



PROVEN.

LOW RATE OF HYPOGLYCEMIA

POWERFUL A1C REDUCTIONS -0.8% to -1.5%*

MAY PROVIDE ADDITIONAL BENEFIT OF WEIGHT LOSS[†]

For adult patients with type 2 diabetes, Victoza® offers these benefits and more. Visit **VictozaPro.com/Care** to learn how the support program helps patients get started.



*Victoza® 1.2 mg and 1.8 mg when used alone or in combination with OADs.

†Victoza® is not indicated for the management of obesity, and weight change was a secondary end point in clinical trials.



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 antiliraglutide 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.

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® on the authority of pancreatitis are at increased 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 adout the fired C-cell tumors and the fired carcinomatic coll tumors are considered to the control of the con including inequality involved action in the 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 relation to the visual relations at oast in an attribution to that is not evolved. And of the first relation 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, calcitonin below the upper limit of the reterence range, shrifts 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® 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 in increases in serum calcitonin. Victo22* due not produce consistent dose-dependent or time-dependent increases in serum calcitonin. Patients with MTC usually have calcitonin values >50 ng/L. In Victoz2® clinical trials, among patients with pre-treatment serum calcitonin <50 ng/L, noe Victoz2®-treated patient and no comparator-treated patients developed serum calcitonin >50 ng/L. The Victoz2®-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 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 cationin 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 ultra-sound 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 natients freated with Victoza® if serum calcitonin is measured and 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. **Pancreati** tis: 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 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® were reported as acute pancreatitis and four were reported as the properties with progressive acceptance of the properties with progressive acceptance of the properties with progressive acceptance and let the details to prove collect acuted. 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 norceased 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 who had experienced nausea, vomiting, diarrhea, or dehydration. Some of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Some 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**: Insere have been postmarketing reports of serious 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 his hist

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® 1.2 mg daily, Victoza® 1.8 mg daily, and glimepiride 8 mg daily; A double-blind 26 week add-on to metormin trial compared Victoza® 0.6 mg once-daily, blacebo, and glimepiride 4 mg once-daily, Victoza® 1.8 mg once-daily, placebo, and glimepiride 4 mg once-daily, Victoza® 1.8 mg once-daily, placebo, and glimepiride 4 mg once-daily, Victoza® 1.8 mg once-daily, placebo, and double-blind placebo, and open-label insulin glargine once-daily, placebo, and victoza® 1.8 mg once-daily, A 26 week add-on to metformin + glimepiride trial, compared double-blind Victoza® 1.8 mg 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 sulfonylure trial compared Victoza® 1.8 mg once-daily and exenatide 10 mog 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 placebo; An open-label 26-week add-on to metformin trial compared Victoza® 1.2 mg once-daily, Victoza® 1.8 mg once-daily, and stagliptin 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® 1.2 mg once-daily, Victoza® 1.8 mg + metformin to continued treatment with Victoza® 1.2 mg once-daily, Victoza® 1.8 mg + metformin to continued treatment with Victoza® 1.2 mg once-daily, victoza® 1.2 mg once-daily once-dail

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	91	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	Placebo + Metformin	Glimepiride + Metformin N = 242
	N = 724	N = 121	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® +	Placebo + Glimepiride	Rosiglitazone + Glimepiride N = 231
	Glimepiride N = 695	N = 114 '	Glimepíride N = 231
Adverse Reaction	(%)	(%)	(%)
Nausea	7.5	1.8	2.6
Diarrhea	7.2	1.8	2.2

Constipation	5.3	().9	1.7	
Dyspepsia	5.2).9	2.6	
	Add-on to Metformin + Glimepiride				
	Victoza® 1.8 + Metformin + Glimepiride N = 230	Placebo +	Metformin + de N = 114	Glargine + Metformin + Glimepiride N = 232	
	+ Glimepiride N = 230	Glimepiri	de N = 114	Glimepiride N = 232	
Adverse Reaction	(%)		%)	(%)	
Nausea	13.9		3.5	1.3	
Diarrhea	10.0	5	5.3	1.3	
Headache	9.6	7	'.9	5.6	
Dyspepsia	6.5).9	1.7	
Vomiting	6.5		3.5	0.4	
	Add-on to Metfor	min + Rosig			
	All Victoza® + Metformin +		Placebo + N	Metformin + Rosiglitazone	
	Rosiglitazone N = 355			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
Constination	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 pharma-ceuticals, patients treated with Victoza® may develop anti-liraglutide antibodies. Approximately 50-70% of CeUICals, patients (realed with Victoza^{oc} may develop anti-majoritud anucours. Approximately 30-70 o or Victoza^{oc}-treated patients in the five double-blind clinical trials of 26 weeks duration or longer were tested for the presence of anti-irraglutide antibodies at the end of treatment. Low titers (concentrations not requiring dilution of serum) of anti-irraglutide antibodies were detected in 8.6% of these Victoza^{oc}-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-irraglutide antibodies to native glucagon-like peptide-1 (GLP-1) occurred in 6.9% of the Victoza^{oc}-treated patients in the double-blind 50-week monotherapy trial and in 4.8% of the Victoza^{oc}-treated patients in the 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 in the double-bind ze-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 and active-control-treated patients, respectively. Among Victoza®-treated patients are compared to active expense whether the control-treated patients are control-treated patients. 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 1,000 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 plucose 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 nasopharyngaal), 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 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: ash and pruritus; Acute pancreatitis, hemorrhag

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

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

Victoza® is covered by US Patent Nos. 6,268,343, 6,458,924, 7,235,627, 8,114,833 and other patents pending. Victoza® Pen is covered by US Patent Nos. 6,004,297, RE 43,834, RE 41,956 and other patents pending.

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BY KIM KISER

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Charles R. Meyer, M.D., Editor in Chief

As I got further into my medical training, it became clear that "professional" was a word that carried a sackful of meanings and not just a little baggage.

What is a professional?

ne Christmas vacation during college, a local clothing store, desperate for holiday help, hired me to sell men's furnishings. During my two-week stint, I learned all I wanted to know at that time about belts, wallets and ties. Like the fulltime salesmen, I was paid partly by salary and partly by commission. I quickly discovered that the main topic of conversation among the regulars was not the latest tie fashion or how to please the customer but rather "How much you got rung up so far?" I grew disenchanted with this narrow view of the job and vowed that my eventual full-time profession would travel beyond the myopic bounds of "how much you got rung up."

Medicine seemed like a fit. Chiseled by long years of education and training, doctors were guardians of a specialized body of knowledge. Although clearly beneficiaries of impressive earning power, doctors seemed respected in their communities for reasons beyond wealth. And the ultimate goal of their work was to help others. Physicians seemed like the quintessential professionals.

Yet as I got further into my medical training, it became clear that "professional" was a word that carried a sackful of meanings and not just a little baggage. After all, in sports, a professional is one who is not an amateur and who gets paid for his or her performance.

Perhaps that is why medical organizations have struggled incessantly to define, and re-define, what a medical professional is. Common to many of those definitions are the qualities of altruism, accountability, excellence, duty and integrity. Indeed, most physicians would like to think that they consider their patient's welfare first, that they take responsibility for their actions, that they strive to improve, that they show up and that they tell truth.

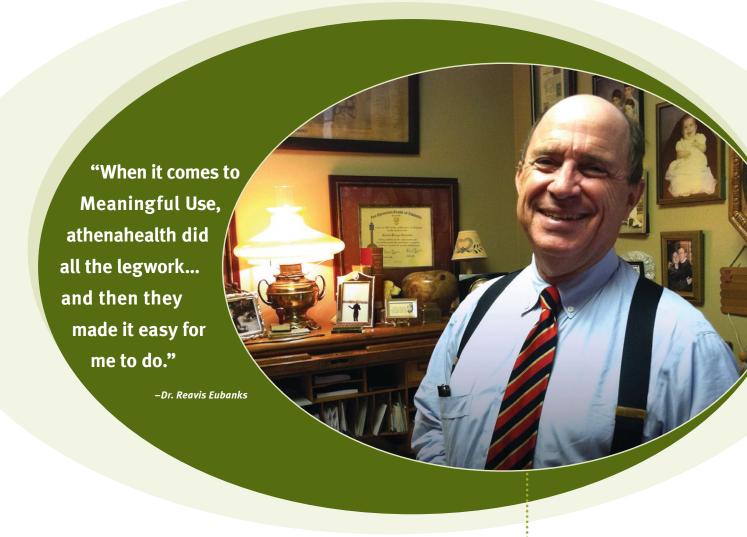
Yet during the course of a medical career, many things challenge our ability to maintain such high standards. Fatigue after endless nights on call tests our commitment to putting patients first. Potential consequences of professional failures threaten our resolve to maintain accountability. The daily tedium of paperwork and minor annoyances may push our intent to pursue continued learning out the back door. And with more and more doctors being employees of large corporations, duty can get redefined as fulfilling a clause in a contract.

So perhaps professionalism "ain't what it used to be." Are my professional standards today the same as those of the five internists I joined in 1977? Are they the same now that I work for a large organization? Are they the same as those of the solo practitioner in rural Minnesota? Will my commitment to professionalism go up in flames if I burn out?

Although there may be nuanced differences in the way each of us perceives professionalism, I think the core values remain static. University of St. Thomas professor Robert Kennedy in his paper "The Professionalization of Work" contended that "the relationship between professionals and those they serve is not a transaction ... but rather a transformative encounter." Sir William Osler said a professional was characterized by his "love of humanity associated with the love of his craft." I think a medical professional takes ownership of the care of his patients, faithfully and consistently applying the finely honed tools of his craft to transform those patients.

And if we physicians embrace this concept, how much we "got rung up" will take care of itself. MM

Charles Meyer can be reached at meyer073@umn.edu.



This is how Dr. Eubanks got paid for Meaningful Use.

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Bias in the exam room

Research is showing that many physicians are biased against patients who are obese. Doctors who take the Web-based Weight Implicit Association test, which involves pairing images of "thin" or "fat" people with negative or positive words, associate the overweight people with negative words, according to a study published November 7, 2012, in PLoS One.

Does such bias affect patient care? According to a study published in Obesity in March, it might. Researchers analyzed audio recordings of office visits and found doctors were 35 percent less likely to demonstrate emotional rapport with overweight and obese patients than with normalweight patients.

The anti-obesity sentiments likely take root long before people become physicians, however. According to a study in July's *Academic* Medicine, nearly 40 percent of 310 third-year medical students were biased against overweight people. Twothirds of those thought they held neutral views of people who were overweight.

Face time or screen time?

How do internal medicine residents spend their time at work? Last year, researchers from Johns Hopkins University set out to answer that question by observing residents at two Baltimore teaching hospitals.

They conducted a time-motion study involving 29 interns in two internal medicine programs in January of 2012. They observed the interns for 873 hours and found they spent:

- 12 percent of their time doing direct patient care
- 64 percent doing indirect patient care (documenting, consulting with other providers)
- 15 percent doing educational activities
- 9 percent sleeping, eating, walking and doing other miscellaneous activities.

Of note, the investigators found residents spent 40 percent of their time in front of a computer.

Source: Journal of General Internal Medicine, August 2013.



Rand reports on physician satisfaction

A new report by Rand Health explores nine factors believed to have an impact on physician satisfaction. The authors of the study of 30 physician practices in six states wrote that the most novel of their findings related to two areas: quality and electronic health records (EHRs).

When physicians think they are providing high-quality care, they're more satisfied with their work. Yet the researchers found only half of the physicians surveyed thought leaders in

Factors studied

Quality of care Electronic health records Autonomy and work control

Practice leadership Collegiality, fairness and respect

Work quantity and pace Payment, income and practice finance

Regulatory and professional liability concerns

Health care reform

their organization listened to their suggestions for improving care, and only half thought the information they received about the quality of their care was useful.

The researchers also found physicians have mixed feelings about EHRs. They like them in concept but find the current state of EHR technology frustrating. "Poor EHR usability, time-consuming data entry, interference with face-to-face patient care, inefficient and less-fulfilling work content, inability to exchange health information between EHR products, and degradation

Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy Mark W. Riedberg • Peggy G. Chen • Kratin R. Van Busum • Frances M. Ac Chau Pham • John P. Caloyeras • Soeren Mattile • Einma Pitchfurth Denise D. Quigley • Robert H. Brook • F. Jay Crosson • Michael Tutty AMA

of clinical documentation were prominent sources of professional dissatisfaction," the authors stated.

Health care reform was found to neither positively nor negatively affect satisfaction, and most physicians were satisfied with their income.

The report was sponsored and endorsed by the American Medical Association. It can be found at http://m.rand.org/ pubs/research_reports/RR439. html.

The difference a thank you makes

BY JEANNE METTNER

We cannot find the words to express how thankful we are to have you as our doctor. You have gone the "extra mile" for us. You are truly beautiful inside and out.

Thank you again for diagnosing our daughter. Our journey to you took 5.5 years. You were the "light" at the end of the tunnel.

—from notes written to Mayo Clinic physicians

For the past four years, Paul S. Mueller, M.D., chair of Mayo Clinic's division of internal medicine, has been making sure kudos and thank yous from patients are shared with those who deserve the credit. Each month, he uses them to create a slideshow that will run for 10 minutes before the start of staff meetings.

Mueller did not come up with the idea of kudos slides (previous chairs occasionally displayed the accolades in some form). He merely formalized the process of collecting, organizing and displaying them every month. "Usually, division meetings are about business—we discuss our monthly clinical productivity reports, policy matters, education and research activities, and so on. Sometimes we delve into controversial health care-related issues," he explains. "Here, with these slides, we're reminding staff that there is a lot of good that is going on, and we want to celebrate that before we tackle the meeting agenda"

Most of the messages of appreciation arrive on Mueller's desk. Other times, they go directly to his colleagues—sometimes with tokens of appreciation ranging from chocolates to paintings to monetary gifts. Anything beyond nominal value (eg, exceeding the cost of a box of chocolates) is turned over to Mayo. For example, a traditional piece of Indian art donated by one appreciative family is now on display on the 17th floor of the Mayo-Gonda building complex, which is home to the Division of General Internal Medicine. The monetary gifts have gone toward the institution's research and teaching missions.

Mueller says the slideshows foster professionalism because they promote doing good work and having quality patient interactions. "Doctors love it; they may get a pat on the back from a colleague sitting next to them at the meeting, or you will see smiles on their faces as they see compliments about themselves on the slides," he says. "And that's what it's about—generating positive energy in an environment that can be pretty hectic and stressful." MM







FIELD	DEGREE	TYPE OF TRAINING	LICENSING BOARD	WORK ACTIVITIES
Allopathic medicine	M.D.	Four years of post-graduate training in an allopathic medical school, plus a three-year (or longer) residency. In some cases, fellowships.	Minnesota Board of Medical Practice	May practice the complete spectrum of medical and surgical specialties. May prevent, screen for, diagnose and treat disease. May prescribe medications and perform surgeries.
Osteopathic medicine	D.O.	Four years of post-graduate training in a osteopathic medical school, including 500 hours of manual medicine training, plus a three-year (or longer) residency. In some cases, fellowships.	Minnesota Board of Medical Practice	May practice the complete spectrum of medical and surgical specialties. May prevent, screen for, diagnose and treat disease. May prescribe medications, perform surgeries and do manual medicine.
Optometry	O.D.	Four years of post-graduate study at a school of optometry plus one year of clinical rotations.	Minnesota Board of Optometry	May examine patients' eyes for vision problems and diseases; recommend treatments; prescribe eyeglasses, contact lenses or other vision aids or procedures.
Audiology	Au.D. Ph.D.	Three or four years of graduate work in a doctoral program and supervised clinical practice.	Minnesota Department of Health's Health Occupations Program	May screen for, diagnose and treat hearing and balance problems; fit and dispense hearing aids; assess candidacy for cochlear implants; provide rehabilitative services.
Psychology	Ph.D. or Psy.D.	Three or more years in a graduate program. Ph.D. programs are research-oriented and require a dissertation. Psy.D. programs are clinically oriented, requiring practicums, internships and a project.	Minnesota Board of Psychology	May identify and diagnose mental, behavioral or emotional disorders; collaborate with physicians and others on treatment; provide behavioral therapy. Cannot prescribe medications.
Podiatric medicine	D.P.M.	Four years of graduate study in a school of podiatric medicine, plus a three-year residency.	Minnesota Board of Podiatric Medicine	May diagnose foot, ankle and lower-leg problems through physical exams, imaging and laboratory tests; treat foot, ankle and lower-leg ailments with orthotics and surgeries; prescribe medications.
Nursing	D.N.P. Ph.D.	Three or more years of graduate study. D.N.P. programs are clinically oriented. Ph.D. programs are research-oriented.	Minnesota Board of Nursing	May provide direct care, case management, consultation, education or research; must have a written agreement with a physician in same specialty to prescribe medications and therapeutic devices.
Naturopathic medicine	N.D.	Four years in a graduate-level naturopathic medical school. In addition to completing a standard curriculum, students also study clinical nutrition, homeopathic medicine, botanical medicine and psychology.	Minnesota Board of Medical Practice	May diagnose and treat diseases, do minor surgical procedures such as removing a cyst or stitching a wound, and prescribe pharmaceuticals. The emphasis is on natural healing agents and modalities, and practice may encompass use of botanicals, naturopathic physical medicine (including naturopathic manipulative therapy), homeopathy, acupuncture and naturopathic obstetrics (natural childbirth).
Physical therapy	D.P.T.	Three years of graduate study with a residency lasting nine months to three years.	Minnesota State Board of Physical Therapy	May evaluate and diagnose patients and do treatments involving exercise, stretching, hands-on therapy and use of equipment. May treat patients without a referral from a physician for up to 30 days.
Chiropractic	D.C.	Four years of postgraduate study in a school of chiropractic.	Minnesota Board of Chiropractic Examiners	May assess patients' medical condition; analyze posture and spine; provide musculoskeletal therapy (adjustments); conduct additional diagnostic tests including X-rays; advise patients on health and lifestyle issues such as exercise and sleep habits.
Doctor of Pharmacy	Pharm.D.	Four years of study in a doctor of pharmacy program. In many cases, a residency in clinical pharmacy or research.	Minnesota Board of Pharmacy	May fill prescriptions and compound, label and dispense drugs; monitor drug therapy; participate in drug and device selection; administer drugs for first dosage and medical emergencies; do drug regimen reviews; administer influenza and pneumococcal vaccines; and manage drug therapy according to a written protocol with a dentist, optometrist, physician or podiatrist.

That darn EHR!

Two Minnesota researchers confirm it: Electronic health records are adding to your stress.

BY SUZY FRISCH

ark Linzer, M.D., has a love-hate relationship with his electronic health record (EHR) system. Although it places the patient's entire record at his fingertips—a convenience not afforded by paper records—it is also a taskmaster.

During each patient visit, Linzer, who directs the General Internal Medicine Division at Hennepin County Medical Center (HCMC), must click through about 100 prompts and race to meet its many requests for action. The system might ask him to follow up regarding a patient's past health concerns, monitor chronic conditions, review consulting physicians' notes, verify lab results, refill medications and schedule screenings—all before asking the patient what he or she would like to discuss. "It's just too much to squeeze into too little time. No one adapted the length of the medical visit to the new technology," says Linzer, who also is a professor of medicine at the University of Minnesota. "Everyone is trying to get everything done, and it's an uphill battle. I'm missing sitting and talking to my patients because I'm doing so much clicking."

Linzer admits he finds the constant prompts and screens stressful, and he has shown other physicians feel the same way. Although clinics and hospitals have been rolling out EHRs for about 10 years, few had studied how they affect physicians' work lives until Linzer and a team of researchers from HCMC, Mayo Clinic College of Medicine and five universities set out to change that. As part of the federally funded MEMO (Minimizing Error Maximizing Outcome) study, they surveyed 471 physicians and managers at 92 clinics across the country to assess whether using

EHRs during office visits contributes to doctors' stress and potential burnout. Their findings were published in the *Journal of the American Medical Informatics Association* in September.

your in-basket, it will find you and tell you what needs to be done."

EHR realities

The researchers found stress levels vary depending on whether a doctor's office uses a low-, moderate-or high-functioning EHR

system. Physicians who use bare-bones (lowfunctioning) systems that provide only basics such as lab results, medication lists, prevention reminders,

guidelines and the ability to email patients generally experience the least amount of stress. Those who use moderate-functioning systems that have features such as notes from previous patient encounters, notes from consulting physicians, and the ability to order tests or scans and exchange information with other physicians, experienced the most stress. Doctors who use high-functioning systems that do all of the above, plus provide lists of a patient's problems

and medications; have eprescribing capabilities; and include information about drug interactions, all patient notes and radiographic reports indicated their overall stress levels were closer to those of the physicians using the low-functioning systems. In addition, many of the study's participants said they believe the quality of the care they provide has suffered because they spend so much time with the EHR, rather than with the patient.

Linzer says they also found the collision of two factors—the arrival of the EHR and organizational pressure to see more patients each day—causes physicians to feel

The research yielded two main findings: One, doctors find it stressful to manage a complicated database requesting all kinds of information while also

interacting with patients, often during 15- to 20-minute appointments. Two, the EHRs' "in-basket" feature, a repository for all the messages, questions and requests for refills, consults or information from insurance, is a major stressor. Many report feeling as if they're chasing endless tasks on a hamster wheel.

"It's tough to get it all done and get home. Even if you leave at 6 or 7, you still have two hours of in-basket work to do at night," Linzer says, adding that some requests get re-sent if they aren't answered within 24 hours. "When you don't clear further stress. "The minutes available to see patients are shrinking, and with every minute you take off, the stress dramatically rises. That's when people start getting burned out," he says. Linzer notes that wherever he goes to speak, the EHR is all anyone wants to talk about.

Bill Spinelli, M.D., a family physician at Allina Medical Clinic in Hastings and a research fellow in Allina's Division of Applied Research, who has been examining physician burnout, found EHRs were a contributing factor. He found in a study of Allina physicians that:

EHRs don't save time. Doctors who took part in a focus group said it takes too long to complete the documentation and work required by the EHR, especially as they transition from traditional paper-based systems to electronic ones. It puts administrative tasks such as chart documentation back into doctors' hands, instead of assistants'. Adding to doctors' workloads is the fact that it takes multiple steps to open a file, create an encounter, then open the documentation section.

EHRs cause information overload. Well-meaning administrators send training tips and other updates to help physicians use the EHR efficiently and effectively. "But the constant barrage of updates and changes can stress people out," Spinelli says. EHRs contain copious amounts of information about each patient—from their problem list to all of the notes from consulting physicians—and sometimes it's difficult to determine what is and is not important.

EHRs require doctors to be multitaskers. Many of the focus group participants were frustrated by having to juggle patient interaction with entering information into the record. They worried that it negatively affected the dynamic with their patients because they are looking at a screen instead of talking with them.

EHRs create a never-ending pile of work. Physicians in Spinelli's study, like those in Linzer's, cited the in-basket feature as being a problem.

Spinelli says privacy laws and liability concerns are two reasons why more of the work falls to physicians. With the EHR, there are certain tasks that physicians now must complete, even if they were once handled by a nurse or medical assistant. For example, the physician is the only one who can go into a patient's file and remove medications he or she is no longer taking.

Spinelli has noticed the increased workload in his own practice. He used to be able to wrap up his workday with about 30 minutes of administrative work before heading home. Since moving to the EHR, he now spends one to six hours catching up on chart documentation, following up on emails and requests, refilling prescriptions and more.

Here to stay

Spinelli's and Linzer's next goal is to seek ways to mitigate EHR-related stress. One possibility is to give physicians more time with patients during office visits so they can complete all of the requested tasks without having to rush. Another is to change the rules so that other medical staff can take over some of the data entry and

do prescription refill or prior authorization requests. That way doctors' in-baskets won't be chock full at the end of each day.

Despite their concern about EHRs causing stress, both Linzer and Spinelli acknowledge that EHRs are here to stay. And they say they hear positive comments from physicians who appreciate having access to all of the patient information the electronic record provides them during office visits. They like that they can review patients' historic blood sugar or cholesterol levels with them, then quickly turn the data into a graph that makes the information easy for the patient to understand.

"They appreciate the power of the tool, the data that's available and the access to clinical decision-making support. But it does make their jobs more stressful," Spinelli says. "They'll say, 'This has been terrible for me. But don't take it away!" MM

Suzy Frisch is a Twin Cities freelance writer.



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AS A SENIOR RESIDENT



at the University of Washington-Seattle in 2000, Tait Shanafelt, M.D., noticed that the interns he was supervising were beginning to act negatively toward patients. "It surprised me to hear so many cynical, unprofessional comments from such great, dedicated people," he recalls.

That got him thinking: What was at the heart of the change? What was it that was tarnishing the idealism and enthusiasm so many had when they started their training? "It made me suspect it was a problem with the system, rather than individuals," he says.

Shanafelt decided to look into the problem. To do so, he surveyed internal medicine residents in Seattle and discovered that burnout not only was common among them but also that it harms the quality of care they provide and increases rates of major medical errors. He published those results in 2002 in the Annals of Internal Medicine.

After finishing his residency, Shanafelt came to Mayo Clinic in 2001 to do a hematology/oncology fellowship. He later joined the faculty and was asked by leaders at Mayo, who had taken note of his initial study, to continue his research on burnout among internal medicine residents. Shanafelt recruited Colin West, M.D., who

was chief internal medicine resident at the time and has a Ph.D. in biostatistics, to his team. In 2004, they were joined by another internal medicine physician, Lotte Dyrbye M.D., M.H.P.E., who had also read Shanafelt's 2002 article on residents and was interested in finding out whether burnout starts to take hold even earlier, in medical school. (It does.)

Shanafelt, West and Dyrbye began exploring the issue in earnest. In 2007, they were tapped to head up Mayo's Physician Well-Being Program to research the causes of burnout and develop evidence-based ways to prevent it and reduce it. Since then, they have published more than 60

peer-reviewed articles and become international experts on the topic.

Into the spotlight

Together, the three researchers have brought the topic of physician burnout out of the closet and into the national spotlight. "Ten years ago, burnout was something you just didn't talk about," West says. "The traditional attitude was that physicians were supposed to be super-human, immune from burnout and capable of handling anything." Professional distress was thought to be a sign of weakness experienced by only a few.

That line of thinking began to change when some of the findings from their early studies were widely reported in the lay press. "After that, it snowballed," Shanafelt recalls. The AMA and the American College of Surgeons, among others, asked them to do more research.

In 2010, the team led the first national study on burnout, comparing 7,300 practicing physicians across all specialties to a probability-based sample of the U.S. population. They found 45 percent of physicians were experiencing professional burnout. "We learned that physicians have significantly higher burnout rates than people in other professions do," West says.

They also learned that burnout crosses all specialties and that emergency medicine physicians had the highest rate, fol-



BUSTERS

How three Mayo Clinic physicians became experts on physician well-being.

BY HOWARD BELL

lowed by those in general internal medicine, neurology and family medicine. The lowest rates, which were still high compared with those of other professions, were among those practicing occupational and environmental medicine, dermatology and general pediatrics. Men and women experienced comparable burnout rates.

Shanafelt's team also discovered that physician burnout manifests in a number of ways: Signs and symptoms include loss of enthusiasm for work, cynicism, lack of empathy for patients and a low sense of personal accomplishment. In addition, they found burnout could be linked to

medical errors, poor quality of care, family strife, substance abuse, depression, suicidality, decreased productivity and early retirement.

A hard sell

Getting administrators and program directors to see burnout as the problem it is wasn't easy. Often while speaking around the country, the researchers would hear administrators say they had bigger fish to fry—that the bottom line would take a hit if they did anything to address burnout that cost money or reduced physician productivity.

"So we had to first build a foundation of evidence that physician burnout is a common and serious problem," West says. "Administrators would often tell us things like 'All professionals are stressed out and physicians aren't any different.' Our response was to study that assertion. That's when we looked at burnout across specialties and learned that physicians do experience burnout at higher rates than other professionals do and that it has more serious consequences than it does in other professions."

West cites the following as some of the factors that contribute to burnout: declining reimbursements, rising productivity expectations, increasing regulations and documentation requirements, electronic medical record headaches, loss of autonomy, increasing complexity of patients, and continuity-of-care challenges that come with team-based medicine. "These stressors hit physicians full force," he says. "The system tends to beat us up, chew us up and spit us out. We want to prevent that."

The question is how. "Many wellmeaning people have come up with interventions," Shanafelt says. "The problem is that for many of these, there's no evidence that they work, which makes it difficult for leaders to support them in an era of limited resources."

Mayo's Physician Well-Being Program has shifted its focus to designing and testing interventions that individuals and organizations can pursue to prevent and deal with burnout. "That will be our research focus in the future," Shanafelt says, "to find practical, cost-effective ways organizations can help physicians cope with the challenges of modern medical practice so they can provide the best possible care to patients."

Practicing what they preach

Defending personal well-being against the forces of the health care system might seem a David-versus-Goliath challenge, but West says they have identified ways physicians can protect themselves against burnout.



SELECHECK-UP

To help physicians and medical students assess their risk for burnout, Lotte Dyrbye, M.D., M.H.P.E., and Tait Shanafelt, M.D., two of the leaders of Mayo Clinic's Physician Well-Being Program, developed the Mayo Clinic Physician Well-Being Index and the Medical Student Well-Being Index. Both self-assessments can be completed electronically. "It's a way to check in with yourself and get some insight into how you're doing compared to national norms," Dyrbye says.

The physicians' index has been shown to predict the likelihood of such personal and professional consequences as major medical errors, suicidal ideation, and intent to reduce hours or leave medical practice.

The index has been tested with more than 12,000 physicians in the United States. Recent results published in the 2013 Annals of Surgery show that half of all surgeons who completed the electronic self-assessment said it helped motivate them to make changes proven to improve their well-being.

The student index identifies medical students whose degree of distress places them at risk for severe consequences such as suicide. It has been tested on more than 4.000 U.S. medical students.—H.B.

Well-Being Index

During the past month:

- Have you felt burned out from work/medical school?
- Have you worried that work/medical school is hardening you emotionally?
- Have you often been bothered by feeling down, depressed or hopeless?
- Have you fallen asleep while stopped in traffic or driving?
- Have you felt that all the things you had to do were piling up so high that you could not overcome them?
- Have you been bothered by emotional problems (such as feeling anxious, depressed or irritable)?
- Has your physical health interfered with your ability to do your daily work at home and/or away from home?

Some, like getting exercise, seem obvious, even mundane. Nevertheless, research shows it can work. Dyrbye, who works full-time and has three young children, either runs, lifts weights, bikes or skis nearly every day. Studies show that mindfulness training also can help some physicians lower their burnout scores. That training includes meditation, writing sessions and discussions on topics such as managing conflict, setting boundaries and self-care. West admits that mindfulness training won't appeal to all physicians. "But it's been shown to work," he says.

West admits he struggles just like everybody else to maintain a work-family balance. When he has a chance, he plays tennis, works out and spends time with family. "One thing that works for me is simply conceding that sometimes work is going to win. But that means at other times I have to make sure home wins," he

West says another burnout buster is having variety in his job. Some days he works with residents. Other days he does research or sees patients. He says it's doing research that really stokes his fire.

Spending at least part of your work day doing something you really like helps prevent burnout, according to another one of their studies that looked at job fit and burnout. "We found that if you spend 20 percent of your work hours doing what you find most professionally meaningful, it dramatically decreases rates of burnout," Shanafelt says. "Interestingly, 20 percent seems to be the magic threshold; spending more than 20 percent doesn't provide incremental benefit."

For Shanafelt, that 20 percent zest-forwork preserver is leukemia research and working with cancer patients. Dyrbye's "20 percent" is her research evaluating ways to change medical school curriculum to prevent burnout and boost resiliency (see "Burnout begins in medical school," p. 18).

This requires work on the part of the physician—identifying what you like best about practicing medicine, which may

change during the course of a career, and making an effort to focus part of your practice in that area. And allowing physicians to carve out time for that 20 percent requires flexibility on the part of their employers.

Finding meaning in work

Over the past three years, Shanafelt has noticed a change in attitude among clinic administrators and CEOs across the country—a desire to make burnout reduction and staff well-being a priority. "Our studies have convinced them that burnout is not only common, but it affects quality of care. As its prevalence has increased, burnout has affected staff morale and caused recruitment and retention problems," West says.

The Mayo team recently conducted one of the first trials of an organization-wide intervention aimed at reducing burnout. They randomized 75 internal medicine physicians into two groups. The first group was given one hour every other week for

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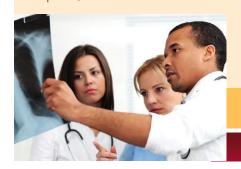
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nine months to do whatever they wanted to do that was work-related, such as catch up on paperwork and phone calls. The second group met in small groups led by a facilitator for the same amount of time. During those meetings, members shared experiences and advice on such things as medical mistakes, everyday frustrations, dealing with challenging patients, how to stay resilient, how to get more meaning from work and work-life balance. A third group of physicians simply worked as usual. All groups completed longitudinal well-being surveys.

Both groups that got the hour of protected time every other week lowered their burnout scores. But the group that met in small groups boosted their scores related to seeing meaning in their work and lowered their scores related to professional cynicism. "Boosting the meaning you get from work is a huge inoculant against burnout," West says.

Although improvements in their scores on emotional exhaustion, overall burnout, mental well-being, depressive symptoms,

empathy, stress and job satisfaction were less striking, those who met in the facilitated small groups still outperformed those in the other two groups in all of these areas. "The benefits these physicians got were still present one year after they last met," West says. "Something about that experience produced substantial, sustainable benefits."

The study results are still being reviewed. "Assuming the study passes the scientific acid test," West says, "we'll explore ways to deploy the small-group intervention at Mayo and look for ways to lower its cost." The average group session participant attended 12 hours of meetings over the ninemonth intervention period. "That doesn't seem like a high price to pay for the kind of benefits we saw," West says. "Studies show that physicians who are more satisfied with their jobs have significantly greater productivity. So this small investment may actually translate into a net gain in productivity and improve clinical outcomes."

Other organizational changes the researchers are studying include restructuring clinic workflows and responsibilities so physicians can spend more time with patients and less time on phone calls, emails and paperwork.

No magic solution

Shanafelt and his team have learned that preventing burnout is often beyond the control of the individual. "A lot of this is about the attitude of leadership and the organizational culture they encourage. Physicians need to see that their clinic or hospital shares their commitment to patients, values the well-being of staff, and is trying to make the work environment as efficient and positive as possible. Taking care of the care provider team is a critical part of achieving the organization's goals," he says, adding that he has had inquiries from other Minnesota health care systems that are interested in finding ways to fight burnout among their physicians. "And organizations that take better care of their physicians have physicians who take better care of their patients." MM

Howard Bell is a medical writer and frequent contributor to Minnesota Medicine.

RNOUT BEGINS



After reading a 2002 article on burnout among internal medicine residents, Mayo Clinic internist Lotte Dyrbye, M.D., MH.P.E., approached the author and Mayo colleague Tait Shanafelt, M.D., about studying whether it began even earlier—in medical school. In their first study together, the results of which were published in

Academic Medicine in 2006, they found that half of 545 medical students surveyed suffered from burnout. "They enter medical school with mental health profiles similar to their peers who don't go to medical school," Dyrbye says. "Something about medical

school tips them over the edge."

Dyrbye also found that students suffering burnout are the ones who have the least empathy for patients.

In another study, published in 2008 in Annals of Internal Medicine, Dyrbye analyzed 2,248 survey responses from medical students at seven medical schools and again found that nearly half met the criteria for burnout. In addition, 11% of surveyed students reported having suicidal thoughts in the past year—a rate substantially higher than age-matched peers who were not in medical school. "These are incredibly disturbing findings," Dyrbye says. "We need to do a better job helping students acquire the skills they need to thrive in medicine. We need to optimize the learning environment and deal thoughtfully with the exploding curriculum that we are asking students to master."

The American Medical Association just awarded Mayo Clinic a \$1 million grant to develop curriculum that among other things increases medical student personal wellness. "Our goal," Dyrbye says, "is to ensure that students thrive and that they are prepared for the realities of practicing medicine."—H.B.



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teven Meister, M.D., M.B.A., remembers the day when he knew he was on to something big. Standing before a room full of physicians at the American Medical Association's annual meeting in Chicago last June, he told the story of how he found himself at the center of a lawsuit against the leadership of the hospital in Marshall, Minnesota, where he has practiced for the last 10 years—a case that centers on whether the hospital's administration can change the medical staff bylaws without physician approval.

The lawsuit had consumed Meister and his colleague, Jane Willett, D.O., for nearly two years, taking them away from their practices and placing them at odds with hospital leaders. He hadn't expected that his story about a situation in a town of 13,000 in southwestern Minnesota would resonate so strongly with physicians from across the country. But it did.

"Several dozen physicians from Texas, Florida, Indiana, came up afterward and spoke to me in support," he recalls. "They said similar things were happening in their health care systems." Although a lawsuit over whether bylaws constitute a contract between a hospital and the physicians who see patients there sounds like fodder for legal scholars, it cloaks a larger issue: Who ultimately decides what is considered to be high-quality medical care—hospital administrators or physicians?

Unlikely litigants

Meister, who was serving as chief of staff at Avera Marshall Regional Medical Center when the suit was filed in January of 2012, and Willett, who was chief of staff-elect at the time, consider themselves unlikely litigants. Committed rural family physicians, neither thought they would find themselves at odds with the hospital—much less embroiled in a case against it that could have national repercussions.

Meister, who grew up in Cloquet, came to Marshall to practice family medicine 10 years ago. He says he "fell in love" with the community while doing a Minnesota Rural Provider Associate Program clerkship with one of the town's doctors during

his third year of medical school at the University of Minnesota. After seven years in the Navy, he joined the staff of Affiliated Community Medical Center (ACMC), which has clinics throughout southwestern Minnesota.

Willett, who is originally from Owatonna, came to Marshall 22 years ago after earning her D.O. at Kirksville College of Osteopathic Medicine in Missouri and doing a residency in Ohio. She wanted to live in a smaller town where, as a family physician, she could practice obstetrics and see patients both in the clinic and the hospital. "A lot of family physicians in larger cities just do outpatient medicine. I like being able to do inpatient care and deliver babies, too," she says.

Both Willett and her husband, an internist, are long-time figures at the hospital. They have served as medical staff officers, playing a key role in writing the medical staff bylaws a number of years ago. Those bylaws are the rules by which physicians govern and police themselves. They define such things as who qualifies for membership on the medical staff and admitting privileges at the hospital, the responsibilities of the medical staff, its various committees (quality assurance, accreditation, infection control and executive committee, for example), and the procedures for instituting corrective action or suspension of a physician. Bylaws must be adopted by the medical staff and approved by the hospital's governing body, according to the Joint Commission, which accredits hospitals in the United States. The fact that the hospital's board and administration changed the

bylaws on their own is what ultimately led Meister and Willett to file the lawsuit.

It started over peer review

Avera Marshall Regional Medical Center opened in 1950 as Louis Weiner Memorial Hospital. For most of its existence, the hospital was owned by the city of Marshall. For years, ACMC was the only medical group in town, and its physicians worked in a clinic attached to the hospital. After outgrowing that space, and later clinic space at a nearby mall, ACMC, which now has 18 primary care physicians, moved into a new two-story 45,000-square-foot building on the northeast side of town, about a mile from the hospital, in March of 2013.

In 2004, South Dakota-based Avera Health was hired by the city to run the 25-bed critical access hospital. The city then decided to sell the hospital to Avera in 2009. In the meantime, Avera brought in its own team of 17 primary care and specialty physicians and housed them at the hospital and a nearby clinic.

Physicians from ACMC worked alongside those who were employed by Avera as well as a few independent practitioners. "Our relationships with the physicians at the hospital have been very collegial and fun," Willett says. The medical executive committee, which represents all physicians who practice at the hospital, was composed of equal numbers of physicians from ACMC and Avera. And the ACMC physicians' relationship with the hospital's administration was "not problematic," according to Willett. But that changed after the sale closed in November of 2009.

According to court records, in 2010, ACMC sued Avera Marshall for allegedly steering patients away from their physicians and toward Avera's employed physicians. But the issue that was what Meister describes as "the powderkeg" was peer review.

As chief of staff, Meister was charged with working with the hospital's CEO to form a quality-improvement committee

ON THE COVER

that would conduct physician peer review. The applicable policy that had been adopted by the hospital's medical staff and board of directors indicated that the committee should consist only of physicians. It did not include any specific requirements as to a member's employment status, but it did indicate that the committee was to

for a physician if it's misused. If you want to use it as a witch hunt to run a doctor out, what better venue to do it?"

Meister says that after the hospital's board and administration set up their own peer-review committee, the medical executive committee created one that was consistent with the existing bylaws and

They demanded to have [non-physician] board members on the Medical Staff Quality-Improvement Committee, and we didn't feel it was appropriate. It's not peer review because they're not peers, and they don't understand when we talk about medicine. But they wouldn't budge on that.

JANE WILLETT, D.O.

be made up of physicians who hold certain medical staff offices or positions and representatives from the medicine, emergency, surgery, maternal-fetal medicine and psychiatry departments. "You want fair and equal balance," he says. Meister proposed a slate of candidates that he describes as "a 50/50 balance" of Avera and non-Avera physicians.

But the hospital's board and administration didn't go along with it and instead set up a peer-review committee predominantly made up of Avera physicians plus one ACMC physician and several non-physician hospital board members. That was what ultimately led to the lawsuit.

"They demanded to have [non-physician] board members on the Medical Staff Quality-Improvement Committee, and we didn't feel it was appropriate," Willett says. "It's not peer review because they're not peers, and they don't understand when we talk about medicine. But they wouldn't budge on that."

Meister and Willett feared that if nonphysicians were involved in peer review, it could lead to unfair treatment of physicians. "Peer review, in my opinion, is about quality. It's about looking out for patients," Meister says. "But it can be horrible included both Avera and non-Avera physicians. "Then they [the hospital] started doing all sorts of funny things," he says, alleging that the administration prohibited the Avera physicians from attending meetings of the medical executive committee's peer-review committee and forbid that committee to meet at the hospital.

Court records show that in January 2012, Avera Marshall sent a letter to the medical staff saying that it planned to repeal the bylaws and establish new ones. Among the proposed changes were additional requirements for eligibility to serve on the medical staff; more clearly defined work requirements for the staff, officers, departments and departmental leaders; modifications to clinical rules and regulations; and changes to the procedure for and timing of elections. The court described the changes as a "transition to a top-down, management-based approach to hospital administration."

The records also noted that the hospital's president and CEO indicated that the changes would not be brought before the medical staff for a vote (the existing bylaws stated that changes to the bylaws must be approved by two-thirds of the medical staff) but that individual mem-

bers could submit comments to hospital administration. Avera asked that written feedback be submitted by March 1; the changes to the bylaws were scheduled to take effect April 1.

"We looked at the changes, evaluated them at the medical executive committee and got input [from the medical staff]," Meister says. Operating under the guidance of the existing bylaws, the staff voted and rejected the repeal by a margin of 18 to 10 and rejected the new bylaws by a margin of 17 to 11, according to the records. Despite the outcome of the vote, Avera went ahead and instituted the new medical staff bylaws. The hospital's board and administration took the position that "they're the hospital; they had the power to just make changes," Meister says.

The physicians' attempts to negotiate with the hospital broke down. "It got to the point where they wouldn't even come to the table," Meister says. "So when you're at a point where we felt it was very important and they felt it was very important and you've exhausted all of your diplomatic opportunities for coming together, what's left?"

Shortly after the hospital's administration announced its intent to change the bylaws, Meister and Willett and the medical staff filed suit against Avera Marshall Regional Medical Center. Their contention: that the medical staff bylaws are an enforceable contract between the medical staff and the hospital and that the hospital should not be able to amend them unilaterally.

Living a lawsuit

The lawsuit, which was filed in Lyon County District Court, thrust Meister and Willett into the unfamiliar world of lawyers and judges, state and federal statutes, case law and amicus briefs.

"It was really foreign to me," Willett says. "I don't have a legal or business background, and I'm an eternal optimist. I thought 'Why can't we all talk and get along? Why do we have to have lawyers involved? Can't we work this out?"

As chief of staff, Meister was the most affected. "My hair is grey," he says with a

laugh, running his hand over his salt-andpepper head as he recalls that period in his life. At the time, he was also working toward a master's degree in business administration at the University of St. Thomasa factor that gave him an appreciation for the business of running a hospital. "I didn't see my family very much," the father of two teenagers and a four-year-old admits. He says he usually spent one day a week dealing with the case.

Physicians and nurses at both the hospital and the clinic were concerned about how this might affect patient care. "When the suit was first initiated, it was pretty contentious," Meister says. "Some perceived this brought up barriers to quality patient care. It didn't. But I didn't blame them for feeling that way," he says.

Patients and others in town wondered what it would mean as well. For Willett, who is known as "Dr. Jane" to the friends, neighbors and patients she sees both in her practice and in the grocery store, it meant answering question and assuaging concerns. "The perception in the community was that ACMC docs and the hospital were one entity because we work at the facility. They couldn't figure out why we were fighting," she says.

Both regret the fact that dealings with the hospital's board and administration often became confrontational. "We used to have very open-ended discussions with them, and they had an open-door policy. Not anymore," Willett says.

Adds Meister: "Our feeling is that the board will do what the board wants to do, physician input be darned. And they do have ultimate credentialing authority ... When you think about going forth in a situation like that where I have to follow the bylaws and we have these meetings but our input doesn't matter, then what's the sense of having a meeting when they make their own rules?"

Confusing ruling

On July 6, 2012, a Lyon County District Court judge ruled that the medical staff was not an unincorporated association with the capacity to sue the hospital, although its officers could bring these claims while acting in their official capacity. In its final order issued September 24, 2012, the court ruled that the bylaws were not a contract, and that the hospital could unilaterally amend the bylaws without approval by two-thirds of the medical staff as long as they substantially complied with the procedures in the bylaws.

"The ruling was very confusing," Meister recalls. "They said the bylaws don't constitute a contract, yet the hospital has to follow them. It doesn't make sense."

Meister and Willett decided to appeal the District Court's decision, knowing that if they didn't take a stand, the consequences could set a precedent for physicians in other parts of the state and the country. "As the elected leadership of the medical executive committee, our job is to protect everyone-Avera docs who may not feel comfortable speaking openly because their paycheck is signed by the administration, and independent docs who don't have the power of a group behind them," Meister says.

Meister and Willett were both disheartened and perplexed by the ruling's contradictory message. Not willing to give up, they took the case to the Minnesota Supreme Court. "Some people think this is about power," Willett says. "It's not. It's about autonomy of physicians and being able to care for our patients and if our opinions make a difference."

Back to business

The two physicians have pretty much resumed life as it was before they became embroiled in the lawsuit. They continue to see patients at the clinic and at the hospital, although relations with the administration continue to be strained. They mentor medical students, schooling them in the good and the bad of practicing rural family medicine. And they have gone back to being active in the community. Meister, who can be seen driving around town in his GEM electric car, attends Bible study sessions at church; his older children's



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STEVEN MEISTER, M.D., M.B.A.

As the case moved to the Court of Appeals, Meister and Willett gained support from the Minnesota Medical Association, American Medical Association, American Academy of Family Physicians, American Osteopathic Association, Minnesota Academy of Family Physicians and Minnesota Academy of Pediatrics, which filed a joint amicus (friend of the court) brief on their behalf.

But on July 23, 2013, the Court of Appeals upheld the lower court's ruling. In his opinion, Judge Michael Kirk wrote that "both sides raise persuasive policy arguments." He also noted that there was no clear case law that could be applied in this situation.

cross-country meets, marching band and dance team performances; and his youngest son's preschool activities. Willett, whose three children are grown, serves as vice chair of the local sports commission and spends time reading, gardening, quilting and traveling.

In mid-October, they received news that made them optimistic: The Supreme Court agreed to hear the case. "It gives obvious credence to the fact that this is a serious issue," Meister says. "They feel it's important enough and has a great deal of bearing on physicians and the way they're able to deal with patients and ensure quality care. It's a real live issue." MM

Kim Kiser is an editor of Minnesota Medicine.

We got broken first

On healing the healers

BY GREGORY A. POLAND, M.D.

e were full and, we thought, complete. Full of ourselves and of the naïve "heal the world" optimism that comes with acceptance into what we were told was a noble profession. What we didn't know then, and never suspected, was who would need healing. And absent understanding this punishing reality, we would suffer. Some of us would die from the wounds inflicted by our calling. As the ancients knew and tried to warn us across the centuries, our organs would cry the tears that our eyes would not.

It was never OK to cry. Not in front of a patient, and absolutely never in front of the chief resident or attending. Unless you were weak. Then you could cry ... but at a price. A price we didn't believe was worth paying. Because, if you did, you were labeled as "the weak one," "probably not cut out for clinical medicine," "lacking the necessary professionalism to be effective." At least, that's what we believed and what the culture of medicine insistently and callously whispered to us every day.

You see, we were going to be doctors—healers, armed with the shields of science and reason, our stethoscopes and our sincerity. Later, we would learn the truth—the kind of truth that only comes unsuspected and uninvited in the middle of the night in the form of nightmares, deep anguish and maybe, if you were lucky, insight.

We started, 76 of us, in the hot and heavy mugginess of the summer of 1977. Perhaps the oppressive atmosphere was an omen. By the end of the first year, one of us would leave school and one of us would be dead. The rest of us didn't know it, but we would all be wounded. Only later, much later, did the toll of broken relationships, divorces, lonely lives, drug and alcohol abuse, and the unfulfilled dreams that come from living with an invisible kind of chronic pain, let us know we were wounded. Were we, who were trained to be observant, really that unobservant of ourselves and our colleagues? We didn't know the risks, and no one told us. If the senior healers, our tribal elders, didn't know, how should we have known or ever given a thought to the cost of healing and what lay before us?

Like soldiers in combat, we were exposed to an endless parade of brutality. Of damages to the human body that are not imaginable and cannot be described—an onslaught of blood, desperation, smells, fear, screaming and pain rushing at us, causing us to think what might have been if not for this. High-definition images that puncture the mind and never leave. Not ever. Not when you sleep. Not even 30 years later.



One of those images was of a young and, I imagined, pretty teenaged girl. I didn't know for sure because I never saw her face, at least not in the way God had made it.

The neighboring state had a legal drinking age of 18 years. Naturally, younger kids would drive with older ones across the state line to buy beer and party. It never entered their minds what could happen. Certainly not to them. It never entered our minds either. At least not yet.

I imagine the fun they had. A warm, bright summer day fading into dusk. Carefree, laughing, free from parents' rules and reminders and with unspoken dreams. They drank heavily, but soon it was time to return home. She was to leave with her family the next day to see Grandma and Grandpa. She liked them. Even though they were old, she thought they were pretty cool. Anyway, the car windows were open, the radio was blasting and everyone was laughing.

I know her mother told her to always wear a seatbelt. I know because I asked her mother—later. The boy driving slammed into the concrete median going 70 miles an hour. She was in the back until suddenly, violently, and in an impossibly fast instant, she shot out of the back seat. The force slammed her occipital bone into the unyielding front windshield. The velocity did more than stun her. It paralyzed her, causing a burst fracture of the fourth

and fifth cervical vertebrae. The normally convex occipital bone transformed into a grotesque concave shell as she proceeded through the windshield, the glass stripping her skull of any flesh. At the same time, a balloon full of red paint must have burst, covering the entire inside of the car and its occupants.

As the car stopped, she was instantly whipsawed back, shredding much of the bilateral large sternocleidomastoid and trapezius muscles that attach the skull to the rest of the skeleton, leaving only sinewy fragments of bare muscle. Within minutes, the

police, fire rescue and paramedics were on the scene. Lights flashing, sirens screaming and the lonely now out-of-place sound of the car's radio, oblivious to the carnage it unknowingly played to.

Three miles away, all we knew was that there had been a car accident. Two dead on the scene, plus a slim white female, approximately 15 to 18 years of age with mas-

sive head trauma and apparent quadriplegia, five minutes out. We were ready. We—with our technology and our bravado.

In a whirlwind, she was in the stab room on a blood-drenched gurney, and seconds later, was stripped of her clothing. Emergency pages overhead demanded immediate attention to the "code red" taking place in front of us. My job was to get an IV into her arm with a large-bore needle so we could replace the blood she had lost. She was barely breathing, in shock and quickly dying. As the senior resident lifted her head gently to insert an airway tube, it bounced downward and dangled off her spinal column like the head of a rag doll. The horrible thought that her head might literally fall off shot through my mind as I instinctively reached out to catch it. And then she was dead. Twisted, mangled, bloodied, nearly decapitated, dead. We all stepped back, almost in unison, ourselves in shock at the eerily still body that lay in front of us. I wondered what she looked like—her face stripped from her skull, unrecognizable and her body covered in streaks of crimson. And bits of gray matter—her brain.

The senior resident explained that it would be a "learning experience" for me to go talk with the family. Numb, and madly searching to find something to say, I walked in to the waiting room covered with blood—her blood. The only family obvious to me was a woman I guessed to be in her mid- to late 30s. Short, brunette, attractive. She didn't belong in this kind of ER. Not here. Not tonight. Her eyes immediately locked, not onto, but somehow into mine, with an intensity that caused me to hesitate. She hurried toward me. I wanted to run. It was all happening so fast none of us had time to think ... or to reason.

I rack my brain trying to remember what I said. All I can recall is, "We did everything medical science could do. I'm so sorry." She collapsed into me, screaming. I caught her and almost instantly she pushed herself off me and hit me square in the chest with her fists. I never saw it coming. It didn't hurt, I don't remember feeling anything other than the surprise and shock of what

has happening in such fast motion that it almost gave me vertigo. Then she wailed. A deep, unending guttural howling. It was so loud, so intense, so visceral and otherworldly that it stunned me. I stood paralyzed not knowing what to do. By then, the nurse and an assistant were at my side. They held this pitiful, injured young mother, while another nurse offered Kleenex. In the final poignant moment, that's what our miracles of medicine had to offer-a Kleenex and an outstretched hand.

Soon another set of sirens and another case demanded our

Like soldiers in combat,

we were exposed to

an endless parade

of brutality.

attention. We need to focus on the living-not the dead. I left the mother with the nurse, and silently walked to the next case—hoping to forget. But here's the truth: You never forget.

I have often wondered about that girl and her family. She would be in her 40s now. Maybe she'd look like her mother and have children of her own. The images from

that night are burned into my being. Things no one in their mid-20s should ever see, feel and hear. I wake from dreams instantly, perspiring, with adrenaline pumping through my system, still responding to the mother's screams and acutely aware of my own inadequacy in responding. There was nothing we could do.

We got broken first by death—by sights and sounds and smells and then by a conspiracy of silence. We never speak about it. Not at class reunions, or during late-night bull sessions with other colleagues on call or in the exam room with a fellow healer. Except that every once in a while, when gently raising the question to one of my physician patients about their pain and their nightmares, tears will silently come as another healer tells me his story. He got broken too. Those who are lucky are reflective and feeling enough to learn that this was the necessary path toward becoming a healer. But it stings nevertheless. For most healers, pain overwhelms reflection and self-preservation steamrolls opportunity. We become wounded and suffer with our patients, the unknowing victims.

The opportunity to know what death is and how it intrudes and robs the innocent of peace and of contentment is lost—overwhelmed, really—by the awful reality. And so goes the cycle of healing. But we should tell the truth, it should be "see one, do one, teach one, heal one."

We got broken first, young students and residents mangled inside the reality that is life and death. And no one ever told us. But now I know, and so do you. You can't heal, really heal, until you have been wounded by the realities of another's pain and trauma. You need to heed our ancient calling to "heal the sick and bind up the injured" by offering what is, in the final analysis, the best of what medicine has ever discovered in healing—an outstretched hand, a Kleenex and our unhurried, caring presence. On the day we do that, we move from broken to healer. MM

Gregory Poland is the Mary Lowell Leary Professor of Medicine and a Distinguished Investigator at Mayo Clinic in Rochester.

Reason for visit: CHECK MEDS

A medical students explores his reaction to an especially difficult patient.

BY BENJAMIN MARSH

hy don't you go in and see Ms. R. first," the family medicine resident told me, adding a wary, "good luck." I opened her chart and immediately felt my heart sink as I was confronted with the longest problem list I had ever seen: CHF, COPD, HTN, DM2, HLD, OSA, PVD, IBS... I scrolled down the list, thankful I had bothered to master so many acronyms. Was there anything this poor woman didn't have? Her reason for visit, CK MEDS (Check Meds), was deceptively simple, almost comically so.

I lingered a few minutes, trying desperately to glean information from her record that might assist me. Then I sucked in a breath feeling doomed as I walked along the cream-colored hallway decorated with tired Rockwell paintings, passing the other exam rooms. I heard a kid rebelling against vaccinations in one room. Boisterous laughter was coming from another. A hacking (probably productive) cough. People speaking languages other than English. I wished I was heading to any of these other rooms.

As I passed the nurses' station, I heard someone say, "Deeead man walkin'!" The medical assistant looked exasperated as she wheeled the blood pressure monitor out of the room where my patient waited. I gulped and opened the door.

Ms. R. looked to be in her late 70s. Her black hair had streaks of grey and stood straight up (like the Bride of Frankenstein, I thought). She smelled of body odor, cigarette smoke and something rotten. Dirty, tattered clothes fell over her like a tent. She shot me a look of distrust.

I led off with my typical "Hi Ms. R. I'm Ben, a third-year medical student working with Dr. G. What can we do for you today?"

She emptied a garbage bag full of half-empty pill bottles, inhalers and insulin pens onto the counter. "My inhalers aren't working. Well, some of them are, but this ah-boo-ter-ahl [albuterol] doesn't work. And I don't take this one 'cuz it's green, and I don't like green. This one I only do on days when I'm feeling sad. And this one is working OK, but it tastes funny when I swallow it. And I'm not taking the Singulair pills 'cuz I ran out a month ago. I've been coughing and wheezing like my chest's all tight. I can't sleep. Those steroids aren't helping neither, and my brother said I ..."

"Wha ... I ...," I stammered, not sure where to begin.

"Don't interrupt. I'm not finished yet. My diabetes is terrible, just terrible, and I've been reading my blood sugars like y'all asked me to, but I never get below 200, and they're sometimes over 400, and my neighbor keeps yelling at me about my cats, but I said ..."



As she continued, I glanced at her chart. Her most recent A1C was 12.2. Today her blood pressure was 158/97 and her hemoglobin was 10.0. She'd visited emergency departments at two different hospitals in the past three weeks.

Ten minutes later, completely overwhelmed, I excused myself, found my resident and proceeded to give the worst patient presentation of my medical school career. "Ms. R is a 69-year-old woman with lots of problems, lots of meds. I don't know what to do."

The resident sighed. I followed him into the room. My stomach did flip-flops as the resident struggled to take a better history.

Here was a patient who had come to us for help, and I felt repulsed by her. Worse, I was repulsed by my response to her. What had become of the empathetic, eager first-year student who would have jumped at the chance to talk to her? Had I become so jaded in such a short period?

Ms. R. had come to us overwhelmed by her health problems, and she had become the butt of our jokes. Everyone in the clinic resented her because of the work she represented. Here was someone who didn't have the capacity to manage the barrage of medications we were throwing at her. Hell, I doubt a pharmacist could have complied with her regimen. She needed much more than what we could provide in a 20-minute visit, but no one wanted to put forth the effort to help her.

Nietzsche once warned that the danger of fighting monsters is becoming one yourself. We had created a monster. We passed her along—provider to provider, ED to ED, hospital to hospital. She

CThis woman wasn't a monster. she was my patient.))

sucked up resources while her medical problems snowballed. Instead of breaking down her issues one by one, we patched her up and hoped that someone else down the

road would rise to the challenge of fixing her up properly. Yet this woman wasn't a monster, she was my patient.

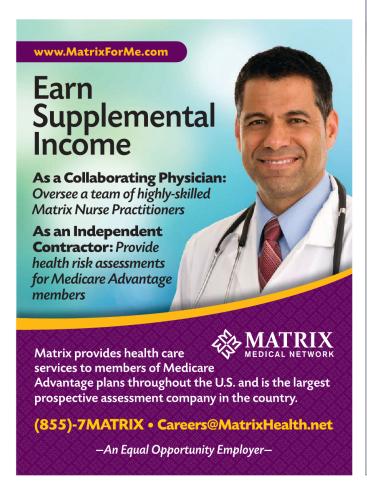
Ms. R. left the clinic that day with her insulin regimen tweaked. We'd deal with her blood pressure, anemia and myriad other issues later. We hadn't solved her problems. It was only a matter of time before she'd return.

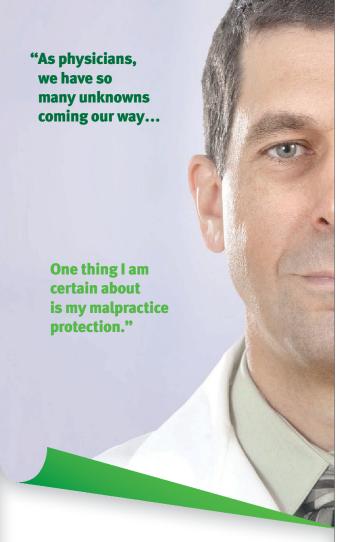
Next time, we would be more prepared, have more time and get to the root of her problems. We'd put her in a patient-centered medical home, get a pharmacist to manage her meds, a home care nurse to check on her sugars and blood pressure, a social worker to assess her home situation ... "Next time will be different," I said to myself, looking at the long list of other patients waiting for care that day.

"Next time." MM

Benjamin Marsh is a fourth-year student at the University of Minnesota Medical School.

The author would like to thank Therese Zink, M.D., M.P.H., for her help with the development of this essay.





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SPEAKING UP

When doctors navigate medical hierarchy

BY RANJANA SRIVASTAVA, F.R.A.C.P.

e's the first patient of the day: admitted overnight, he's scheduled for surgery this morning. "Do you want to catch him before or after?" the resident asks.

"Is there anything we need to do for him right away?" I say. When she says that the night resident mentioned some pain issues, I decide to drop by.

As we walk, the resident describes the handover. The patient is a smoker in his early 50s who has a malignant pleural effusion

that couldn't be managed at his local hospital. There was infection mixed with effusion, and antibiotics were ineffective. So he was referred here for video-assisted thoracoscopic surgery (VATS). After recovery, he would be transferred back closer to home for treatment of metastatic lung cancer.

In these situations, my role as a medical oncologist is usually limited to a courtesy call. It reassures the surgeon that there's an oncologist on board, and the patient appreciates seeing a friendly face without having to discuss serious news. But in the patient's room, what I find is unexpected. He's scrunched up in bed, tossing and turning, his sheets tangled between his legs. He's pale and uncomfortable, licking his lips, his IV fluids having run out. My immediate impression is that he's dying. But I remind myself that he's scheduled for surgery.

When I introduce myself, he's startled but speaks lucidly.

"I hear you are having an operation," I say.

"Yes, they need to get this fluid off my chest."

"Are you in pain?"

"Yes, it hurts like hell, doc. Every time I breathe, it stabs me."

The resident hands me the sheet of inadequately charted pain relief. "His kidneys are not great, so they've gone easy on the drugs," she says.

"What's wrong with his kidneys?"

"He's been hypercalcemic for the last few days, though they gave him bisphosphonates."

"You are going to have your chest drained soon," I tell the patient, "but let me arrange for you to get some pain relief right now. Also, you need some fluids to help your kidneys."

"Thanks, doc," the patient groans before resuming his fidgeting. "You'll be OK," I reassure him, but I'm unnerved: he looks delirious, and I have to check his chart to confirm that he's only 50. A nagging voice tells me he doesn't seem fit for surgery, but I suppress it, telling myself that a VATS is a straightforward palliative measure for patients drowning in an effusion. Outside the room, we run into the surgeon, whom I know well. He's about to meet the patient before the operation.

"We're done," I say. "By the way, he looks dry and needs better pain management, which I've attempted to fix."

I pause, hoping for a sign of a reservation granting me permission to unleash my own mounting ones. But he simply says, "I think the VATS will give the poor man relief. He's been struggling for days."

We part ways, but when he's out of earshot, I tell my resident, "I can't believe they operate on such patients; he just doesn't look right."

"I suppose surgeons are used to it," she shrugs, still convinced that we dabble in drugs whereas surgeons save lives. Seeking reassurance, I accept hers: if the surgeon admitted the patient, surely he can decide what's best. If necessary, the anesthesiologist can call off the procedure. I quickly convince myself that I'm a bit player in this patient's journey. And that if my gut instinct says "Don't operate," it's no stronger than the surgeon's instinct that says "Get it over with." The winning argument in my head is the one saying "Who are you to question a surgeon?" Although I know this attitude is baseless, it sits comfortably with me; my

colleagues and I commonly defer to surgeons—considering them unequivocally right, unassailable, or simply not worth antagonizing. In an era when many patients have multiple reasonable treatment options, it seems more expedient to yield to the surgeon

than go to bat for a patient. And that attitude is absorbed by generations of doctors who simply have to watch to learn.

In the clinic, I become enveloped in other patients' concerns. Later, when the resident tells me that the man made it through surgery, I'm relieved at not having embarrassed myself before the surgeon. I take the incident as a reminder to remain within the limits of my expertise. Of course the surgeon knew best. So the next day, when the resident points me toward the patient in the ICU, I'm stunned. "Actually, he crashed and had to be intubated."

The patient soon dies, as his stricken family looks on. Talking to his daughter, I'm taken aback by her understanding. "Everyone was great — what else could we have asked for? Of course, we didn't expect this, but this is the way it is."

The conversation leaves me disturbed. Is this really the best we could have done? I think not. For though we probably couldn't have changed the fact of his death, we held the circumstances in our hands. We could have canceled the surgery, aggressively con-

> trolled his pain, and called an urgent family meeting to ascertain his wishes and be guided in shared decision making. But this model, to which we aspire, went astray, as it often does.

Days later, I speak to the surgeon. "I feel so sorry that he died," he reflects. "I thought we could help him, but he was clearly too unwell to have an operation."

The nagging voice returns to my head. Banking on our rapport, I say, "I keep wishing that I had mentioned my doubts to you that morning. He looked like he was dying."

Seizing on my comment, the surgeon asks, "Why didn't you tell me?" He adds, with amazing honesty,

"When I walked out of his room, I wondered for a minute, but I told myself that since you had also seen him, he would be OK."

"But that's exactly what I thought," I protest. "I thought you knew best and I shouldn't interfere."

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"If you had so much as mentioned your fears, I would have stopped," he assures me remorsefully.

We realize that, each of us unsure, we gained confidence from the perceived assurance and expertise of the other. We unearth the other specialists who participated in the patient's care. The oncologist had wanted the infected effusion drained so he could safely commence chemotherapy. The respiratory physician had recommended referral to a larger center for drainage. The infectious diseases physician had no more antibiotics to offer. The general internist bowed to the others, and the surgeon was approached as the next service provider in line. Tragically, no one person looked beyond the effusion to the whole patient. Although he saw myriad specialists in his last week of life, he died lacking holistic care.

His obituary and a thank-you note reflect the grief of a family who lost their loved one more suddenly than anticipated. So, where does the buck stop? It seems unfair to pin it on the surgeon: he was merely the last clinician in line, no more morally responsible for the patient's death than any other participant in his care.

When I ask colleagues what they would have done, each recalls sometimes harboring misgivings about another doctor's treatment of a patient but feeling unable or reluctant to comment, even when a patient's life might be threatened—preferring to swallow their discomfort rather than challenge another physician's viewpoint. Some are afraid, while others aim to "live and let live," believing that there's no such thing as constructive criticism when it comes to one's peers. When a single perceived slight can spoil

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relationships that take years to create, doctors understandably tiptoe around each other.

Yet we all agree that if we were inadvertently harming our patient, we would appreciate being told.

Haunted by the incident and wishing never to repeat it, the surgeon and I agree on a simple pathway for decision making. He will question other hospitals more comprehensively before assuming that patients have been thoroughly worked up. In cases that aren't clear-cut, he will ask me to independently assess the patient's robustness for surgery. If uncertainty remains, we will jointly speak to the patient about our recommendations and record our conversation in the notes. One could argue that all these things happen with modern multidisciplinary team management, but not all team members eyeball the patient, and decisions are heavily influenced by the lead clinician.

Our agreement, forged from loss, has allowed some subsequent patients to avoid invasive, painful surgery in favor of better quality of life and others to undergo successful operations. The cooperation between internist and surgeon has been a salutary lesson for junior doctors who perceive the two as inimical. Early in training, we learn to spot the budding surgeon among internists, and it is worrisome that the main perceived point of differentiation is disparate notions of patient welfare. When internists jest about "rescuing" surgical patients, they signal to surgeons that their role is to operate, while everyone else is the supporting cast. Apart from being disingenuous, this thinking engenders more stereotypical behaviors.

In a profession abounding with experts, no one person's expertise can always count for more. Although certain technical skills may be specialty-specific, there's a much broader range of skills on which no group has a monopoly. There's no chain of command in using gut instinct, showing concern for the whole patient, avoiding harm or curtailing futile care. We must recognize that debate is healthy and that without open communication, we fill the space by guessing at each other's motives.

Recognizing the pitfalls of blind adherence to hierarchy and broaching with a surgeon my misgivings about a patient: such an "intervention" seems deceptively simple, uncontroversial, even cheap. Yet in my years of working with surgeons, it feels like the best thing we've done together for patients. MM

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A FEW MINUTES WITH...

Jim Chase, president of Minnesota Community Measurement



hen Jim Chase started as president of Minnesota Community Measurement (MNCM) in 2005, the organization wasn't much more than him, a computer and a telephone. It began as an idea of the MMA and the Minnesota health plans to develop public reporting mechanisms to compare patient care outcomes across the state. Now, nearly a decade later, MNCM has a staff of 20 and is often held up nationally as the vanguard on measuring health care quality.

Many laud the organization for its efforts and believe in its cause. But some physicians have expressed concern about the

administrative burdens it creates. We recently talked with Chase about this and the growth of MNCM.

What is your response to physicians who have expressed concern over the administrative burden quality measurement has placed on their clinics?

Right now, we are not balancing well the burden of data collection with the benefits. That said, I don't think it's going to be easy to limit the number of measures or to do other things because of the demand. There's going to be a greater interest in having more information about the value of care, and there will be a greater interest in primary care. Primary care has a real opportunity to show value in this new environment, and that will probably result in expectations for additional data. With all that said, our role is to find more efficient ways to collect the data. We need to move forward with retiring measures when we've demonstrated that there's been improvement and scores start to plateau.

Some have said MNCM needs to focus more on outcomes and less on processes in health care delivery. What do you say in response?

When we first got started, a lot of clinicians would have said that for accountability measures, for public reporting, they couldn't really be held accountable for outcomes. They needed to be held accountable for process. Our thinking on that, as a community, has changed in a good way. There's a bigger pressure on finding more meaningful measures. Let's look at outcomes because that's where you are going to get the biggest impact. I think it's a balance. We need to move more toward the outcomes, and we've been doing that, though we will probably never completely abandon process measures.

Is MNCM where you envisioned it would be when you started nearly nine years ago?

I think it's grown to have a much bigger impact than I had hoped. I am quite pleased that we've been able to provide benefit across the community. Part of what's motivating to the community, to individual organizations, to medical groups and to clinicians is to see how they compare with others who are in similar circumstances.

Another big change for us is the ability to access clinical data. When we first started, we never anticipated that we could collect

that kind of data out of medical records. With the advent of the HITECH Act and other things, it's moved very rapidly. Another interesting change is that when we got into this we thought we'd make this information public. [The public using the information to choose a physician] hasn't been the impact. It's much more about getting patients engaged, knowing it's important that there be standards. I think we're getting some traction there.

How do Minnesota's measurement efforts compare with those of other states?

We have a very robust system. We can do things statewide. We've established this to be sustainable in the sense that it is getting used by organizations across the state and across health plans and medical groups. There are some things that we could do

differently. One is that other states are moving more rapidly in how they collect data more efficiently from either health informa-

"We need to move forward with retiring measures when we've demonstrated that there's been improvement and scores start to plateau."

JIM CHASE

tion exchanges or electronic medical records. I think some other states are doing a better job of helping the medical groups use

the data for improvement. We do provide some support in terms of getting data back to organizations, but we don't have much capability to do analytics. There are some initiatives—both Oregon and Washington come to mind—where their collaboratives are providing their participating medical groups with more analysis of the data. We do have ICSI [Institute for Clinical Systems Improvement] and Stratis Health here that do some of that work, but I think it is an opportunity for us to learn from some other communities how we can provide more support there.

What do you see as the greatest success for MNCM so far?

I think it's that we've gotten the information to be used for improvement. It's always hard to prove whether public reporting is driving change. Clearly, Minnesota has better

outcomes, but it's due to a whole lot of things that we do differently here. I hope that the measurement/reporting infrastructure we have contributes to that. I think when you talk to clinicians around the state, especially those in leadership positions, they will acknowledge that this information can be helpful to drive change. The other thing—something we didn't anticipate but has been a huge success—is that the measures that have been developed by practicing clinicians in our community are now being used nationally. The optimal vascular care, the optimal diabetes care, the depression screening, now potentially asthma or the components of asthma that are patient-reported are getting picked up by CMS and others. That's rewarding to see.

Aside from public reporting, what does MNCM do to support the physicians of Minnesota?

We hope part of the value we bring to medical groups that are interested in improving care for their patients is having comparable information about what's working and what isn't. We try to develop support tools for patients about how they can help themselves get better with help from their clinician. I think one of the biggest values that we've brought to groups is the alignment efforts. Almost all of the health plans are using our core set of measures. There may be additional ones that are being piloted, but at least we have aligned those and we are working to try and keep Medicare aligned. That's the real challenge now. [Medicare has] really proliferated their measures at a national level and they aren't even consistent within their own programs. Can we get them to align so they can use similar things so we can reduce the collection burden for the practices?



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MINNESOTA MEDICAL **Association**

O&A with MMA President Cindy Firkins Smith, M.D.

eing in the public eye is nothing new for Cindy Firkins Smith, M.D. She has been the face of the MMA's Twitter account for the past few years. The Willmar-based dermatologist has also lent her visage to various marketing materials to promote the MMA, from leaflets to websites to a seven-foot display that is used at health care conferences across the state.

Firkins Smith's public life dates back even further than her days in the MMA, though. Growing up in Emmetsburg, Iowa, she tried a little bit of everything-competing in track, basketball and swimming, serving as the first female student body president at her high school and entering her first beauty pageant. While attending Mankato State University, she won the Miss Mankato Scholarship Pageant. She said at the time she entered to meet people and establish herself in her new community.

Her outgoing nature will be put to good use in her new role as the MMA's president. She says she plans to talk to as many physicians across the state as possible during her tenure. We asked Smith about how she plans to lead the organization in the upcoming year.

What are your goals for 2014?

Probably most pressing is that I want to talk to as many Minnesota physicians as I can and remind them that no matter our specialty, geography or ideology, in the end we're all doctors. We take care of people and we need to stick together so we can keep doing just that. There are so many barriers interfering with our ability to do our job well: bureaucracy and mindless paperwork, fear that the government will slash reimbursement and force us to make unpalatable choices like deciding whether we can see patients who need us or just the patients whose insurance plans pay us enough to keep our doors open. There

never seems to be enough time to get everything done.

Physicians face a lot of big issues—a primary care physician shortage, prescription opioid misuse, administrative burdens. How does the MMA begin to tackle them all?

Luckily, physicians are problem-solvers.

The key is to choose the right "specialists" for each problem, those MMA physicianleaders who are passionate about each issue. Have them apply their natural passion, innovation and problem-solving ability to the task. I think it's time to take each issue outside the box. For example, I have a real love-hate relationship with the electronic medical record. Some things are very good and will likely make information-sharing better. Some things, like the repeated generation of nonpertinent information, are useless, redundant and dangerous. In my opinion, the EMR is contributing to administrative burdens, physician burnout and, by consuming increasing amounts of physician time, probably the primary care physician shortage as well. Let's get some smart people to sit down and fix it. How much of this information is really important? Can someone else besides the physician do this? Let's let doctors take care of patients and eliminate or delegate everything that's interfering with that.



"No matter our specialty, geography or ideology, in the end we're all doctors. We take care of people and we need to stick together so we can keep doing just that."

CINDY FIRKINS SMITH, M.D.

How long have you been a member, and what is one of the highlights?

I've been an MMA member since I started medical school at the University of Minnesota in September of 1982. I didn't become active until 1994, when I attended our component medical society's Christmas party and they announced the need for delegates. Since the Annual Meeting was being held in St. Cloud and since they were going to pay for the hotel room, I volunteered. The highlight is—and has always been-meeting physicians from different specialties, backgrounds and ideologies from across Minnesota. Some may remember Lyle Munneke, M.D., a family physician from Willmar who was my friend and early MMA mentor. For many years we were the only delegates from the Mid-Minnesota Medical Society. We were quite a couple, he in his jeans and Harley-Davidson gear and me in my skirts and Imelda Marcos shoes. We didn't always agree on the issues, but we agreed that patients came first.

How do you try to convince others to join the MMA?

There are a few physicians who are not aware of what the MMA does for Minnesota physicians and their patients, so I educate them and encourage them to join us in our mission. Frankly, there are more Minnesota physicians who know about the MMA but don't make it a priority to pay their dues and become one of the MMA's 10,000 making Minnesota medicine the best. To those physicians I say: We need you. The more Minnesota physicians who are members of the MMA, the better our representation at the Capitol, in board rooms and in the courts. Your responsibility to your patients does not end at your office door. We want you involved and engaged, but at the very least we want you to join the organization so we can continue to fight the good fight for you and your patients. I really believe that this is a responsibility of every Minnesota physician.





The MMA has never fought for a bill that benefits only MMA members; everyone gains. Everyone should contribute.

As a dermatologist, what's your favorite SPF?

Now, you're talking my language. My favorite SPF for patients depends on history, skin type, exposure, activity and other variables. But my personal favorite SPF is 30 to face, neck and hands 365 days a year. SPF 50+ if I'm actually going to be outside. But then, of course, I would be wearing a hat, sun-protective clothing and standing in the shade as well.

Do you have any hobbies?

I like to talk about skin, so I write and deliver dermatology lectures. I'm interested in medical history and am researching and writing the early history of the department of dermatology at the University of Minnesota. I'm a sports fan—Go Wild! I enjoy fiction and film and belong to a screenwriting group. I took a screenwriting class in L.A. a few years back and wrote a screenplay. It provided me with a lovely fantasy that revolved around red carpets and the Academy Awards, but unfortunately was garbage, thus the fantasy was short-lived. I used to dabble in drawing cartoons and painting, so a couple years ago thought I would revisit that. I bought an easel, canvases, acrylics and brushes. They're all still in the packages. Maybe next year...

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News briefs

Raise it For Health Coalition wins award for anti-smoking efforts

In September, the Minnesota Department of Health presented the Raise It For Health Coalition with a 2013 Community Health Award for its efforts to advocate for an increase in the state's cigarette tax this past legislative session.

The coalition, of which the MMA is a member, received a Certificate of Recognition for its "success in raising prices on tobacco products in Minnesota as a means to deter tobacco use and raise community health."

This award comes on the heels of news that cigarette sales have dropped dramatically after the tobacco tax increase of \$1.60 per pack went into effect July 1. The Minnesota Department of Revenue reported that sales of the tax stamps that are required on all packs of cigarettes sold

in Minnesota were down 35 percent in July 2013 compared with a year ago.

The Community Health Awards are presented each year for significant contributions to public health in Minnesota. Recipients are nominated by their peers and chosen by the State Community Health Services Advisory Committee.



Independent practice still kicking according to **AMA**

A recent study from the AMA shows that the state of indepen-

dent practice isn't as bad as previously reported. A 2012 AMA survey found 53 percent of physicians are self-employed, 60 percent work in practices that are wholly owned by physicians. Eighteen percent are in solo practice.

The AMA survey shows that the shift toward hospital employment hasn't been as great as expected. Twenty-three percent of physicians work in practices that are partially owned by a hospital and another 5.6 percent are directly employed by a hospital.

The study, "New Data on Physician Practice Arrangements: Private Practice Remains Strong Despite Shifts Toward Hospital Employment," noted that Accenture, the management consulting company, had projected that the share of physicians in independent practice would fall to 36 percent in 2013, down from 57 per-



MMA, AMA provide advice on employment contracts

More than 80 residents, fellows and medical students gathered in St. Louis Park in mid-October to take part in a free program on negotiating employment contracts. Hosted by the MMA and AMA, the event, "Negotiating with Confidence: Know What's in Your Contract, "focused on what to expect in an employment contract.

> cent in 2000. According to the 3,466 physicians who responded to the survey, that hasn't occurred yet.

U of M medical student receives national scholarship

Brian Park, a fourth-year student at the University of Minnesota Medical School, is one of six students selected as a 2013 Pisacano Scholar.

The Pisacano scholarships, valued up to \$28,000 each, are awarded to students attending U.S. medical schools who demonstrate a strong commitment



to family medicine. In addition, each applicant must demonstrate leadership skills, superior academic achievement, strong communication skills, identifiable character and integrity, and a noteworthy level of community service.

Park graduated cum laude from the University of Minnesota-Twin Cities with a bachelor's degree in psychology; he recently completed his Masters of Public Health degree at the University of Minnesota. He was one of two students selected to participate in the Metropolitan Physician Associate Program (MetroPAP), a nine-month community-based clerkship program during the third year of medical school. During his MetroPAP year, Park developed academic and community service projects that became the focus of his thesis. Additionally, his MetroPAP experience led

him to create and host "The Waiting Room," a live medical storytelling event.

Following his residency, Park plans to remain in academic medicine and practice family medicine in an underserved urban area.



Minnesota Medicine a finalist for Magazine of the Year

The MMA's award-winning monthly, *Minnesota Medicine*, is one of five publications under consideration for the Minnesota Magazine and Publishing Association's Magazine of the Year. The other publications are: *Experience Life Magazine*, *Lake Superior Magazine*, *Midwest Home* and *Mpls. St. Paul Magazine*. The award ceremony is November 7 at the Nicollet Island Pavilion in Minneapolis.

MMA in action

In early October, MMA President **Cindy Firkins Smith**, M.D., attended a North Dakota Medical Society meeting in Fargo. She also took part in the interview process for the first of three candidates for the University of Minnesota Medical School dean/vice president of health services position.

Eric Dick, manager of state legislative affairs, and **Dave Renner**, director of state and federal legislation, met with Rep. Tina Liebling in September to discuss the MMA's opposition to legislation that would expand the scope of practice for Advanced Practice Registered Nurses. They were joined by lobbyists for anesthesiologists, pain medicine physicians, family physicians, pediatricians and psychiatrists.

In October, Renner also presented to the Minnesota Orthopedic Nurses Association on anticipated legislative issues for the 2014 session.

Dick also attended a physician-only meet-and-greet for state lawmakers in October. Attended by Sen. Melissa Franzen (DFL-Edina), Rep. Ron Erhardt (DFL-Edina) and Rep. Paul Rosenthal (DFL-Edina), the event was held at the home of MEDPAC board member Robert McKlveen, M.D. Participants enjoyed the opportunity to renew or build a personal relationship with their legislators and ask questions about the health care issues the elected officials anticipate will be considered during the upcoming session.

MMA Policy Analyst **Juliana Milhofer** attended several meetings of the Minnesota Cancer Alliance to discuss developing a communication strategy for increasing HPV vaccination rates. The MMA is a member of the Alliance.

Barb Daiker, R.N., Ph.D., the MMA's manager of quality, attended a meeting of the task force on Violence Prevention in the Healthcare Workplace. This task force was formed by the Minnesota Department of Health to identify tools and resources that health care organizations can use to reduce risk and effectively manage hostile and assaultive behaviors in the workplace. Daiker also attended a meeting of the



Eric Dick



Dave Renner



Brian Strub



athleen Baumbach

Minnesota e-Health Initiative Advisory Committee, a private/public collaboration to accelerate the use of health information technology to improve quality.

Brian Strub, MMA manager of physician outreach, met with Dale Osterman, administrator at Central Pediatrics and Priority Pediatrics, to discuss issues important to physicians at their two Twin Cities area locations.

In September, **Kathleen Baumbach**, MMA manager of physician outreach, met with Darla Becker, the chief operating officer for the Center for Reproductive Medicine, to discuss MMA initiates and specifically the burden of medication prior authorizations. She also met with Stephanie Olson, public affairs manager at Mayo Clinic Health System in Owatonna, to discuss clinic initiatives/challenges and ways to connect with Owatonna physicians. In addition, she met with Molly Van Binsbergen, R.N., clinic manager at Allina Medical Clinic–Faribault.

Strub and Baumbach met with Jo Peterson, the new executive director of the Minnesota Academy of Family Physicians Foundation, about collaboration opportunities specifically related to training physicians to work with interpreters. In mid-October, they met with first-and second-year medical students during a lunch-and-learn at Mayo Medical School in Rochester. The event was co-sponsored by the Zumbro Valley Medical Society and the MMA. They also met with Madalyn Dosch, an Allina Health sourcing specialist, to discuss collaborating on resources for residents and fellows.

Strub visited with physicians at Sawtooth Mountain Clinic in Grand Marais. The meeting was hosted by the Lake Superior Medical Society (LSMS) as part of its Remote General Membership Meetings. These meetings, which are open to all LSMS and MMA members,

provide an opportunity for North Shore physicians to personally connect with and support other physician members outside the city of Duluth.

VIEWPOINT

Is that necessary?

n medical school, we are taught to do whatever it takes to help our patients get better. So it may seem counterintuitive to join an effort that calls for reducing tests and procedures. But that's exactly what the Choosing Wisely campaign is about.

As the name suggests, it's about selecting only the appropriate tests or procedures for each patient. Given today's litigious society, it may be tempting to run a test just in case—to cover your back, to be extra sure about a diagnosis. But sometimes another test just isn't necessary. And sometimes they can lead to harm. As physicians, we have a professional responsibility to support the fair distribution of scarce resources. Choosing Wisely is one tool, based on strong medical evidence, to help us do just that.

Since Choosing Wisely launched in April 2012, more than 80 national, regional and state medical specialty societies, health collaboratives and consumer groups have joined the cause. Together, we're trying to improve patient outcomes through better physician-patient communication. Our goal is to help stem the use of unnecessary care that contributes to additional risk for the patient and the high cost of health care. Evidence shows that much of the care delivered in the United States is duplicative or unnecessary.

The MMA joined the effort this past March. We received a grant from the American Board of Internal Medicine Foundation to help build awareness of the project among Minnesota physicians. The MMA is also developing tools to help physicians have conversations with patients

about what is appropriate and necessary care.

The MMA will share these tools through our standard communication vehicles—our enewsletter, blog, Minnesota Medicine. We also are partnering with the award-winning Guthrie Theater to develop patient communication training. The sessions will focus on improvisation and role-playing techniques.

Choosing Wisely is gaining momentum across the country. So far, 58 national medical specialty societies, including the American Academy of Pediatrics and the Society for Vascular Medicine, have signed on.

Most of these partners have recommended five tests or procedures pertaining to their specialty that physicians and patients should question. You can find each group's list online at www.choosingwisely.org/doctor-patient-lists. Some groups, like the American Academy of Family Physicians (AAFP), have recommended even more. Here's an idea of what you'll find on the AAFP list:

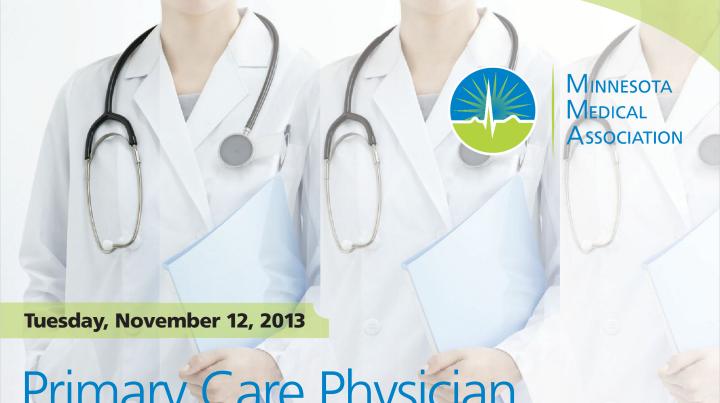
- Don't do imaging for low-back pain within the first six weeks unless red flags are present.
- Don't order annual electrocardiograms or any other cardiac screening for lowrisk patients without symptoms.

Please join us in our efforts. Take a proactive leadership role. Go online and learn more about the Choosing Wisely program and volunteer your clinic to be a leader in embracing these conversations with patients. Contact the MMA at mma@mnmed.org and be a part of the solution.



Cindy Firkins Smith, M.D.

Take a proactive leadership role. Go online and learn more about the Choosing Wisely program and volunteer your clinic to be a leader in embracing these conversations with patients. >>



Primary Care Physician Workforce Summit

Minnesota is in the middle of a crisis. As the Affordable Care Act kicks into high gear in January thousands of Minnesotans will gain access to health care coverage. In addition, an increasing number of primary care physicians are retiring and our population continues to get older.

How are we going to meet this growing need for care and how will it affect your practice?

Help the MMA tackle one of Minnesota's largest challenges by taking part in "Finding Solutions: the Primary Care Physician Workforce Summit." Examine trends with national experts, learn how groups across Minnesota are responding, take away strategies that will help you meet the challenge, and share your ideas and concerns.

Together, we can find the answer.

Event details

Tuesday, November 12, 2013 4 – 8 pm

Ramada Plaza Minneapolis 1330 Industrial Blvd NE Minneapolis, MN 55413

COST: (includes dinner) \$50 for MMA members, \$75 for nonmembers, \$25 for residents, \$10 for students

Keynote Speaker

Scott Shipman, M.D., M.P.H.

Director of Primary Care Affairs and Workforce Analysis Association of American Medical Colleges "A New Day for Primary Care: Will Medical Schools Deliver the Goods?"

Closing Speaker

Paul Rockey, M.D., M.P.H.

Scholar in Residence

The Accreditation Council for Graduate Medical Education "National Trends in GME and What States Can Do to Place Physicians They Need"

General Session

The Economics and Business Side of Primary Care

Breakout Session Topics (attendees will choose one):

- 1 The Current State of Medical Education in Minnesota
- 2 Primary Care Practice Transformation

To register, visit

www.mnmed.org/PCPSummit

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Duty to Speak Up in the Health Care Setting A Professionalism and Ethics Analysis

BY RACHEL J. TOPAZIAN, C. CHRISTOPHER HOOK, M.D., AND PAUL S. MUELLER, M.D., M.P.H.

Staff and students working in health care settings are sometimes reluctant to speak up when they perceive patients to be at risk for harm. In this article, we describe four incidents that occurred at our institution (Mayo Clinic). In two of them, health care professionals failed to speak up, which resulted in harm; in the other two, they did speak up, which prevented harm and improved patient care. We analyzed each scenario using the Physician's Charter on Medical Professionalism and *prima facie* ethics principles to determine whether principles were violated or upheld. We conclude that anyone who works in a health care setting has a duty to speak up when a patient faces harm. We also provide guidance for health care institutions on promoting a culture in which speaking up is encouraged and integrated into routine practice.

atients trust that the professionals involved in their health care are acting in their best interests and will protect them from harm. For the most part, that is exactly what happens. However, these same committed individuals fail to promote patients' interests when they do not speak up in certain situations such as when it looks like a surgery may be performed on the wrong site, when they witness a co-worker's unprofessional behavior or when they see a process that could be improved. Speaking up is simply not being silent when confronted with "risky" topics such as broken rules and incompetence.^{1,2} In the health care setting, speaking up involves alerting team members when a patient faces unnecessary harm and, if appropriate, engaging others to prevent future harmful acts.

In this article, we describe two incidents that occurred at Mayo Clinic that resulted in patient harm because health care professionals remained silent and two in which professionals spoke up and prevented harm and improved care. In addition, we offer an analysis of the ethics and professionalism principles that were violated or upheld in each scenario. We also make the case that everyone working in a health care setting, from physicians to medical students, has a duty to speak up when patients face harm. Finally, we offer practical advice for encouraging health care staff to speak up.

Methods

We selected the four cases because the details of them are in the public record. They either received coverage in the media or were the subject of journal articles. For each scenario, we analyzed the ethics and professionalism principles that were violated or upheld using the Physician's Charter on Medical Professionalism and the principles of medical ethics as a framework. The Charter lists three fundamental principles: 1) primacy of patient welfare, 2) patient autonomy and 3) social justice. These principles are similar to the four

prima facie principles of medical ethics: beneficence (duty to promote patient welfare), nonmaleficence (duty to prevent or do no harm), patient autonomy (duty to respect persons and their rights) and justice (duty to treat patients fairly). These principles encompass most ethical and professional concerns in health care.

SCENARIO 1

On December 18, 2007, *The Arizona Republic* reported that a Mayo Clinic surgeon-in-training had used a cellphone to photograph a patient's [tattooed] genitals during surgery.⁵ The surgeon took the photo on December 11, 2007, during a gallbladder procedure.^{5,6} On December 17, 2007, a member of the operating room staff reported the incident to the *Republic* through an anonymous phone call (naming the patient and the surgeon). On the same day, the surgeon called the patient, apologized and warned him that the incident would be reported in the newspapers. The patient told the *Republic*, "... I feel

violated, betrayed and disgusted."5 The surgeon was placed on administrative leave and was later said to no longer be practicing at Mayo Clinic. As of July 2008, Mayo was still attempting to identify the staff member who reported the incident to the Republic.7

Respect for patient autonomy requires health care professionals to maintain patient confidentiality. In this case, the surgeon certainly violated patient confidentiality by taking a photograph of the anesthetized patient without his permission. Likewise, the individual who reported the incident with the patient's name to the press egregiously violated patient confidentiality. The other professionals who were in the operating room at the time the photograph was taken also failed to respect the patient's autonomy because they did not speak up and stop the surgeon from taking the photograph.

Mayo Clinic immediately admitted that the infraction occurred and apologized. In addition, the surgeon was dismissed.

SCENARIO 2

In late 2006, at Mayo Clinic's Jacksonville, Florida, campus, two transplant recipients were identified as having contracted hepatitis C. A three-and-a-half-year investigation ensued, and more cases were discovered. Mayo officials partnered with the local Department of Health and the Centers for Disease Control and Prevention and determined that all of the infected patients had undergone procedures in Mayo's radiology department. Twenty-three employees in that department underwent testing; one tested positive for hepatitis C infection. That employee, whose role was to support a nurse and physician during invasive procedures, was removed from patient contact.

In August 2010, this employee's hepatitis C virus was shown to be a genetic match to strains from three infected patients. The employee subsequently admitted to using medications intended for patients and refilling used (and contaminated) syringes with saline. Law enforcement, the local Department of Health, the state licensing bureau, and patients

and their families were contacted.8 Since then, Mayo has tested approximately 3,500 patients. Of those, two more have tested positive for hepatitis C, and their strains have been linked to that of the employee.9

The employee who diverted drugs obviously violated the principle of beneficence by denying patients their medications. In addition, he violated the principle of nonmaleficence by harming patients (eg, infecting some with hepatitis C virus and causing psychological distress for others). Although it is unclear whether the employee's co-workers witnessed the perpetrator diverting drugs or manifesting behaviors associated with drug diversion, it is possible some did. And if they did, failing to speak up also would have violated nonmaleficence.8

Mayo Clinic officials promptly investigated the matter and alerted affected patients, authorities and the public. Thousands of patients were contacted and offered free testing, care and counseling. In addition, the employee was terminated and prosecuted.9 Mayo has since implemented protocols to prevent drug diversion at its facilities that include encouraging employees to speak up if they suspect diversion of controlled substances.

SCENARIO 3

In 2002, a man contacted Mayo Clinic in Rochester asking to be a living, unrelated kidney donor. He identified a potential recipient through the Internet. After he underwent physical and psychological screening, successful organ retrieval and transplantation occurred. Following the procedure, the donor was identified as the leader of the Jesus Christians, a small Australian religious group that teaches that adherents should be "living sacrifices" by donating organs to others.10 After his organ donation experience, the leader encouraged his followers to participate in similar donations. Subsequently, a group of six Jesus Christians arrived at Mayo Clinic with the intent of donating kidneys. Social workers, concerned that some of the potential donors were being coerced, spoke up to the transplant team. As a result, operations were delayed, an ethics

consultation was conducted and appropriate donors were selected. Those events also prompted a formal ethics analysis of mass altruistic, living, unrelated organ donation and the creation of new procedures for handling such situations. 10,11

The social workers who spoke up adhered to several ethics principles. They acted with patients' best interests in mind and attempted to prevent harm (ie, unwanted kidney donation). They also respected patients' autonomy by working to ensure that potential donors made their own decisions regarding organ donation without coercion. The social workers also drew attention to Mayo's procedures regarding living organ donation, leading to an institutional analysis and new procedures regarding group donations.10

SCENARIO 4

A quality review conducted at Mayo Clinic in Rochester revealed that outpatient thoracenteses were associated with more pneumothoraxes when performed in the Division of Pulmonary and Critical Care Medicine than when performed in the Department of Radiology (9% vs 2% of cases, respectively). Although both groups' performances were within the acceptable standard for iatrogenic complications associated with this procedure, the disparity between the two groups troubled physicians and prompted them to speak up and advocate for improvement. They discovered that thoracenteses increasingly were being referred to the Department of Radiology, and the physicians, residents and fellows in pulmonary and critical care consequently were receiving less training and had less experience in performing the procedure. The group implemented a quality-improvement project that focused on physician training and procedure standardization, including use of ultrasound guidance. Two years after the intervention, the pneumothorax rate in the Division of Pulmonary and Critical Care Medicine decreased to 1%.12

This scenario illustrates how speaking up can lead to quality improvement. Health care professionals must be willing to question and continuously assess their practices for the benefit of patients. In this scenario, the clinicians' actions were consistent with beneficence and nonmaleficence. The redesign and implementation of new procedures resulted in better patient care and fewer complications. Furthermore, the ethics principle of justice was exemplified by this scenario through reduced complications and, therefore, use of fewer resources.

Discussion

In addition to noting that the physician's duty is to promote patients' welfare, prevent harm, respect patient autonomy and promote justice, the Physician's Charter on Medical Professionalism lists responsibilities that include having a "commitment to improving quality of care," in which health care personnel and professionals work "collaboratively ... to reduce medical error, increase patient safety, minimize overuse of health care resources and optimize the outcomes of care."3 Dwyer summarizes these duties as a Socratic maxim: Primum non tacere or "First, do not be silent."1 Based on tenets of the Charter, we believe all health care workers—from physicians to staff to students—have a duty to speak up to promote patient welfare, prevent harm, respect patient autonomy and promote justice.

Unfortunately, evidence suggests that individuals often are inclined to remain silent when they should speak up. For example, in Vitalsmarts' Silence Kills study,2 more than half of nurses indicated they were concerned about a colleague's competence, but fewer than 1% were willing to speak up. Of the one-third of nurses who were concerned about a physician's competence, fewer than 1% were willing to voice their concerns. Likewise, although more than four of five physicians had concerns about a nurse or other allied health provider's competence, fewer than 1% were willing to share those concerns with that individual. Furthermore, of the two-thirds of physicians who had concerns about another physician's competence, fewer than 1% were willing to discuss their concerns with that colleague.

What underlies the fear of speaking up? Medical students and residents may be concerned about retaliation in the form of poor grades and evaluations. Confronting an attending physician can be intimidating, and prior experiences and the "hidden curriculum" (a set of influences that function at the level of organizational structure and culture13) may encourage medical students and residents to remain silent.1 This hidden curriculum, in turn, may be passed on to the next generation.14 Nurses may have similar reservations, although their reticence may stem from lack of confidence, previous failed confrontations, pressure from supervisors and fear of retaliation. Nurses also fear that speaking up will be perceived negatively and could result in their being ostracized by colleagues. Indeed, research has shown that speaking up can have negative consequences, with nurses reporting verbal abuse, threats and pressure to retract their statements after doing so.15

The Vitalsmarts study also showed that health care professionals avoid speaking up because of discomfort associated with confrontation, perceived lack of ability and obligation (ie,"not my job") and lack of confidence about successfully affecting change. Lack of time and opportunities also prevented them from voicing concerns. Instead, many professionals resort to discussing problems informally with peers. Depending on the issue, onequarter to one-half of the participants in the Silence Kills study said they vented to co-workers and warned them, rather than tried to solve problems.2

As illustrated by two of the scenarios in this article, remaining silent can result in harm to patients. In its seminal report "To Err Is Human,"16 the Institute of Medicine lists communication failure as a cause of medical errors. Remaining silent when a patient faces harm is a communication failure. Patients must trust that their health care providers will act in their best interest, and this includes speaking up. Indeed, according to the Physician's Charter on

Medical Professionalism, health care professionals have a clear responsibility to speak up.

German philosopher Immanuel Kant advocated a duty-based morality. Although self-interest, sympathy and fear of consequences can be motivators, actions are not moral unless they are driven by duty. Health care professionals have a duty to promote patients' well-being, and this involves speaking up when appropriate. The professional who remains silent is choosing his or her own interests (ie, avoiding discomfort) over the patient's interests. Kant formulated a categorical imperative that can be used as a guide in difficult moral situations: "Act only in accordance with that maxim through which you can at the same time will that it become a universal law."17 With this imperative in mind, speaking up becomes mandatory.

Applying the Lessons

How can health care professionals, staff and students be encouraged to speak up? First, individuals and institutions must be committed to promoting a culture conducive to speaking up. Second, institutions should provide training on how to speak up. Speaking up (eg, how to respectfully refuse to comply with an inappropriate order, how to confront a colleague who is about to harm a patient) can be taught. Third, health care professionals need multiple avenues for speaking up. Although direct verbal communication is the most obvious one, that approach does not always work as it may elicit anger or retaliation. At Mayo Clinic, individuals are encouraged to direct concerns to their supervisors and, if necessary, to Mayo's Compliance Office, which offers a confidential and anonymous hotline for employees to express their concerns about events and behaviors witnessed in the workplace. Fourth, institutions should support and protect those who speak up, should their identities become known to others, through nonretaliation policies. Mayo's policy states: "Anyone who honestly and in good faith reports suspected

wrongdoing will be protected from retaliation."18 Those who speak up should have ready access to institutional leaders who are their advocates.

Scenarios 1 and 2 culminated in three institutional initiatives: 1) initiation of a campaign encouraging employees to speak up when harm is threatened or observed, 2) an enhanced focus on promoting a culture of safety and 3) creation of professionalism consultations by Mayo Clinic's Program in Professionalism and Ethics. These consultations are offered to work units, divisions and departments that have professionalism concerns beyond those involving individuals (eg, poor communication and teamwork). The consultation team interviews stakeholders, gathers data, formulates an assessment and makes recommendations for addressing any concerns that are identified.

In most cases, speaking up is a straightforward undertaking. It might take the form of a resident respectfully disagreeing with an attending's diagnosis. It might be a concerned nurse pausing in the operating room and saying "I need clarity" before surgery is performed on the wrong site. Such nonthreatening statements prompt listeners to stop what they are doing and check in with team members about concerns.

In all cases, mitigated speech, which is any attempt to downplay or sugarcoat the meaning of what is being said, should be avoided.19 Individuals, typically subordinates, often use mitigated speech when they are ashamed, embarrassed or trying to be deferential to authority. The intended recipient, typically a superior, consequently does not hear, understand or consider the message.¹⁹ Take, for example, a pharmacist who knows a physician has prescribed a medication that will harm a patient. The pharmacist should not say to the physician, "You might consider another medicine." Instead, the pharmacist should say, "Don't prescribe that medicine. I recommend"

"To Err Is Human" recommends that health care institutions develop cultures "in which communication flows freely regardless of authority gradient." If an individual is uncertain about whether an event should be reported, he or she should discuss the matter with a trusted colleague, supervisor or administrator. Speaking up can be integrated into everyday practice. One way this is being done is through use of the checklists that all team members in clinical units must use.20 Such lists flatten hierarchies and facilitate communication and thus reduce the potential for patient harm and improve outcomes. In addition, speaking up can be integrated into qualityimprovement efforts. The physicians in Scenario 4 stated, "... we learned to view the 'problem' as one outcome variable of an overarching process, and we clarified our goals to improve the process of training and patient care, not just to reduce pneumothoraces."12 Their efforts helped create a positive outcome.

Conclusion

Although it is impossible to stop all who seek to do harm or to eliminate all risk associated with human error, individuals can speak up when they suspect someone's actions could lead to harm. To prevent harm and provide high-quality, patientfocused care and adhere to the Physician's Charter on Medical Professionalism and the requirements of well-established medical ethics principles, every member of the health care team must be willing and encouraged to speak up. MM

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Contemporary Issues in Medical Professionalism Challenges and Opportunities

By Darcy A. Reed, M.D., M.P.H., Paul S. Mueller, M.D., M.P.H., Frederic W. Hafferty, Ph.D., and Michael D. Brennan, M.D., FRCPI

Physician organizations, academic institutions and accrediting bodies agree that professionalism is important to medicine. A number of them have created codes of conduct and competencies related to professionalism. Yet studies have shown that physicians face challenges as they seek to put the principles of professionalism into practice. This article examines four realities of medicine today—the potential for conflicts of interest, the advent of social media, the lack of professionalism education beyond medical school and residency, and the lack of support from organizations for which physicians work—that challenge medical professionalism.

n 2002, the American Board of Internal Medicine (ABIM) Foundation, the American College of Physicians and the European Federation of Internal Medicine published "Medical Professionalism in the New Millennium: A Physician Charter," which identified three ethics principles and 10 professional responsibilities that comprise a modern definition of professionalism. To date, more than 130 professional organizations have endorsed the Charter.² Professionalism is also central to the Liaison Committee for Medical Education's standards for medical schools,³ the Accreditation Council for Graduate Medical Education's core competencies for residents and fellows,4 and the American Board of Medical Specialties' requirements for Maintenance of Certification. 5 In addition, the Joint Commission requires health care organizations to have codes of conduct and processes for addressing

unprofessional behavior in order to receive accreditation and certification.6

Although there is broad agreement that physicians must consistently demonstrate professionalism throughout their careers, the medical community continues to struggle to sustain professionalism in the face of the complex and multifaceted challenges physicians face today. In this article, we review four realities in medicine that present challenges to professionalism: 1) the growing potential for conflicts of interest, 2) the advent of social media, 3) lack of professionalism education beyond medical school and residency, and 4) lack of support from the organizations for which physicians work. In addition, we propose strategies for addressing them.

The Growing Potential for **Conflicts of Interest**

On July 26, 2013, the Wall Street Journal ran the front-page story "Surgeons Eyed over Deals with Medical-Device Makers: Justice Department Investigation Shines

Light on Federal Authorities' Broader Scrutiny of Physician-Owned Distributorships." The article recounted how one particular medical device manufacturer had set up a series of distributorships in which surgeons operated as distributors/ owners, and thereby generated revenue for themselves above and beyond that which they received for implanting the devices. Although the article noted that such activities can be legal, it also cited concerns raised by the Department of Health and Human Services' Office of Inspector General that such arrangements "pose dangers to patient safety" by motivating surgeons to undertake unnecessary surgeries and to favor their own devices over more "clinically appropriate" ones.

The story gets at one of the fundamental tenets of medical professionalism: the primacy of the patient's welfare or medicine's promise to place the well-being of patients

ahead of its own interests. In this way, medicine promises to approach patient care more as a public service than as a business. Because physicians have special knowledge and skills and because patients are vulnerable, physicians have an obligation to place the welfare of their patients ahead of their own welfare. This concept is ubiquitous in medicine. For example, the AMA Code of Medical Ethics (Opinion 8.03) opens with the sentence: "Under no circumstances may physicians place their own financial interests above the welfare of their patients," and closes with the following enjoinder: "If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit."8 At issue is the fundamental trustworthiness of medicine.

Although there always has been a potential for conflicts of interest, new concerns about the influence of "big industry" and "medical commercialism" began to surface in the late 1980s and early 1990s in response to the corporatization of medicine. Those concerns led some to believe that medicine had begun to lose its vaunted status as a trusted social institution. Arnold Relman's 1980 New England Journal of Medicine commentary on the rise of a "medical industrial complex" is a classic expression of concern about the influence of industry over medicine and the potential for conflicts of interest in medical decision-making.9

Prior to this time, most physicians believed it was impossible for their decisions to be influenced by anything other than the patient's interest. But as scientific data on physician decision-making and industry intentionally influencing medical practice and research began to emerge, 10-12 physicians started to acknowledge that they might be subject to influences from industry. 11,12 Today, with accumulating evidence of the presence of conflicts of interest,13 the prospect that physicians may hold divided loyalties or act as "dual agents"—and thus represent the interest of stakeholders other than patients—should

continue to concern the public and the medical community.

Both the medical community and the public have taken steps to prevent conflicts of interest. For example, most academic medical centers, teaching hospitals, medical schools and health care systems now have fairly robust policies governing institutional and individual relations with industry.14 Nonetheless, questions regarding the effectiveness of these initiatives continue to mount.15

The Advent of Social Media

The advent of new Internet-based technologies such as social networks, blogs and micro blogs presents both opportunities and challenges for physicians. Use of social media is so pervasive today that the question is no longer whether physicians will participate but rather how they can best use social media to advance the health of the public.

If used appropriately, social media has the potential to significantly extend the influence of medicine within society.16 Specifically, it can facilitate informationsharing between physicians and the public and help connect physicians with patients in underserved areas.¹⁷ Social media also may be useful in medical education, as it could enable instructors to reach learners across geographic boundaries and allow for more flexibility for both teachers and students. Surveys suggest that physicians are receptive to the idea of learning through social media and related technologies.18

Unfortunately, research also demonstrates that physicians and medical trainees exhibit unprofessional behavior online. 19,20 The type of behaviors most frequently reported to state medical boards include inappropriate communication with patients, misrepresentation of credentials, use of the Internet for inappropriate practice, breaches of patient confidentiality, failure to reveal conflicts of interest, depiction of intoxication and use of discriminatory language.21 Such behaviors may result in serious consequences including termination of employment and disciplinary actions from state medical

boards. 21 Medical students should also be aware that program directors increasingly use online content when selecting residents and fellows.22

The American College of Physicians (ACP) and the Federation of State Medical Boards (FSMB) recently published guidelines to help physicians make wise decisions about online behavior.²³ They state that all students, residents, fellows and practicing physicians must understand that professional codes of conduct applicable in medical schools, hospitals and clinics extend online.²⁴ The role of health professions schools to enforce codes of conduct online was recently upheld by the Minnesota Supreme Court, when it ruled on June 20 of this year that the University of Minnesota did not violate a mortuary student's free speech rights by punishing her for posting on Facebook comments about a cadaver she was working on.25 Physicians are encouraged to "apply ethical principles for preserving the relationships, confidentiality, privacy and respect for persons" to all online activities.23 The ACP and FSMB guidelines also suggest physicians should separate their online professional and social activities,23 although this is difficult as patients are increasingly reaching out to their physicians online.

One tactic we have found helpful in coaching medical trainees about online behavior is derived from Jostens' "Pause Before You Post" public service campaign.26 Before communicating online, pause to reflect on the following questions: 1) Who will be able to see what I post? 2) Will anyone be embarrassed or hurt by it (including me)? 3) Am I proud of what I'm posting? 4) Is this consistent with my professional values as a physician or medical student?

Lack of Professionalism Education Beyond Medical School and Residency

Professionalism is a core competency for physicians. Behaving in a professional manner is associated with a physician being perceived as knowledgeable, skilled and conscientious.27 In contrast, unprofessional behavior is associated with reduced staff productivity, lower morale, increased staff turnover, poor communication, reduced efficiency, a higher risk for errors, and decreased satisfaction and increased burnout among learners.28 Students and residents exposed to unprofessional behaviors among physicians may, in turn, learn and manifest those behaviors themselves.²⁹

Although we would all like to assume that physicians know how to manifest professional behaviors, it's not always the case. For example, a survey of practicing physicians showed that although most embraced the Charter's ethics principles and responsibilities, their self-reported behaviors sometimes conflicted with those principles and responsibilities (eg, being aware of an impaired colleague but not reporting the individual to authorities). 30 Vitalsmarts' "Silence Kills" study showed that, although a majority of physicians had concerns about a colleague's competence, fewer than 10% were willing to discuss their concerns with that individual.³¹ In another survey of physician executives, most reported regularly encountering physicians exhibiting unprofessional behaviors such as delivering insults, yelling, showing disrespect and refusing to complete duties.32

Most of the literature about professionalism education is focused on medical students and residents. To presume such education should end at residency is wrong. It needs to continue through the course of a physician's career. There are multiple reasons why. First, patients expect their physicians to demonstrate professional behaviors. Second, professionalism is associated with improved medical outcomes such as increased patient adherence with treatment programs.33

Practicing physicians should be taught the elements of professionalism (eg, communication skills, ethics, humanism, excellence, altruism and accountability) using Arnold and Stern's framework.34 Providing physician education on professionalism is important because doing so conveys a strong message about its importance as a competency. 28

For professionalism to flourish, it must be assessed as well as taught, as assessment drives learning, improves skills and promotes professional behaviors. 28 Because there's no single measure for assessing professionalism in practicing physicians, multiple measures must be used.34 These include 360-degree reviews (by colleagues, allied health staff and learners), selfassessments, patient assessments and patient complaint reviews-all of which can be combined in a "professionalism portfolio." The Division of General Internal Medicine at Mayo Clinic-Rochester has begun doing this as part of the annual review process. The process provides opportunity to give feedback, promote reflection, reward exemplars, evaluate professionalism training programs and generate research hypotheses. Physicians who repeatedly manifest unprofessional behaviors must be confronted and undergo corrective action.35

Lack of Organizational Support

If an organization's culture does not support professionalism, it is unfair to expect it from the people who work for the institution. Health care organizations need to support and encourage a culture of professionalism.36 This is especially relevant today as more and more physicians are joining larger groups or going to work for large health care organizations, where they do not enjoy the autonomy they may have once had. 37

Having an environment that encourages professionalism is especially important in organizations charged with teaching medical and other students. Learners are heavily influenced by attending faculty and will often readily adopt their behaviors, good or bad.

Professional behavior benefits the organization as well. It generates trust and promotes the reputation of individuals and the organization;38 it encourages staff engagement, greater productivity, and favorable recruitment and retention rates;39 and it encourages communication and speaking up in situations where it is critical to patient safety and the quality of care.40 Disruptive behavior, the antithesis

of professional behavior, is all too common in hierarchical organizations such as hospitals. 40 Such behavior can lead to dysfunctional teams, safety and quality lapses, and depression and burnout.41

Organizations can do a number of things to promote professionalism. They can select, train and monitor their teaching faculty, who can promote a culture built on professional values and behaviors. 42 They can emphasize the importance of proper dress and decorum, let employees know they can speak up without fear of retaliation and teach them to work as teams. Lucey and Souba proposed that organizations address lapses in professionalism similar to the way they address lapses in safety (eg, skills training).43 They can redesign or develop curriculum on professionalism that includes narratives collected from within the organization. Such changes have led to desirable results in a number of organizations. 44 The ABIM Foundation has published an analysis of these and other organizational approaches to advancing professionalism. 45

Summary

The potential for conflicts of interest, the rise of social media, the lack of professionalism education beyond medical school and residency, and the lack of organizational support challenge professionalism in medicine. Avoiding conflicts of interest and optimally using social media require individual physicians to monitor their own behaviors. Organizations should commit to providing physicians with education on professionalism throughout their careers. In addition, they need to reward professional behavior and see that examples are set from the top down. Future initiatives should explore ways to support and enhance professionalism at both the individual and organizational level. MM

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ICD-10 Is Coming

An Update on Medical Diagnosis and Inpatient Procedure Coding

BY BURKE KEALEY, M.D., AND APRIL HOWIE, CPC, CPMA

In October 2014, the United States will switch from using the ICD-9 coding system to ICD-10. This change will allow for greater specificity in describing medical conditions and the addition of new codes as medical knowledge and technology evolve. The change will be a big one for hospitals and clinics. This article describes what physicians need to know about the new system and what the organizations they work for need to consider when preparing for the change.

Since 1979, the United States has been using the ninth revision of the International Classification of Diseases (ICD-9). The ICD is used to classify diseases and other health problems on death certificates, in health records, and for national morbidity and mortality statistics. It is also used to monitor the incidence and prevalence of disease and is essential for resource allocation and reimbursement. ICD-10 was endorsed by the World Health Assembly in May 1990 and came into use in 1994. Most other countries now use ICD-10. The 11th revision will be available in 2015.

The Health Insurance Portability and Accountability Act requires hospitals and health systems to switch from ICD-9 to ICD-10 by October 1, 2014. ICD-10 differs from ICD-9 in that it allows for greater specificity in describing a patient's condition; it also allows for new codes to be added as medical knowledge and technology change. That greater specificity will allow for better quality measurement and better analysis of disease patterns. It

also will aid researchers, as it captures the severity of illness, which is currently not possible with ICD-9. In addition, ICD-10 will result in more accurate bills being submitted for reimbursement, theoretically reducing waste in the medical system.

With ICD-10, the number of diagnosis codes (-CM codes) will expand from 14,000 to 68,000 and the number of procedure codes (-PCS codes) will increase from 4,000 to 87,000. No physician will need to learn all of these codes. And many of them will be embedded in the drop-down menus of electronic health record (EHR) systems. All physicians, however, will need to know something about the changes headed their way, as they do affect the way they will need to document patient care.

Physicians and ICD-10

The fundamental point for physicians to understand is that because ICD-10 allows for more specificity, the supporting documentation in the medical record will need to be more specific as well. Physicians will need to note the primary diagnosis as they currently do with ICD-9, but with

ICD-10 they also will need to attend to the following new sub-classification criteria: laterality, stages of care, specific diagnosis, specific anatomy, associated/related conditions, cause of injury, additional signs/symptoms/conditions, dominant vs. nondominant side, external cause(s) and/ or places of occurrence, cause and effect relationship, and recurrent vs. initial. For example, the documentation for a patient with asthma would need to encompass the specific diagnosis, severity, whether it is intermittent or persistent, the level of exacerbation, cause and effect, the history of tobacco use, and exposure to environmental smoke (even prenatal exposure) (Table). In the case of a neoplasm, the supporting documentation would still need to include notations about site (the ovary) and behavior. It also would need to include information about such details as laterality; whether the malignancy is on the left or right side; whether the malignant neoplasm is of the isthmus uteri, endometrium, myometrium, fundus uteri or overlapping sites of the corpus uteri or whether it is unspecified; the disease stage; and the

patient's presentation for a specific treatment related to the condition (eg, chemotherapy, immunotherapy, radiation).

The new codes for procedures allow for more specificity as well. Under ICD-10, documentation for joint replacement would continue to include classification of an injury by specific body part and approach, as was required for ICD-9. But it also would need to address the type of material used (metal, metal on polyethylene, ceramic or ceramic on polyethylene).

Making the Transition

Coding is the key to billing and reimbursement. In some hospitals and clinics, charges are reviewed by a coder before they are submitted. During the initial phase of ICD-10 implementation, coders may not be as available for such checks as they have been in the past because of the increased workload. Yet at the same time, payers may be scrutinizing billing documents more closely to determine coverage.

To ensure that the revenue cycle is not disrupted, clinics and hospitals should be preparing for the transition from ICD-9 to ICD-10. It is critical that the physician's perspective is considered in planning for this transition. Ideally, there should be a physician champion (or several) on your organization's ICD-10 steering committee. In addition, a physician representative from each specialty or department needs to be involved in communicating the coming changes to others in their departments.

The ICD-10 steering committee should consider the following issues and how they affect physicians as they prepare for the transition:

TRAINING

The impact of ICD-10 is vast, as it will affect nearly everyone in your medical office: staff from the lab, nurses, coders, those who work at the front desk, clinic managers, and physicians and other clinical staff. It also will affect reporting, prior authorizations, policies and procedures, vendor and payer contracts, and Advance Beneficiary Notices, to name a few. Assessing the level of training needed by

A Comparison of ICD-9 and ICD-10 Coding

MEDICAL PROBLEM	ICD-9-CM CODE	ICD-10-CM CODE	
Asthma	493.10 Intrinsic asthma unspecified	J45.31 Mild persistent asthma with acute exacerbation	
Neoplasm	183.0 Malignant neoplasm of the ovary 182.0 Malignant neoplasm of the corpus uteri	C56.2 Malignant neoplasm of the left ovary C54.2 Malignant neoplasm of the myometrium	

each employee will be vital, as the amount of training needed will vary, depending on the person's position. A coder will need in-depth training. Whereas, a physician may need just-in-time training on how to document and code conditions he or she frequently sees. The physicians on the ICD-10 steering committee can help determine how to train their colleagues most effectively, as they best understand how physicians learn and how to do the training so that it has minimal impact on their work schedules.

THE EHR

Representatives from your organization will need to work closely with your EHR vendor to make sure the system is ready for ICD-10. The EHR is critical, as it will allow you to choose diagnoses from a menu and then track those diagnoses to specific ICD-10 codes. (The appropriate code will either be placed directly into the claim or into a queue for further editing by a coder.)

Your organization may need to upgrade its EHR or switch to an entirely new version of the software. The process of ramping up a new system can be a substantial undertaking, and it will require testing of not only the current version of software but also any new interface. Those involved in testing will need to identify any changes to physicians' workflow that are the result of ICD-10 and include physicians in the design of new processes.

CLINICAL DOCUMENTATION IMPROVEMENT

Your organization should embed ICD-10 into its clinical documentation improvement (CDI) program. To do that, it will

need to take steps to find out where physicians and other providers already deliver great specificity in their documentation and then work to maintain it.

Data analytics can help identify where gaps do and will exist. Those involved in finding out where documentation improvements can be made should take small steps to integrate changes well ahead of the full rollout of ICD-10. They should also focus efforts on specific changes around how diagnoses are classified and whether they match up with those used for billing and history purposes.

If your organization does not already have a CDI program, consider creating one. A CDI program is the best bet for embedding ICD-10 concepts in your physicians' current practice patterns and workflows as well as those they'll use long after the rollout is complete.

The Big Picture

Finally, remember to pause every now and then. Know that the switch to ICD-10 will not be a rapid one. Before the full rollout takes place next October, clinical staff should focus on building relationships with coding, technical and administrative support staff who have the skills necessary to meet the many of the challenges associated with this transition. Everyone should think big picture; and leaders should remember to tend to their organization's culture during a shift as vast as this.

Physicians did not go to medical school to learn how to document; but they should respect that ICD-10 provides them an opportunity to provide more complete clinical information about their patients. Better information is better care. In order to best serve your patients, make sure you or another physician is involved in your

organization's ICD-10 implementation; don't leave it to others. Every physician is dealing with this transition—view it as an opportunity. MM

Burke Kealey is associate medical director for hospital specialties for HealthPartners Medical Group and April Howie is manager of care systems compliance operations for HealthPartners Medical Group.

LEARN MORE ABOUT ICD-10 BY GOING TO THE FOLLOWING WEBSITES:

The Centers for Disease Control and Prevention

(www.cdc.gov/nchs/icd/icd10cm.htm)

The World Health Organization

(www.who.int/classifications/icd/en/)

Minnesota ICD-10 Collaborative

(https://www.bluecrossmn.com/internet_core/en_US/ ccurl/615/602/ICD-10_Collaborative_Webinar,0.pdf)

American Medical Association.

(www.ama-assn.org/ama/pub/physician-resources/solutionsmanaging-your-practice/coding-billing-insurance/hipaahealthinsurance-portability-accountability-act/transaction-code-setstandards/icd10-code-set.page)

Center for Medicare and Medicaid Services

(http://cms.gov/Medicare/Coding/ICD10/index.html)

AAPC (www.aapc.com/ICD-10/icd-10-codes.aspx)

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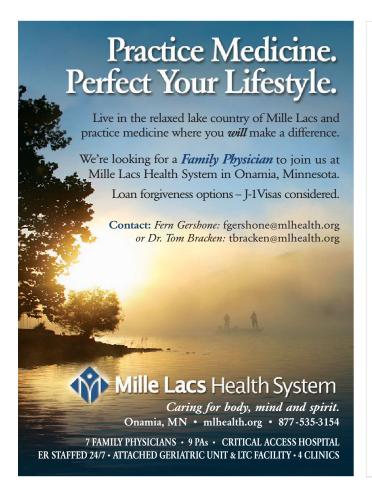
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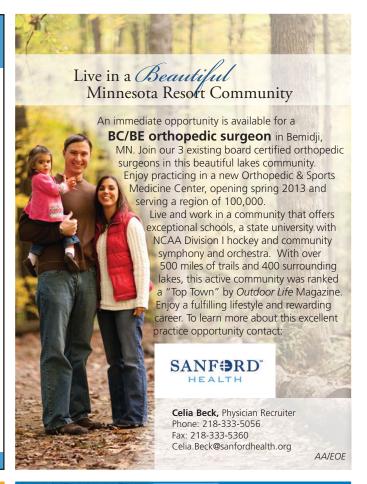
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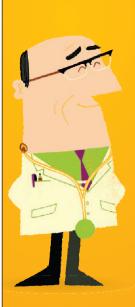
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A boy named Joey

Traveling north to remember

BY CHARLES OBERG, M.D., M.P.H.

t has been more than 30 years since I last drove north on I-35 to Ely, the gateway to the Boundary Waters Canoe Area. The last time was a trip with my wife to attend the funeral of a young man, the first patient I lost as a pediatrics intern.

Joey had cystic fibrosis, the most common congenital disorder, and he was my first encounter with the disease. He had been referred to the University of Minnesota for repeated pneumonias that had sapped his energy and left him with limited pulmonary function. I remember looking at his X-rays and thinking his lungs looked like those of an elderly person with end-stage emphysema rather than those of an adolescent. Joey struggled with each breath. Yet he had a strong will to live and displayed a sense of peace as his impending death approached.

I am not sure why I spent time with Joey. It would have been easy enough to avoid his room, except to take his vital signs and do a quick daily exam. Yet, I remember sitting with him on the ward late at night while on call. He was in a small negative-pressure isolation room so as to minimize the chance he would contract an infectious disease. We would tell each other stories or sometimes just sit silently. There was little I could do for him medically. He had stopped responding to antimicrobial, respiratory and nutritional therapies. At the start of my four-week rotation he required oxygen only occasionally, but by the end he needed it for every breath. He experienced loss of appetite, loss of weight, loss of energy—but never loss of spirit. I was his young doctor, companion and friend, and I cared for him until his last breath.

Joey had a loving family. They still live in Ely, and each Christmas my wife and I receive a card from them saying that if we are ever that far north to drop in. So I need to head north to see his mom. To let her know how much her son touched my life, that he taught me more about courage and grace in four weeks than I could have ever imaged. So today I am driving north—and looking back on a boy named Joey. MM

Charles Oberg is a professor and director of the Maternal and Child Health Program in the University of Minnesota's School of Public Health. He also practices pediatrics at Hennepin County

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