feet tall. The US Supreme Court rendered a decision on Roe v Wade. Skylab, the first American space station, was launched. And Nuclear Magnetic Resonance, the technology behind Magnetic Resonance Imaging (MRI) scanning, was developed.

Just as the world has changed since 1973, so has health care. We are using new approaches and techniques, along with technology, to improve the ways we care for our patients and their families.

In Wisconsin, 1973 was the year 2 organizations were established under the new federal Professional Standards Review Organization (PSRO) program: the Foundation for Medical Care Evaluation of Southeastern Wisconsin (FMCE) and the Wisconsin Professional Review Organization (WisPRO). In 1984, with the transformation of the PSRO program into the Peer Review Organization (PRO) program, the organizations merged to become the Wisconsin Peer Review Organization (WIPRO). The PRO program soon would be transformed to employ a quality improvement approach to health care. In 1996 WIPRO reorganized and began using the name MetaStar, which can be taken to mean "guiding change."

As we mark our 40th year, MetaStar is proud to have spent the last 4 decades with the mission to effect positive change in the quality, efficiency and effectiveness of health care.

"We have successfully used state, federal, and private support to push the envelope of health care quality improvement across Wisconsin for 40 years while remaining independent and true to our mission," said Greg Simmons, CEO of MetaStar.

As both health care and MetaStar have evolved over the years, so has the concept of quality in health care.

"Forty years ago, quality was evaluated almost entirely by expert or peer opinion," said Simmons. "Since then, by applying the principles of science-based measurement and continuous improvement, we are much more capable of measuring quality objectively and of using those measurements to elicit improvements."

Simmons pointed out that quality in some areas, where the science is unambiguous, has improved markedly. In others, the improvement has been incremental. And there is still a lot to be done.

MetaStar's focus continues to be on quality improvement in health care services through collaborative efforts with hospitals, clinics, physicians, and other caregivers.

"Since our inception we have realized that all of our work—our very mission itself—depends upon a solid grounding in science and professionalism if it is to be credible and effective," said Simmons. "Likewise, it is essential to incorporate the perspective of the people delivering care on the front line. It is crucial for us to have physicians and other health care professionals on our team."

As we look toward the future, MetaStar is ready to continue "guiding change" as we improve the quality and safety of health care. And we know it will be a challenge. MetaStar will continue to follow the basic principles of continuous quality improvement, collaboration with clinicians as the most effective way to produce lasting change, and the application of evidence-based health care science.

"Even in areas where medicine knows the right thing to do, the system may fail to do it 20% to 30% of the time," said Simmons. "It has been estimated that there is solid science behind only about 30% of what we do in medical care. This means we are doing a lot that doesn't help people and may even hurt them. Organizations like MetaStar, along with physicians and other health care practitioners, must continue to work together in order to produce higher-quality care, controlled costs, and improved health of the population."

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Doctor Gold is senior vice president and chief medical officer for MetaStar, Inc.

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