

MINNESOTA MEDICINE

SEPTEMBER 2013



THE



APPLICATION



OF



PRACTICE



PHYSICIANS DISCOVER APPS THAT HELP THEM PROVIDE **BETTER, MORE EFFICIENT CARE.**



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MINNESOTA
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Creating tomorrow's cures...today.

"Your child has cancer."

Those words can turn a parent's world upside down.

At University of Minnesota Amplatz Children's Hospital our pediatric cancer experts can promise parents, like those of 7-year-old Cecilia, the most advanced treatments available including access to the longest-standing and one of the most respected blood and marrow transplant (BMT) programs—just for children.

Whether it's at the time of initial diagnosis or if the cancer recurs, our patients have access to medical breakthroughs—such as expanded cord blood stem cells to speed recovery—that often lead to cures for cancer and other severe diseases. For Cecilia, this meant that when chemotherapy was no longer enough, the BMT team was right there offering compassionate care, spacious family-friendly rooms and onsite teachers that helped make the time away from home a little easier.

As the care team partners with referring providers, we strive to move patient care beyond where it is today and will not be satisfied until there is a cure. After all, what matters most to kids like Cecilia and their parents is that we help them get back to just being kids.

Read more about Cecilia's journey and our cancer care and BMT programs at uofmchildrenshospital.org/cancerreferral.

Cecilia



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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.

VICTOZA®
liraglutide (rDNA origin) injection

Indications and Usage

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

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

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

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

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

Important Safety Information

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

human risk of thyroid C-cell tumors. Patients should be counseled regarding the risk and symptoms of thyroid tumors.

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

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

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

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

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

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

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

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

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

Please see brief summary of Prescribing Information on adjacent page.

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

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

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

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

WARNINGS AND PRECAUTIONS: Risk of Thyroid C-cell Tumors: Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors (adenomas and/or carcinomas) at clinically relevant exposures in both genders of rats and mice. Malignant thyroid C-cell carcinomas were detected in rats and mice. A statistically significant increase in cancer was observed in rats receiving liraglutide at 8-times clinical exposure compared to controls. It is unknown whether Victoza® will cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors could not be determined by clinical or nonclinical studies. In the clinical trials, there have been 6 reported cases of thyroid C-cell hyperplasia among Victoza®-treated patients and 2 cases in comparator-treated patients (1.3 vs. 1.0 cases per 1000 patient-years). One comparator-treated patient with MTC had pre-treatment serum calcitonin concentrations >1000 ng/L suggesting pre-existing disease. All of these cases were diagnosed after thyroidectomy, which was prompted by abnormal results on routine, protocol-specified measurements of serum calcitonin. Five of the six Victoza®-treated patients had elevated calcitonin concentrations at baseline and throughout the trial. One Victoza® and one non-Victoza®-treated patient developed elevated calcitonin concentrations while on treatment. Calcitonin, a biological marker of MTC, was measured throughout the clinical development program. The serum calcitonin assay used in the Victoza® clinical trials had a lower limit of quantification (LLOQ) of 0.7 ng/L and the upper limit of the reference range was 5.0 ng/L for women and 8.4 ng/L for men. At Weeks 26 and 52 in the clinical trials, adjusted mean serum calcitonin concentrations were higher in Victoza®-treated patients compared to placebo-treated patients but not compared to patients receiving active comparator. At these timepoints, the adjusted mean serum calcitonin values (-1.0 ng/L) were just above the LLOQ with between-group differences in adjusted mean serum calcitonin values of approximately 0.1 ng/L or less. Among patients with pre-treatment serum calcitonin below the upper limit of the reference range, shifts to above the upper limit of the reference range which persisted in subsequent measurements occurred most frequently among patients treated with Victoza® 1.8 mg/day. In trials with on-treatment serum calcitonin measurements out to 5-6 months, 1.9% of patients treated with Victoza® 1.8 mg/day developed new and persistent calcitonin elevations above the upper limit of the reference range compared to 0.8-1.1% of patients treated with control medication or the 0.6 and 1.2 mg doses of Victoza®. In trials with on-treatment serum calcitonin measurements out to 12 months, 1.3% of patients treated with Victoza® 1.8 mg/day had new and persistent elevations of calcitonin from below or within the reference range to above the upper limit of the reference range, compared to 0.6%, 0% and 1.0% of patients treated with Victoza® 1.2 mg, placebo and active control, respectively. Otherwise, Victoza® did not produce consistent dose-dependent or time-dependent increases in serum calcitonin. Patients with MTC usually have calcitonin values >50 ng/L. In Victoza® clinical trials, among patients with pre-treatment serum calcitonin <50 ng/L, one Victoza®-treated patient and no comparator-treated patients developed serum calcitonin >50 ng/L. The Victoza®-treated patient who developed serum calcitonin >50 ng/L had an elevated pre-treatment serum calcitonin of 10.7 ng/L that increased to 30.7 ng/L at Week 12 and 53.5 ng/L at the end of the 6-month trial. Follow-up serum calcitonin was 22.3 ng/L more than 2.5 years after the last dose of Victoza®. The largest increase in serum calcitonin in a comparator-treated patient was seen with glimepiride in a patient whose serum calcitonin increased from 19.3 ng/L at baseline to 44.8 ng/L at Week 65 and 38.1 ng/L at Week 104. Among patients who began with serum calcitonin <20 ng/L, calcitonin elevations to >20 ng/L occurred in 0.7% of Victoza®-treated patients, 0.3% of placebo-treated patients, and 0.5% of active-comparator-treated patients, with an incidence of 1.1% among patients treated with 1.8 mg/day of Victoza®. The clinical significance of these findings is unknown. Counsel patients regarding the risk for MTC and the symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea or persistent hoarseness). It is unknown whether monitoring with serum calcitonin or thyroid ultrasound will mitigate the potential risk of MTC, and such monitoring may increase the risk of unnecessary procedures, due to low test specificity for serum calcitonin and a high background incidence of thyroid disease. Patients with thyroid nodules noted on physical examination or neck imaging obtained for other reasons should be referred to an endocrinologist for further evaluation. Although routine monitoring of serum calcitonin is of uncertain value in patients treated with Victoza®, if serum calcitonin is measured and found to be elevated, the patient should be referred to an endocrinologist for further evaluation. **Pancreatitis:** Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with Victoza®. After initiation of Victoza®, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, Victoza® should promptly be discontinued and appropriate management should be initiated. If pancreatitis is confirmed, Victoza® should not be restarted. Consider antidiabetic therapies other than Victoza® in patients with a history of pancreatitis. In clinical trials of Victoza®, there have been 13 cases of pancreatitis among Victoza®-treated patients and 1 case in a comparator (glimepiride) treated patient (2.7 vs. 0.5 cases per 1000 patient-years). Nine of the 13 cases with Victoza® were reported as acute pancreatitis and four were reported as chronic pancreatitis. In one case in a Victoza®-treated patient, pancreatitis, with necrosis, was observed and led to death; however clinical causal-

ity could not be established. Some patients had other risk factors for pancreatitis, such as a history of cholelithiasis or alcohol abuse. **Use with Medications Known to Cause Hypoglycemia:** Patients receiving Victoza® in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogues) or insulin. **Renal Impairment:** Victoza® has not been found to be directly nephrotoxic in animal studies or clinical trials. There have been postmarketing reports of acute renal failure and worsening of chronic renal failure, which may sometimes require hemodialysis in Victoza®-treated patients. Some of these events were reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Some of the reported events occurred in patients receiving one or more medications known to affect renal function or hydration status. Altered renal function has been reversed in many of the reported cases with supportive treatment and discontinuation of potentially causative agents, including Victoza®. Use caution when initiating or escalating doses of Victoza® in patients with renal impairment. **Hypersensitivity Reactions:** There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema) in patients treated with Victoza®. If a hypersensitivity reaction occurs, the patient should discontinue Victoza® and other suspect medications and promptly seek medical advice. Angioedema has also been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of angioedema with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to angioedema with Victoza®. **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Victoza® or any other antidiabetic drug.

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

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

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

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

Adverse Reaction	Add-on to Metformin Trial		
	All Victoza® + Metformin N = 724 (%)	Placebo + Metformin N = 121 (%)	Glimepiride + Metformin N = 242 (%)
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
Adverse Reaction	Add-on to Glimepiride Trial		
	All Victoza® + Glimepiride N = 695 (%)	Placebo + Glimepiride N = 114 (%)	Rosiglitazone + Glimepiride N = 231 (%)
Nausea	7.5	1.8	2.6
Diarrhea	7.2	1.8	2.2

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

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

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

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

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

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

the incidence of hypoglycemic events defined as symptoms accompanied by a fingerstick glucose <56 mg/dL was comparable among the treatment groups (approximately 5%).

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

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

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

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

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

More detailed information is available upon request.

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

Date of Issue: April 16, 2013

Version: 6

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

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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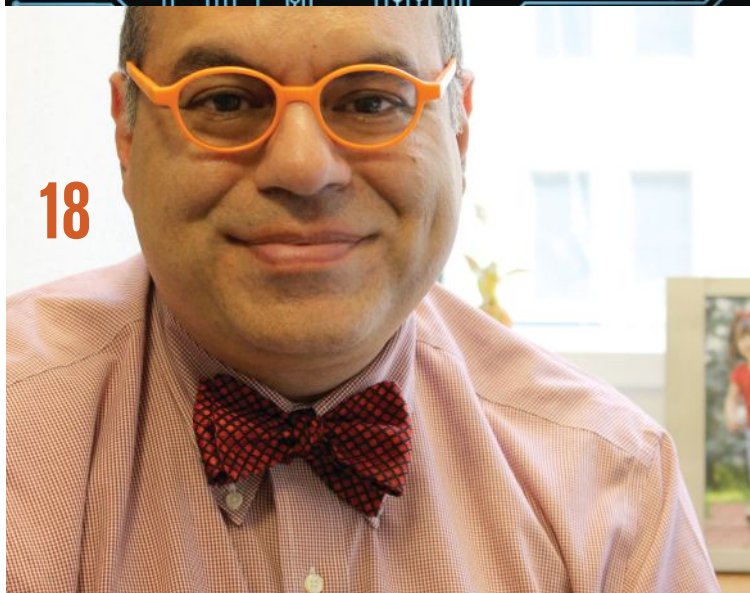
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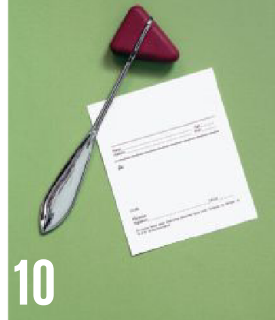
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PHOTO BY SCOTT WALKER

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

I have been sitting on top of the Holy Grail, using a full-featured EMR for all of my patient encounters, and the gleam of the Grail has become a bit tarnished.

A work in progress

Shortly after buying an Apple II Plus in 1981, I was regaling my dinner mates with tales of my amazing machine and what it could do. A woman across the table, who had been looking puzzled and bemused during my discourse, finally piped up and asked, “But, Chuck, what are you going to do with it?” Momentarily taken aback, I weakly replied, “Recipes?” and then added, as an afterthought, “Maybe I’ll put patient records on it.”

Thus began an odyssey through innumerable computers and software programs searching for the Holy Grail that would computerize my medical records. I moved from the Apple to IBM desktops to laptops. I experimented with Visicalc, Dbase III and Microsoft Access. I finally concluded that building a true electronic medical record (EMR) was beyond my expertise and that I would have to wait for a commercial one.

The wait wasn’t long. Program after program hit the market touting ease of use and instant access to all the patient information one would ever want. As chair of an information systems committee for one Twin Cities hospital system, I sampled some of the offerings of the “big players” in the burgeoning EMR field and gave talks to insurance providers, acting as a veritable cheerleader for what these systems could accomplish. Finally, we could simplify the work providers do every day. We could meaningfully measure what we do and see what works. I was preaching the Holy Grail. The future was now, and it was going to be good.

For the last two years, I have been sitting on top of the Holy Grail, using a full-featured EMR for all of my patient encounters, and the gleam of the Grail has become a bit tarnished. Every day is a “clickfest,” as I click on all the requisite tabs to accomplish the necessary patient tasks and complete the needed documentation for various quality standards being measured. I have become a victim of the dictatorship of the inbox, obsessively trying to keep up with the stream of information that pours into it. And it seems like the software will never do what should be a two-click job in less than five clicks.

And yet the EMR is an improvement. The prescription refill process has been trimmed by many steps. Information gathered anywhere within my health care system’s network of hospitals and clinics is readily available. Patients’ past medical histories and problem lists are easy to access once they have been accurately recorded. And the prompts to enter quality information, though irritating at times, do make me do a better job of doctoring.

Really the EMR is just like any technology—a work in progress.

Most depictions of the Holy Grail in art and movies portray it as a treasure, a chalice or a goblet hidden in an obscure place waiting for a Harrison Ford to find it and achieve ultimate wisdom. But wisdom and technological progress don’t occur in one “aha” moment. They emerge slowly over time. Holy Grails are found only in the movies.

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

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Communication equals control

Using a home blood pressure monitor and transmitting the readings to a pharmacist may be an effective way to control hypertension, a condition that affects approximately 30 percent of adults in the United States and costs more than \$50 billion annually.

Those were the findings of a study led by Karen Margolis, M.D., M.P.H., director of clinical research at HealthPartners

Institute for Education and Research in Bloomington.

The randomized clinical trial involved 450 patients with uncontrolled hypertension from 16 primary care clinics in the HealthPartners system. The patients included individuals with severe uncontrolled hypertension as well as other medical conditions including diabetes, kidney disease and heart disease.

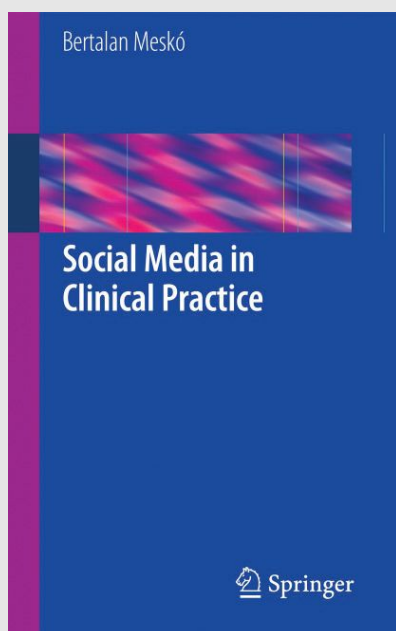
Patients in eight clinics (n=228) received home blood pressure telemonitors that transmitted readings to pharmacists, who could then adjust their medications as needed over the phone. Patients in the other eight clinics (n=222) received usual care.

Patients used the intervention for 12 months and were followed for six months afterward. Their blood pressure was assessed at six, 12 and 18 months.

Margolis and her team found about twice as many patients in the telemonitoring program (57.2 percent) as in the control group (30.0 percent) had controlled blood pressure at six and 12 months. More than 70 percent of the telemonitoring patients had controlled blood pressure at six, 12 and 18 months. At the 18-month follow-up visit, 71.8 percent of those in the telemonitoring program had their blood pressure under control compared with 57.1 percent of those in the control group.

The study was a follow-up to earlier tests of a similar approach that did not include patients with other conditions or a follow-up visit.

The findings were published in the July 3 *Journal of the American Medical Association*.



New manual on social media

A new book *Social Media in Clinical Practice* provides practical advice for physicians seeking to become social media savvy. In an online interview in *MedPage Today*, author Bertalan Meskó says he wrote the book to get doctors up to speed on the topic. When asked why he wrote a book instead of developed an e-learning platform, he said because physicians “stick with the traditional way of learning new things.”

In the book, Meskó explains how to do such things as podcasting, blogging and tweeting and provides information about how to use apps, Facebook and Google. He also addresses the No. 1 concern for many physicians—privacy.

Meskó believes doctors need to use social media. “Using digital technologies, especially social media, is now an integral part of medical communication, and as more and more patients use these platforms, their physicians must be able to deal with this in an evidence-based manner,” he said in the interview.



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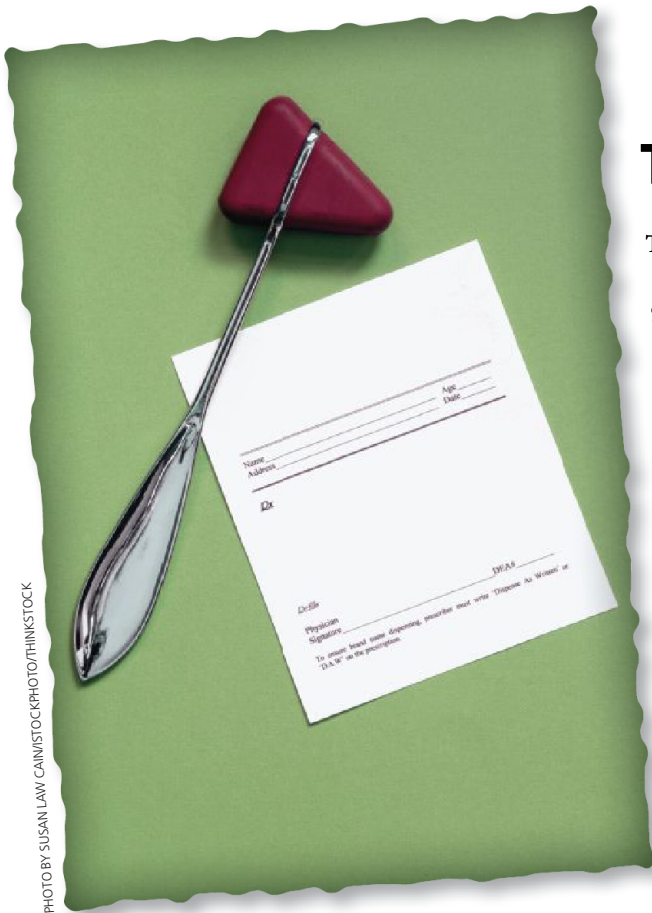
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The vanishing Rx pad

The physician's prescription pad is becoming a thing of the past.

According to Surescripts, an e-prescribing network used by more than 95 percent of pharmacies in the United States, 69 percent of U.S. office-based physicians prescribed electronically in 2012—up from 58 percent in 2011 and 10 percent in 2008. Eighty-seven percent of e-prescriptions were sent through an electronic health record system and 13 percent were sent through a stand-alone prescribing system.

One reason for the increase in e-prescribing was the fact that 93 percent of community pharmacies now accept electronic prescriptions (98 percent of chain pharmacies and 85 percent of independent drug stores use them).

Minnesota ranked second in the country in terms of its progress in adopting e-prescribing. The study found 95 percent of physicians in the state were e-prescribing, up from 49 percent in 2010.

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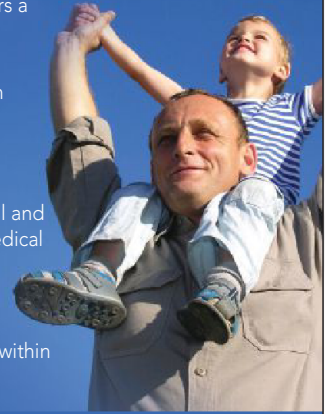
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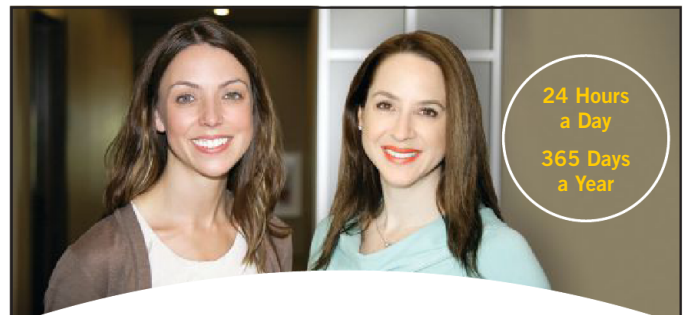


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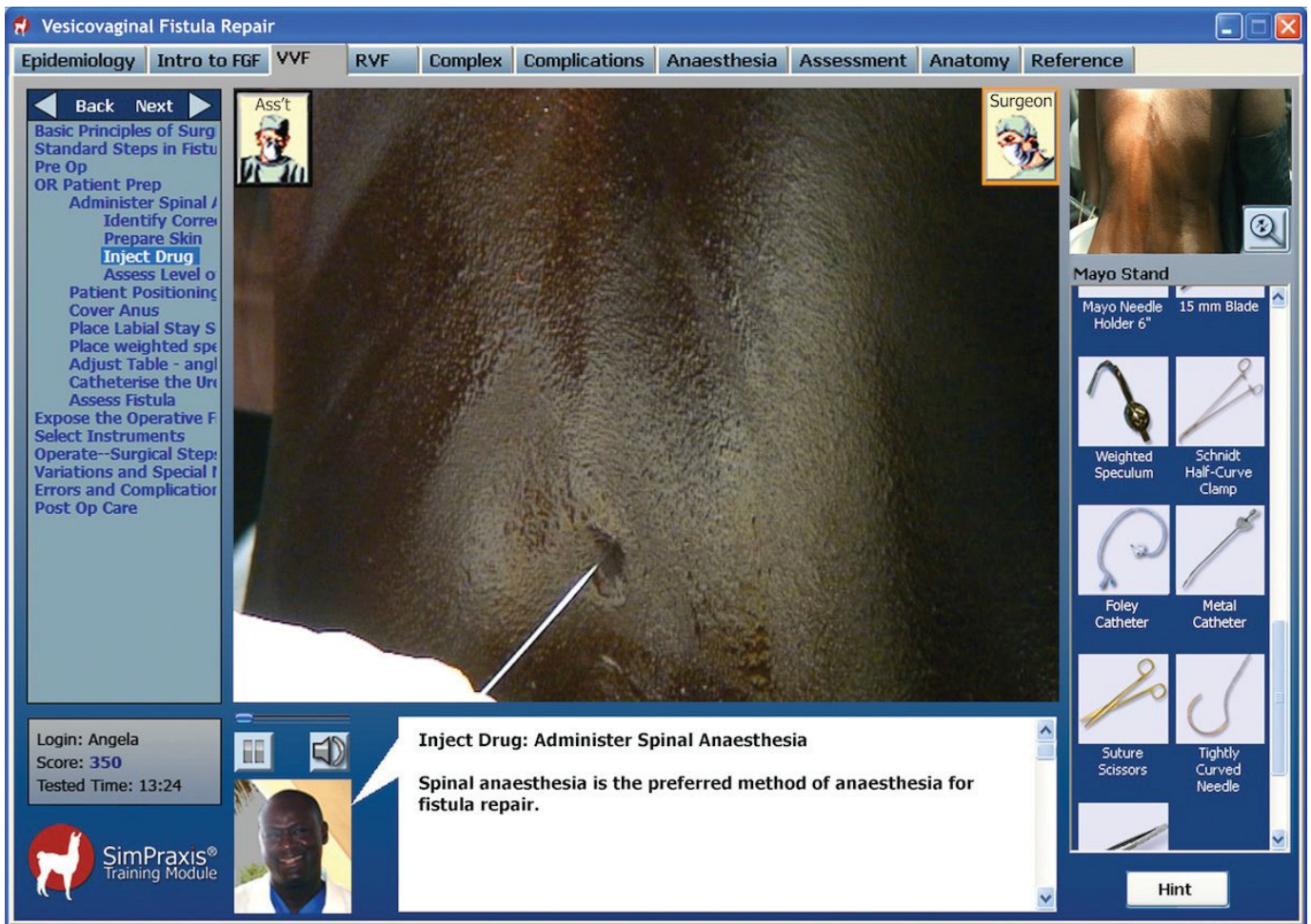
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A screen shot from the software Pete Melchert and his team are developing.



A simulator for fistula repair

A team led by a Twin Cities doctor is creating an interactive training program for surgeons in the developing world.

BY KIM KISER

In a tiny office outside the hyperbaric chamber at Abbott Northwestern Hospital in Minneapolis, Pete Melchert, M.D., appears to be playing a video game. He uses the mouse on his laptop to pick up a virtual instrument and place it on a virtual patient, racking up points when he picks up the correct one and losing them when he gets it wrong. Melchert isn't sneaking a quick game of Code Blue. Rather, he's demonstrating software he has created for teaching physicians in Africa to repair obstetric fistulas.

As medical director of the nonprofit Medical Simulation International (MSI), Melchert's goal is to help train doctors in countries where the problem is endemic. "Obstetrical fistula afflicts millions of women in the developing world," he says. "The problem remains because of the lack of sufficiently trained medical personnel. There are perhaps 10 qualified surgeons who can treat and train others on the entire continent of Africa, and there's an enormous backlog of cases to be done."

The World Health Organization estimates that between 50,000 and 100,000

women primarily in Africa and parts of Asia develop an obstetric fistula each year. Most are young and malnourished and thus have a small pelvis. Few have had prenatal care, and most delivered their baby without the help of a health care professional. The problem begins when the baby's head gets stuck in the birth canal. If it remains in that position for long, it can cut off the blood supply to the surrounding tissue. When the necrotic tissue falls away, the woman is left with a hole between her vagina and bladder or rectum.

Fistula has both medical and social consequences. Not only does the baby often die during birth, but the woman may be unable to have more children. The fistula also causes her to leak urine or feces. “So the girl is rejected by her family, has this physical trauma and can’t be part of society,” Melchert says.

The power of technology

Melchert, who practices internal medicine/pediatrics, admits he hadn’t heard of obstetric fistula until 2003, when he traveled to Ghana as part of a Children’s Surgery International team to care for children being treated for cleft lip and palate at Komfo Anokye Teaching Hospital in Kumasi. “Our hosts welcomed our help with clefting, but they said the real problem they had was with fistulas,” he recalls. “All I knew of were GI intestinal fistulas.” In the United States and other western countries, obstetric fistula is unheard of. “When a woman enters obstructed labor, they know how to get her out,” he says of the ob/gyn teams here.

Consequently, the problem wasn’t on the radar of surgeons in developed countries until recently. And no one had written a curriculum on repairing obstetric fistula until two years ago, when the International Federation of Obstetrics and Gynecology (FIGO) created the Global Competency-Based Fistula Surgery Training Manual. But the manual itself wasn’t enough to solve the shortage of trained surgeons. So representatives from FIGO contacted Melchert, who also now serves as medical director of Children’s Surgery International, which sends surgeons to Third World countries to do procedures and training, and asked for help. “The problem with training is that it takes time and is very costly,” he says. “Many surgeons don’t have the time to go to a center for months to learn to do this.”

The first challenge was figuring out how to make fistula repair training more efficient. “Simulation technologies are becoming the standard for training in the developed world,” Melchert says. “We envisioned an interactive simulator that would bring the manual to life.” But the

type of simulators used in the United States are impractical in Africa, as they cost millions and need regular maintenance and repair. Melchert and his team needed something that would work in locations where resources were scarce.

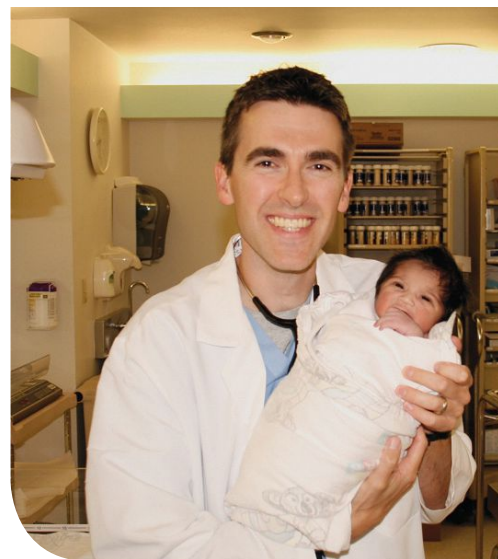
Since establishing MSI two years ago, they have been working with a Seattle company to create software that would run on a basic PC. “Even the most low-resourced hospitals in Africa have a computer for their physicians,” he says. Their idea was to combine video recordings of master fistula surgeons performing procedures, narrative commentary, and interactive assessments and quizzes.

To build the software, they have had to record entire fistula repair procedures using high-definition endoscopic camera equipment, identify the key images, and organize the video clips into a logical sequence. The software engineers then embed “hot spots.”

Surgeons who take the training will be required to select the correct instrument from a virtual Mayo stand and drag it to the correct location in the surgical field, among other things. When they make a correct choice, they will progress to the next step. If they make an incorrect choice, they lose points. “We want them to make errors on the simulator, not on a young woman,” Melchert says.

All along, the learner will be tested on pre-op assessment, patient positioning, instrument management, anatomy, post-op management and awareness of complications that may develop. Upon completing a module, the learner will receive a print-out with his or her score and feedback about areas where additional training is needed.

The idea is that surgeons will use the software before going to a training center. “This is intended to make it highly productive when they are in the OR,” Melchert says. Surgeons also will be able to refer to the module in their home hospital. “They can pop the disc in, get a refresher and boost their confidence.”



Pete Melchert, M.D., with a young patient.

IMAGES COURTESY OF PETE MELCHERT

Only the beginning

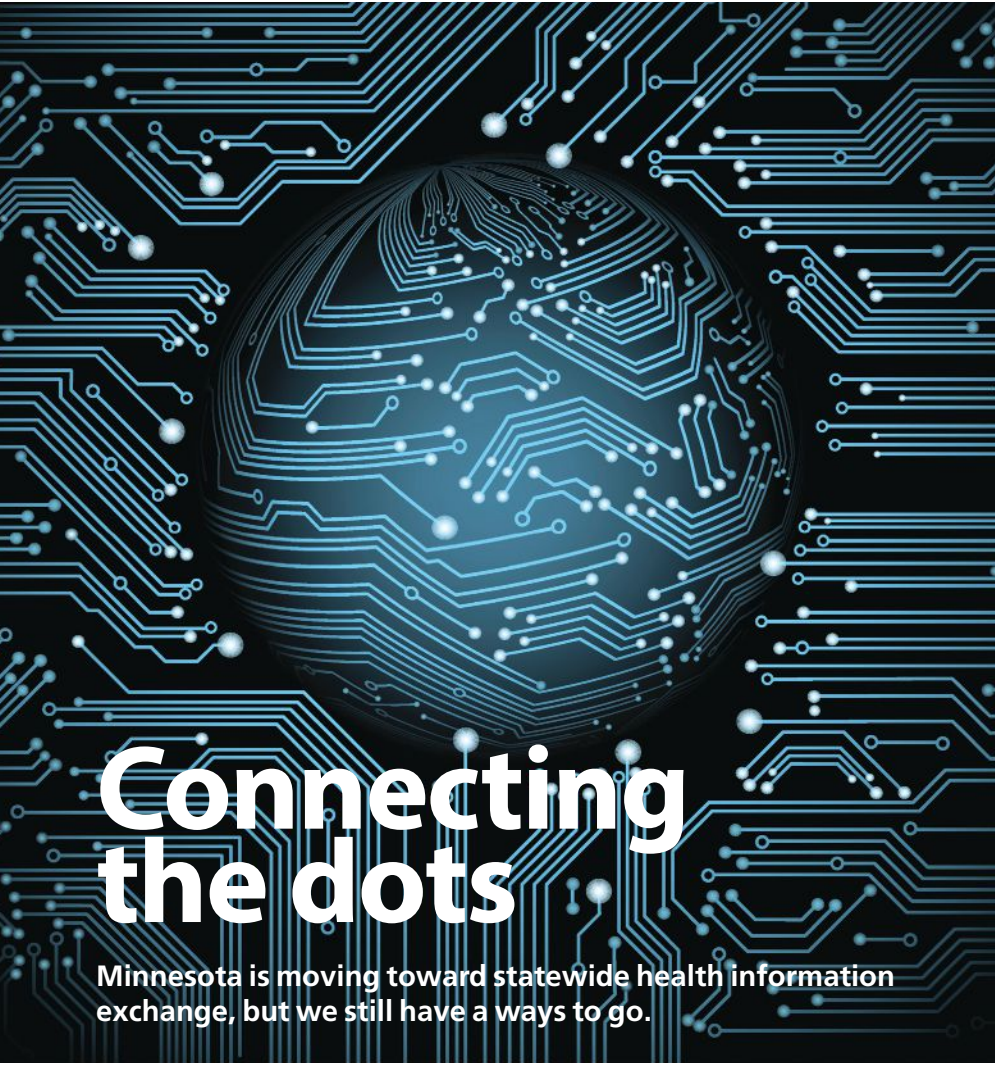
The first version of the fistula repair simulation will include three cases, which are representative of the types of cases surgeons most often see. Thus far, they have filmed procedures at hospitals in Dakar, Senegal, and Arusha, Tanzania, and are building and testing the modules developed around them. They will film the final case at Addis Ababa Fistula Hospital in Ethiopia in October.

Melchert says MSI plans to begin distributing the software (on CDs) in about a year, adding that it will be included as a supplement to the FIGO manual. “It will be free to providers in the developing world.”

Thus far, the project has been funded through private donations, and the support of fistula foundations and Stryker Corporation.

Melchert says once they complete the fistula repair simulator, the MSI team wants to make others for cleft lip repair, prostatectomy, female incontinence, cataract removal and pediatric airway management. “This will dramatically augment the current capacity,” he says. “The master surgeons who are helping author these are wildly enthusiastic about how much quicker they’ll be able to train their students.” MM

Kim Kiser is an editor for *Minnesota Medicine*.



Connecting the dots

Minnesota is moving toward statewide health information exchange, but we still have a ways to go.

BY HOWARD BELL

Minnesota has set a January 1, 2015, deadline for all hospitals and clinics to have an electronic health record (EHR) system that allows them to securely share patient information with other clinics and hospitals outside of their organization. And it looks like the state will meet that deadline in some fashion.

Already, 87 percent of clinics in Minnesota use EHRs and an estimated 90 to 95 percent of clinic-based physicians in the state work in facilities that have them, according to the Minnesota Department of Health. About 80 percent of those EHR systems are certified as “exchange-ready”—meaning they can share patient information in a way that meets state and federal requirements.

The state has created a system in which a digital hub, the Health Information Ex-

change Bridge (HIE-Bridge), will facilitate the sharing of information. Hospitals and clinics will be able to tap into it through their own EHR systems to request or receive information from others. To begin with, all information will be exchanged in a standard report called a “continuity of care document” (CCD). A CCD will include information about a patient’s immunizations, medications, medical problems, test results, allergies, care plan and insurance.

Avoiding tin-can tangle

Exchanging information through a hub is cheaper and more efficient than everyone connecting to everyone else on their own, says Clark Averill, chair of the board for the Community Health Information Collaborative (CHIC), which oversees HIE-

Bridge, and director of information technology for St. Luke’s Hospital in Duluth. With a centralized hub, he says, “you avoid thousands of point-to-point connections that create an untenable tangle of tin cans connected by strings.”

CHIC’s HIE-Bridge is already used by 11 hospitals, 63 clinics and two long-term care facilities in northeastern Minnesota. The system will be upgraded by September 30, and it will take at least another year after that to get the entire state connected, says Cheryl Stephens, Ph.D., CHIC’s president and CEO. CHIC also manages a patient consent repository (patients may opt out of allowing their health information to be exchanged).

The HIE-Bridge will be a two-lane structure, with one lane for sending out (pushing) information and the other for retrieving (pulling) information about patients. A hospital might use HIE-Bridge’s record locator to identify all the hospitals and clinics that have cared for a patient and then send them (push) all a secure electronic message about that patient. Or if a patient is admitted to the emergency department, the hospital could use HIE-Bridge to identify others who treated the patient and request (pull) information going back as far as five years. The information can be imported into the patient’s EHR if the system has that capability or attached to the record if it doesn’t.

RSVP

CHIC has invited all Minnesota hospitals and clinics to subscribe to HIE-Bridge. So far, sign-up has been slow. HealthPartners’ chief information officer Alan Abramson, Ph.D., thinks his organization and others will eventually subscribe partly because HIE-Bridge is currently the only full-service HIE service provider.

Most Twin Cities-area health systems are in no hurry to sign up for a couple of reasons. “The fees charged to connect to HIE-Bridge are an issue,” Abramson says. “And we’re already exchanging a CCD level of patient information electronically with nearly all users of EPIC EHR software.” EPIC users in the metro area have been exchanging patient information for

PHOTO BY VLADGRINISTOCKPHOTO/THINKSTOCK

a few years using EPIC's CareEverywhere software. Abramson says by the end of 2013 HealthPartners hopes to exchange information with non-EPIC users using its CareElsewhere software. "Everyone's kind of waiting for someone else to go first with CHIC because the more subscribers you have, the less expensive it is for everybody," he says. Meanwhile, EPIC users see little

"[With a centralized hub] you avoid thousands of point-to-point connections that create an untenable tangle of tin cans connected by strings."

— CLARK AVERILL

need to subscribe to HIE-Bridge, as it largely duplicates what they're already doing.

But the 2015 mandate requires subscribing to an HIE service provider. "The goal," says Stephens, "is to not have silos of patient information, but to have seamless push and pull exchange among all providers."

That will mean bringing together separate efforts in geographic pockets around the state, according to Abramson. "You've got CHIC in the northeast, EPIC users in the metro area and Mayo's Beacon network in the southeast."

Beacon is a network of hospitals, clinics, schools and public health departments in 11 southeastern Minnesota counties that

The HIE infrastructure

The Duluth-based Community Health Information Collaborative (CHIC) is the organization designated to oversee construction and operation of the infrastructure for exchanging health information electronically in Minnesota. Its HIE-Bridge platform might be considered the state's main highway. HIE-Bridge is connected to the national network called eHealth Exchange.

Three health data intermediaries (HDI) will soon be connected to HIE Bridge. Surescripts, primarily used for e-prescribing, now also offers push and query exchange capabilities. Likewise, Emdeon, which has been used for lab transactions and e-prescribing, now also offers push and query messaging. ApeniMED offers push messaging. A clinic or hospital that subscribes to an HDI will connect indirectly to CHIC's HIE-Bridge.

Initially, Minnesota clinics and hospitals will exchange information using continuity of care documents (CCDs). Like cars on a highway, CCDs are the vehicles for conveying patient information.—H.B.



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are exchanging asthma action plans for children. CHIC's role would be to link these regional exchanges to the statewide network, Abramson says, "which is probably the direction we're headed."

Miles to go

A number of hospitals and clinics are on track to meet many of the 2015 interoperability goals, according to Jennifer Fritz, deputy director of the Minnesota Department of Health's Office of Health Information Technology. And many are well into meeting federal meaningful use Stage 2 requirements that include exchange of patient information with providers outside their system. But technical and cost hurdles remain.

Vendors are still scrambling to upgrade some clients' EHRs so they can exchange CCDs. "Many providers don't realize they can't export a CCD until they connect to HIE-Bridge," Stephens says.

And exchange needs to become simpler for users, according to Averill. "The ultimate goal is seamless, purely electronic exchange of patient information where data is automatically placed in the patient's record without interrupting EHR workflow," he says. "Right now, we've got manual electronic exchange, where you can send and receive CCDs, but you need a middle step of manual intervention to get the data into a patient record."

Getting physicians up to speed on using EHRs has been another challenge, one which Paul Kleeberg, M.D., has been deal-

ing with as clinical director for Minnesota's federally funded Regional Extension Assistance Center for Health Information Technology (REACH). REACH's field staff have spent the past three and a half years helping mostly smaller clinics and hospitals implement EHR systems and achieve meaningful use. Abramson says he frequently gets "blow-back" from frustrated physicians. "What I hear is 'Why can't you IT guys just make this happen? Why does it have to be so hard?' These are big, complex systems that take hours of time to get comfortable with using—and now we're adding exchange, another thing for physicians to learn. It's especially frustrating for physicians when they have to leave their EHR workflow to send or receive summaries of care that are just a bare-bones snapshot



National exchange coming

Minnesota clinics and hospitals that subscribe to the state's health information exchange network will eventually be able to connect to a nationwide exchange.

The eHealth Exchange will allow Minnesota providers to electronically share patient information with providers in other states, according to Cheryl Stephens, Ph.D., president and CEO of the Duluth-based Community Health Information Collaborative (CHIC), which is guiding the state's efforts related to health information exchange. "It'll enhance the quality of care for Minnesotans who winter in the South and then return to Minnesota," she says. "Providers in each state are kept abreast of any changes in the patient's health status."

A Minnesota physician searching for information about a patient will be able to send a query through Minnesota's health information exchange to providers around the country who either subscribe to the eHealth Exchange or indirectly access it through their state exchange. There currently are no plans to charge for this, although that could change, Stephens says.

The eHealth Exchange has 41 subscribers that include large medical centers, state health information exchanges and federal agencies. Altogether, those entities represent more than 30,000 users, more than 65 million people and more than 1 million shared patient records.

Minnesota clinics and hospitals will be able to use the nationwide exchange to share patient records with federal agencies including the Centers for Medicare and Medicaid Services, the Department of Defense, the Social Security Administration and the Veterans Affairs (VA) Department. Being able to exchange information with the Department of Defense and the VA will allow physicians in the community to combine into one record the care received by patients who transition from active duty to veteran status. It will also greatly reduce processing time for Social Security Disability claims.—H.B.

that's helpful but not nearly as helpful as the patient's full record."

Even Kleeberg says that "as a physician, exchange will be more meaningful to me when it's easier—when it just happens." Until then, he says, some will continue to fax information.

Perhaps the biggest challenge is making electronic information exchange affordable. "Exchanging patient information with CCDs cost about 8 cents per patient per month when we began this a few months ago," Abramson says. "To cover all Minnesota residents, that works out to roughly \$5 million per year, which seems an unsustainable burden. We need to get that cost down to a couple of cents patient per month."

That would require two things: a critical mass of subscribers to a statewide HIE system (currently HIE-Bridge), which would spread out the operating cost, and major government contributions. Connecticut is experimenting with a tax on

each medical insurance claim processed to defray the cost of exchange. "I wouldn't be surprised if our group starts working on financially sustainable ways to support clinical exchange," says Abramson, who co-chairs the HIE Workgroup for Minnesota's e-Health Advisory Committee.

Until now, there hasn't been a business reason for physicians to participate in HIE, says Kleeberg. But that's changing with the emergence of medical homes and accountable care organizations, in which physicians receive bonuses for providing care to a population of patients at a cost that is lower than projected and still meet quality benchmarks. "These require information exchange amongst everyone caring for the patient," Kleeberg says, "so that care can be coordinated and costs controlled by avoiding duplication. It can also assure patients don't fall through the cracks and end up costing money for care that could have been avoided or that the patient may not even need."

Averill believes statewide HIE eventually will be "very routine." But when the January 2015 deadline for interoperable exchange rolls around, he predicts not all EHRs will be talking to each other seamlessly. "It will still take a person doing something to make the electronic exchange work," he says, "similar to the step required to check email. All exchange won't happen within a physician's routine EHR workflow."

Meanwhile, mandates, money and the quest for quality will motivate physicians to forge ahead with exchange across different health systems and EHRs. "Interoperability," says Averill, "has become critical to providing the best care." MM

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



continuing education

Managing Life Limiting Illness and End of Life Care (two-day event)	October 1 and October 3, 2013
Primary Care Update: Pathways to Knowledge	October 10-11, 2013
<ul style="list-style-type: none"> ▪ Customized learning with over 50 breakout sessions ▪ Lunchtime Learning ▪ Advanced Cardiac Life Support – Recertification ▪ Basic Life Support for Health Care Providers – Recertification ▪ ABFM SAM Study Group Session ▪ ABIM Maintenance of Certification Learning Sessions 	
Fundamental Critical Care Support	October 24-25, 2013
Simulation Facilitator Course	November 6-8, 2013
Pediatric Fundamental Critical Care Support	November 14-15, 2013
35th Annual Cardiovascular Conference: Current Concepts and Advancements in Cardiovascular Disease	December 12-13, 2013



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PHOTOS BY SARAH T. WILLIAMS

glasses and striped socks), he tells them: “It’s not optional anymore.”

Timimi, program director for the Mayo Clinic’s Advanced Heart Failure and Transplant Cardiology Fellowship Program, also serves as medical director for the institution’s three-year-old Center for Social Media—a second calling for the cardiologist, who specializes in treating patients with advanced heart disease. Officially, he devotes approximately 10 percent of his time to bringing social media tools to life for practitioners, patients and caregivers nationwide. Unofficially, he admits he invests much more of his own time in the endeavor, “because I like it.”

His job, along with that of Director Lee Aase and 10 other full-time staff members at the center, is to get every employee at Mayo Clinic up to speed on making effective use of such tools as blogs, Twitter, Facebook, YouTube, Pinterest and LinkedIn. That includes providing guidelines and training for current employees and orientation for new ones.

Some of the training is practical: How do you open a Twitter account? How do you film, edit and embed a video? How do you govern your privacy settings? How do you monitor your social network channels effectively? Which tool is best for reaching a certain demographic or accomplishing a certain goal?

And some covers legal principles and best practices: How do we separate the professional from the personal? How do we protect patient information and proprietary business information? What kinds of statements by employees posted on social media sites are protected under the National Labor Relations Act?

“We want to make sure [employees’] behavior online is professional, appropriate, and represents themselves and their institution correctly,” Timimi says. “We also want them to have a degree of comprehension and some competence with the tools. So when specific opportunities arise for them to engage with specific patients or explore research or educational opportunities, they’ll understand how to pursue that.”

facebook friend

Mayo Clinic’s Farris Timimi is on a mission to bring the social media revolution to medicine.

BY SARAH T. WILLIAMS

Farris Timimi, M.D., has heard all the reasons why medical professionals are reluctant to use social networking tools as part of their daily practice: “I don’t have the time.” “I’m worried about HIPAA

violations.” “I don’t want to lose control of the conversation.”

In a firm but nonscary way (enhanced by the fact that he wears neon-colored eye-

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Timimi got his start on social media as so many do—by using Facebook to reconnect with old friends. For those of his professional colleagues who are reluctant or worried or doubtful, Timimi cites some compelling facts about U.S. adults (mostly from recent Pew Research Center studies) in order to convince them of the growing

acceptance of social media and the importance of getting involved in it:

- 85 percent use the Internet
- 72 percent are social network site users
- Roughly one in four minutes of their time online is spent on social media sites
- Looking for health-related information is their third most common online

activity (after checking email and using search engines).

“Our patients are there waiting for us,” Timimi says. “So it becomes a moral imperative that we put content in their path, that we walk with them on their journey through illness to recovery, be it online or offline.”

A very high ROI

Although not everyone is comfortable diving in, Timimi is undeterred. And he delights in witnessing colleagues experience their own “aha” social media moments. One such moment came in 2012, after Facebook devised a way for its users to show their organ donor status on their profiles. The change drove up donor registrations, which made headlines. Mayo’s Center for Social Media seized the opportunity to have one of its esteemed transplant cardiologists, Brooks Edwards, M.D., do a Twitter chat and a YouTube video about the importance of becoming an organ donor.

It was Edwards’ first foray into social networking. “He’s not a Luddite, but he’s not far from it,” Timimi says affectionately. “This is not something he would think of doing on his own.”

The Twitter analytics were persuasive: 294 contributors made 952 tweets in eight days after the hour-long chat took place, reaching 3,423,537 separate accounts. Edwards “was shocked at how many lives he was able to touch with what in essence became an investment on his part of an hour and a half of his time,” Timimi says. “It was a compelling argument for how many people you can potentially reach ... with a tool that is so profoundly archived and scalable. I mean the conversation has no geographic limitation at all.”

Edwards has since filmed more YouTube videos and now has his own Twitter account, which he uses to pass on heart-healthy tips and words of encouragement: “I’ve walked 13,630 steps today!” he posted recently, along with a link to Fitbit.

Timimi recalls another aha moment from 2009, a few years after Richard Berger, M.D., a Mayo hand surgeon, pioneered a treatment for the wrist injury that



Words to the wise

Farris Timimi, M.D., whose two young children (ages 5 and 7) have inspired him to hone his rhyming skills, lives by this simple, nearly self-explanatory 12-word social media policy:

- Don’t Lie, Don’t Pry
- Don’t Cheat, Can’t Delete
- Don’t Steal, Don’t Reveal

Here are some of his other suggestions about using social media:

- Don’t endorse as a matter of course.
- Supervisors: Don’t initiate an employee friend request at your own behest.
- Separate your circle of friends from the patients you mend. (He uses a criteria he calls “the bread test.” “If I break bread with someone, I’ll friend them on Facebook.” But beyond that, he would advise providers not to friend patients. I think it creates a disquieting exposure that is difficult to effectively control.”)
- Corporate logo in your user name is a no go.
- Adding a disclaimer is probably saner.
- Don’t practice on the Internet, regardless of your good intent.
- Always surmise that HIPAA applies.
- Speak on your behalf, not that of staff.
- Anonymity is really gimmicky.
- If you chat about your company, identify abundantly.

nearly ended the career of Los Angeles Dodgers outfielder Jayson Werth. Dozens of media outlets picked up the story after Berger successfully repaired the “split tear” in Werth’s ulnotriquetal ligament (an injury that resembles “a tear in a stalk of celery” that is often missed by MRIs, Timimi explains).

The story might have ended happily enough with Werth resuming his red-hot career. But a follow-up Twitter chat with Berger, co-hosted by Mayo and *USA Today*, gave it a second chapter. It so happened that a Baltimore woman, whose daughter had been plagued for years by wrist pain, was monitoring the chat. She alerted her daughter, Erin Turner, who was poised to have surgery to immobilize her wrist. “She was going to trade a lifetime of pain for a lifetime of disability,” Timimi says.

Based on what she learned during the Twitter chat, Turner got a second opinion at Mayo and had successful surgery to repair the tear. “That’s a patient whose

life was changed in a positive way because she learned something on Twitter,” Timimi says.

The cost of silence

There are good reasons why it’s no longer an option for physicians to opt out of social media networking, Timimi says. The silence, he says, creates a void that can hurt their reputations and, worse, put whole populations at risk.

“Vaccine hesitancy” is a good example, he says, citing the 2011 pediatric measles outbreak in France and other areas where MMR vaccine penetration is low.

“There are 60,000 members of the American Academy of Pediatrics. If each one of them once a week put out one blog post, one YouTube video, one Facebook post, who becomes the moral authority on this issue? Us or Jenny McCarthy? I think our hesitancy has catastrophic impact. It truly does,” he says.

Physicians risk their own reputations if they don’t participate, he says, explaining

that he regularly meets physicians who are upset about a Healthgrades comment or something someone said about them on Yelp or Rate My Doctor. “What we found is if those physicians will open a Twitter account, do a YouTube video, tweet on occasion, and populate a LinkedIn profile, within a few weeks all that [negative] content drops to page 2. And nobody goes to page 2; that’s the hinterlands. For those providers, their digital silence allows someone else to populate their digital avatar.”

Timimi believes social media is simply an extension of what used to be a one-way conversation, from providers to patients. “Transparency is powerful,” he says. “It’s scary at first, but once you get over the fear, the value of bi-directional conversations is truly breathtaking.” **MM**

Sarah T. Williams is a longtime Twin Cities journalist.

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BY SUZY FRISCH

WHAT A DIFFERENCE AN APP CAN MAKE.

When staff from Mayo Clinic's pediatrics clinic used to mail questionnaires to teenaged patients asking them to assess the state of their asthma, it often took weeks for them to respond, if they bothered. And getting them to return a phone call? Forget it.

But when 25 teenagers received the same questionnaire via the new Asthma Connected Care app developed by internal medicine physician Rajeev Chaudhry, M.D., and others from Mayo's Center for Innovation, the majority responded within four hours—some even within 10 minutes. Not only did the teens use the app to answer questions about their asthma, they used it to watch videos showing proper use of an inhaler, find out about common allergens, and, if an asthma attack was looming, to quickly look up their individual action plan instead of calling their doctor in a panic or rushing to the emergency room.

"We know that the traditional way to get care is to either come to the clinic or call someone," Chaudhry says. "Why not use your smartphone to manage your disease and connect with your care team?"

After nine months, 68 percent of users reported the app helped them control their asthma. "We need larger studies going forward. But what we're seeing is promising," he says, adding that Mayo plans to develop similar apps for other chronic conditions.

MEDICAL APPS ON THE RISE

Roughly 97,000 health-related apps were available for smartphones and tablets as of the spring of 2013, according to a report by the market research firm Research2Guidance. Most of those are designed to help people improve their health or stay healthy by tracking their exercise or eating habits, reminding them to take their medications, or providing information about conditions and diseases.

But apps like Mayo's for asthma that allow physicians to interact with or

diagnose patients are starting to appear as well. In April, a Johns Hopkins University medical student made headlines at the TEDMED conference on medical innovation by doing a "smartphone physical," using 10 apps that turned his smartphone into a medical device. The apps included one for doing an EKG, one that turned the phone into a pulse oximeter and one that enabled ultrasound imaging of the carotid arteries. Former Cleveland Clinic cardiologist Eric Topol, M.D., captured the public's attention when he used the CellScope app on his smartphone to examine television host Stephen Colbert's ear during an interview about Topol's book *The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care*. Topol, who is now with Scripps Health in San Diego, believes smartphones will become an integral part of medicine in the future. "These days I'm prescribing a lot more apps than medications," he said in

“WE KNOW THAT THE TRADITIONAL WAY TO GET CARE IS TO EITHER COME TO THE CLINIC OR CALL SOMEONE. WHY NOT USE YOUR SMARTPHONE TO MANAGE YOUR DISEASE AND CONNECT WITH YOUR CARE TEAM?”

RAJEEV CHAUDHRY, M.D.



an NBC News interview earlier this year. “This is a powerful device.”

Most physicians don’t yet use apps beyond reference tools such as Epocrates and UpToDate, according to a March 2013 Kantar Media survey. But that hasn’t stopped doctors in Minnesota from designing mobile tools that help patients take better care of themselves or communicate with their doctor, or experimenting with those that turn their smartphones into medical devices. These innovators believe that apps are emerging tools that are here to stay.

With the proliferation of medical apps comes the question: Which ones are truly useful? A group of faculty, staff and students from Johns Hopkins University in

Baltimore has launched an effort to evaluate them as part of its Global mHealth (mobile health) Initiative. They currently have 49 studies taking place around the world. In addition, apps that turn phones into medical devices have been subject to approval by the U.S. Food and Drug Administration since 2011. Earlier this year, the FDA clarified that it will regulate apps used for patient care such as those for mobile ultrasound or blood pressure monitoring to ensure they work as intended. About 75 apps have received FDA approval, and the agency has said it aims to review about 20 a year.

Some recently approved apps include AliveCor, which converts a smartphone into a heart monitor and mobile echocar-

diogram device, and MobileMIM, which helps physicians share diagnostic images and consult on challenging cases. The MyVisionTrack app, which requires a prescription, enables patients with retinal diseases to scan their eyes twice a week; the test results are then uploaded to a server in the physician’s office, where they are read and recorded.

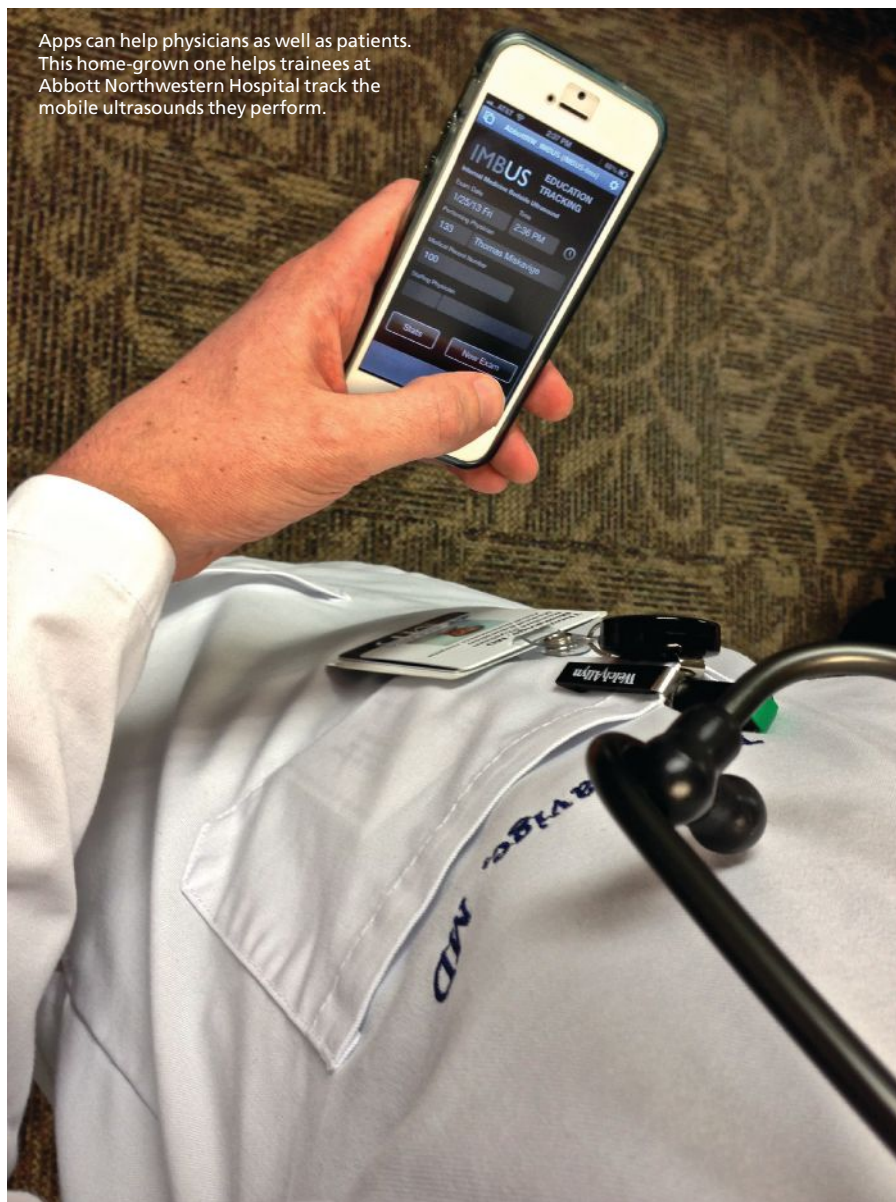
Despite concern that the regulatory approval process might bog down development, that the data gleaned from monitoring patients or that patients submit themselves may not be secure, and that spotty cell phone service in certain areas may render apps unreliable, many believe the “appification” of medicine is inevitable. That’s because apps and mobile medicine truly could improve health care, says Stephen Parente, a professor in the Carlson School of Management at the University of Minnesota who specializes in health economics. Apps could even cut costs by eliminating some office visits or preventing some emergencies.

“I do think, in the end, they will help physicians and they will help consumers, because generationally people are getting more comfortable with these mobile technologies,” Parente says. “With chronic conditions, more surveillance and reminders are better than less, and mobile can help with that. Physicians will see that mobile will help them manage patients better because they are more engaged with them. It will be a win-win eventually; but there will be skepticism as they get used to the technology.”

PARDON THE DISRUPTION

Cardiologist Robert Schwartz, M.D., medical director for education at the Minneapolis Heart Institute and Foundation at Abbott Northwestern Hospital, has gotten used to the technology—and he likes it. Schwartz is an early adopter who regularly uses apps in his practice. He is especially enthusiastic about AliveCor’s mobile heart monitor and the AliveECG app.

They’re timesavers, for one thing. When a patient is experiencing an irregular heart rhythm, Schwartz snaps the \$199 AliveCor device on his iPhone and does an electro-



Apps can help physicians as well as patients. This home-grown one helps trainees at Abbott Northwestern Hospital track the mobile ultrasounds they perform.

PHOTO COURTESY OF DAVID TIERNY

“RIGHT NOW, [THE ALIVECOR ECG APP] IS COMPLEMENTARY, BUT I THINK IT’S GOING TO BE DISRUPTIVE. **CARDIOLOGISTS WOULD NO LONGER NEED LARGE AND EXPENSIVE EQUIPMENT IN THE HOSPITAL.**”

ROBERT SCHWARTZ, M.D.



cardiogram on the spot—no need to order the test and wait 20 minutes for a technician to do it.

He thinks the technology may have a future for monitoring patients with heart palpitations. Holter monitors, which must be worn for 24 to 72 hours, are bulky and uncomfortable and, thus, are often removed before the patient experiences palpitations. Schwartz envisions one day giving patients who have an iPhone an

AliveCor case. They could clasp their phone to their chest when they feel palpitations, hit record, and it would instantly send him a report.

“It’s an excellent triage device,” Schwartz says, and one that he’s happy to have on flights in case someone is having a medical emergency and the plane lacks the right equipment. “Right now, it’s complementary, but I think it’s going to be disruptive. Cardiologists would no longer need large

and expensive equipment in the hospital. The information could be stored in the cloud, and I could conceivably get direct communication from patients anywhere in the world, immediately.”

Although insurers don’t currently pay for AliveCor electrocardiograms, Schwartz believes it and other apps ultimately will lower the cost of care by making doctors more efficient and improving quality. He points to two free apps that are already

2013 CME Activities

(All courses in the Twin Cities unless noted)

SEPTEMBER – NOVEMBER

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September 5-6, 2013

Bakken Symposium: Evaluation, Management & Long-Term Follow-up of Children with Congenital Heart Disease
September 16, 2013

Annual Minnesota Pediatric Hospital Medicine Conference
September 25, 2013

Care Across the Continuum: A Trauma & Critical Care Conference
September 27, 2013

NPHTI/Pediatric Clinical Hypnosis
October 3-5, 2013

For a full activity listing, go to www.cmecourses.umn.edu.

Twin Cities Sports Medicine
October 4-5, 2013

Maintenance of Certification in Anesthesiology (MOCA) Training
October 5, 2013

Psychiatry Review: New Directions in Diagnosis & Treatment
October 7-8, 2013

Got Your Shots? 2013 Immunization Conference
October 10-11, 2013

Transplant Immunosuppression 2013
October 16-19, 2013

Practical Dermatology
October 25-26, 2013

Pediatric Trauma Summit
November 1-2, 2013

Donald Gleason Conference on Prostate & Urologic Cancers
November 8, 2013

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November 13-15, 2013

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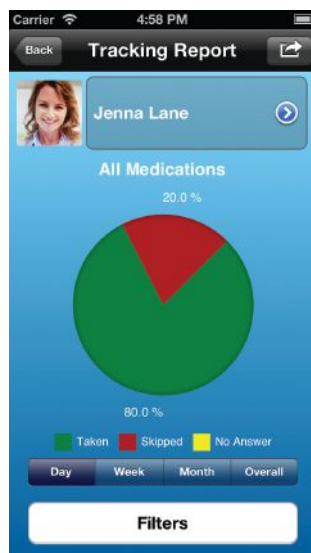
helping accomplish this—Calculate by QXMed and Skyscape, which walk physicians through complicated calculations needed for intensive-care patients and offer a compendium of best practices and the latest guidelines.

STRONGER LINKS

Physicians using Mayo’s asthma app, which garnered a silver Edison Award this spring for Innovative Services in Health Management, have found teens more willing to talk about their condition when they use text messaging. In the clinic, teens would often give one-word answers to questions or just say that things were fine, but “they’d go into all sorts of detail in a text,” Chaudhry says. The teens have noted that they like knowing there is a person on the other end of the texts. Care providers have indicated that they spend significantly less time playing phone tag to get information, which eliminates the need for appointments in some cases. And patients have reported that the app helps them remember to take their medication because it keeps their asthma top-of-mind.

“With this app, patients had easy access to their asthma action plan and, thus, were able to take care of themselves. That was very encouraging,” Chaudhry says. “We can stay connected with patients, providing care when they need it and where they need it, and not necessarily through the clinic.”

Improving communication between doctor and patient was a major reason Rajiv Shah, M.D., created an app called MyMeds. Shah sought to solve the thorny



Rajiv Shah’s MyMeds app is designed to get to the heart of medication nonadherence.

problem of medication nonadherence, which is estimated to cost the United States nearly \$300 billion a year, according to the New England Healthcare Institute. The app, which costs \$9.99 for an annual subscription, helps doctors work with patients to make sure they take the right amount of their prescribed medications at the right time and at the right frequency.

“I have a philosophy that your patients are your partners and they have a vested interest in their own health. The more you can help them with tools they control, the better,” says Shah, a nephrologist at InterMed Consultants in Edina and CEO of Minneapolis-based MyMeds Inc. “It’s really empowering for patients, and it makes for a better health care experience.”

Inspired by the Institute of Medicine report “To Err is Human,” Shah first developed a computer program in 2003. About

a year ago, he powered up the app for both Android and iPhones and tablets. It has been winning raves from pharmacists ever since. Researchers from the University of Arkansas who reviewed 160 medication adherence apps in the *Journal of the American Pharmacists Association* ranked MyMeds as one of the three most promising ones for tackling the problem.

Shah’s app addresses the major causes of nonadherence: forgetting to take the drug, forgetting to refill the drug, not having enough education/information about the purpose of the drug, cost and side effects.

Shah, who has a bachelor’s degree in psychology from Boston University, incorporated numerous principles from cognitive psychology into the app. Its WhyMeds feature strongly reiterates why patients need to take a medication, what it does (in plain English), and how it helps them stay healthy. Patients on blood pressure medication, for example, see the name of a drug, a statement that it helps control high blood pressure, and an information explaining that controlling their blood pressure will prevent strokes or kidney failure.

MyMeds also promotes adherence by looping in doctors, pharmacists, other caregivers or family members, with the patient’s permission. Pharmacists handling medication therapy management for a patient—now required by all Medicare Part D drug programs—can help monitor their prescription regimen, dosages and interactions using MyMeds.

In their review, the University of Arkansas researchers considered the app’s ability

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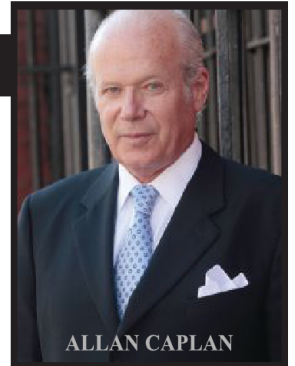
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to track the doses patients have taken—and missed—and electronically send a report to their doctor especially helpful. Those reports give physicians more detailed information when they talk to patients about why didn't take their medication. Is it the side effects? If so, they could try a different dosage or a different drug. If the patient has trouble remembering the mid-day pill, the

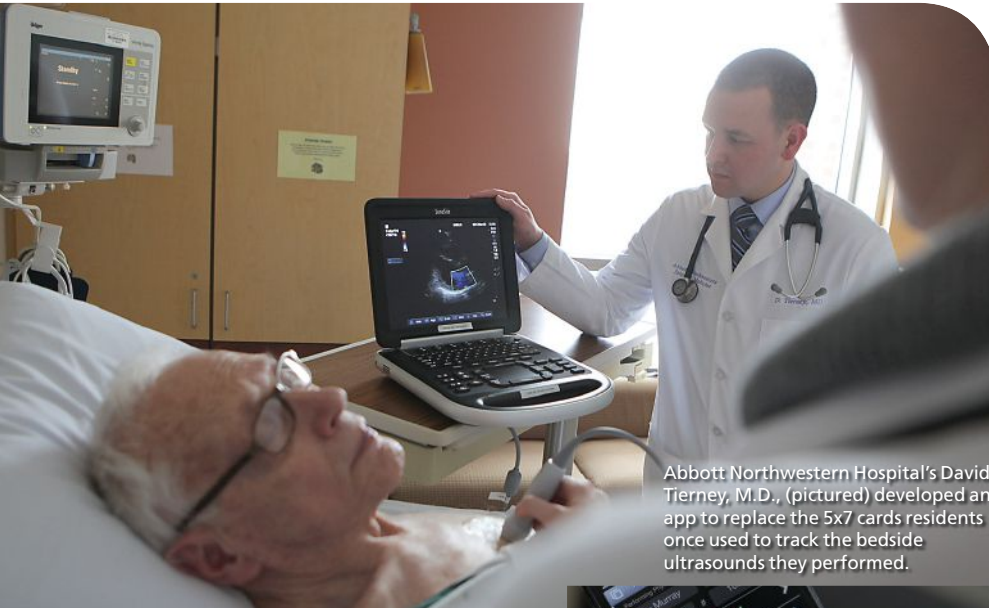
physician could switch them from a three-pill-a-day prescription to two. "It really gives you the ability to dig deeper into why they aren't adherent," Shah says.

RELATIONSHIP BUILDER

As the field of mobile medicine continues to evolve, apps may have a real effect on cost, quality and efficiency in health care.

More than anything, they may influence the physician-patient relationship. "The future will see a subset of traditional physician/patient interactions that incorporate a mobile interface," says David Tierney, M.D., assistant program director of Abbott Northwestern Hospital's internal medicine residency, who developed an app to track resident training on bedside ultrasound (see "Teaching App"). "The person-to-person relationship between physician and patient is an essential component of what we do. The question is, Can telemedicine or mobilized medicine maintain the essential personal aspects of this interaction? There has to be a balance. You can't be an internal medicine physician without being in front of patients, but there are rapidly changing expectations that will make mobile technology an important part of future interactions between health care providers and their patients." MM

Suzy Frisch is a Twin Cities freelance writer.



Abbott Northwestern Hospital's David Tierney, M.D., (pictured) developed an app to replace the 5x7 cards residents once used to track the bedside ultrasounds they performed.

TEACHING APP

SOME MEDICAL APPS HELP PHYSICIANS THEMSELVES.

One being used at Abbott Northwestern Hospital helps internal medicine residents track the exams they do in order to become certified in bedside ultrasound. Abbott started the bedside ultrasound program in 2011 and started developing the app six months in. The app has been in use for a little more than a year.

During their training, residents work on mastering a range of bedside ultrasound exam skills. To get credentialed, they must perform exams in more than 50 areas and document each one.

The method they were using to do that was decidedly old-fashioned. Residents had to jot down information about each exam they did on a 5x7 note card. That is, if they had time, if they remembered, and if they had the cards on hand. That wasn't always happening. David Tierney, M.D., assistant program director of Abbott's internal medicine residency and director of its Internal Medicine Bedside UltraSound (IMBUS) program, thought there had to be a better way. With all of their residents carrying smartphones as pagers, he thought, why not use them to keep track of residents' progress in learning bedside ultrasound? Teaming with a local developer, he created the IMBUS app.

"We came up with an interface that was quick for them to use and that is auto-populated with the user, date and time," he says. With just a few clicks, the physician enters information about the ultrasound exam they just performed.



The ultrasound images and physician interpretation are then sent wirelessly to a central server, where Tierney can review the individual exam findings to see whether a resident is properly obtaining and interpreting ultrasound images. The app then updates the resident's progress using color-coded bars. If, for example, the resident needs to do a minimum of 20 liver exams to be eligible for credentialing and they have completed eight, the bar code for that category shows red. If they have done 20, it's yellow, and once they are felt to be competent in the technical and interpretation aspects of the exam, the bar turns green. At that point, the resident no longer needs to have a credentialed faculty member with him or her when doing bedside ultrasounds in that area. Tierney says the app makes getting credentialed simpler and faster for all involved. And as more physicians become credentialed in using bedside ultrasound, patients will ultimately benefit.

"Bedside ultrasound will help internal medicine physicians take better care of patients; but it takes a significant amount of time to safely and rigorously train physicians in this new technology. The IMBUS app has made one piece of that training process more efficient, which means a little more time for physicians to spend with their patients."—S.F.



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Kirk and Marianne Bernadino with their sons Sam and Frank.

PHOTO COURTESY OF MARIANNE BERNADINO

Honorary M.D.

A birth, a near-death experience and an unusual graduation ceremony.

BY MARIANNE BERNADINO, M.D.

Around the time I turned 30, I asked myself, What would I want to accomplish if I knew I had only 10 years to live? I knew the answer was, Go to medical school. Despite my best efforts, I had been unable to shake the draw toward medicine ever since watching Alan Alda play Capt. Benjamin Franklin “Hawkeye” Pierce in an especially poignant episode of “M*A*S*H.” The question launched three years of prerequisites, MCAT preparation and interviewing. I met my future husband, Kirk, a practicing gastroenterologist, weeks after

being accepted. He was thrilled with my career goal and shared my desire to have a family. We were married in our Minneapolis home after my first year of medical school and welcomed Sam into the family at the end of year two. By the end of my fourth year, we were anticipating the arrival of another son.

Even as we planned for the future, I found myself preoccupied with the possibility of my premature death. I had a sense of vulnerability, an awareness that our lives could change in an instant. Perhaps

this was due in part to the tragic drowning of an adolescent boy near our home. His body washed out into the lake from a local swimming hole, and the rescue and recovery efforts unfolded outside our back door. Or it may have been the result of watching as a 500-year flood made ribbons out of roads and washed away things I had considered to be permanent.

Regardless of the reason, at my insistence, we completed our wills and advance directives one month prior to Frank’s birth. I counseled my husband on my last wishes and provided him with unsolicited advice on whom to date and marry. I ordered our 2-year-old son his fall and winter wardrobe and told my husband that if I were to die, I would want him to approach the medical school about giving me an honorary M.D. I reasoned that my 12 years as a social worker should make up for the eight weeks of electives I hadn’t completed. I reflected on my personal readiness for death and felt that for the first time in my life, I would be at peace.

Waking

On a Thursday afternoon, I am climbing up through a fog of confusion. Slivers of harsh light crack through the cover of darkness. I am waking up in the wrong place. I try to go back, to re-emerge at home. I listen for the lake and can almost hear the rolling waves gently brushing the beach. I look for the sky-blue walls of our bedroom and the worn edges of our white duvet. I look for my husband and children, but they are not here. I am alone.

As the fog begins to break up, I hear a phone ringing and will it to stop. I catch a glimpse of a trauma surgeon I know and think that I have inserted him into my dream. Why else would he be here? But it is not a dream, it is too real for that. It is some kind of coma. If it is my coma, I reason, then I should be able to control it. I consider everything I see, hear and feel as support for my theory that this new reality may still be escapable. I reach to pull at something on my face and find my wrists are in restraints. My foot finds something firm, and I push against it as hard as I can.

As I continue to wake up, I find my mother is at my bedside. She tells me

Frank is OK, and I recall with difficulty that I was pregnant. It seems so long ago. Then things come back to me slowly, the first glimpse of Frank over the surgical drape and the nurse telling me he looks good. Then there is nothing. The trail ends. My mother explains something about a bowel resection, and I tell her I have seen many. I have no idea what that has to do with me. I think she also is part of the dream and wait for Kirk to come.

I see him walk into the room, but when I turn to him he is gone. He comes over and over but is never there. I close my eyes and feel the bed tipping backwards. I am being pulled down eight stories to a hospital atrium. My bed is turned so I can see the lake. It is beautiful here. But this isn't real and goes away.

I realize that I am having hallucinations, but I can't make them stop. I decide it is better to go with them rather than to fight them. I look out over the lake and see hundreds of people in a park. They are walking toward the hospital. I also see that I am there with my husband and our children, except that our kids are older, school-aged. We have our bikes and we are happy. I see myself very clearly, and my future self sees me. We look at each other. I am in both places. My family is all together. Everything will be OK.

Eventually, Kirk arrives with the infant carrier in one hand and the diaper bag slung over his shoulder. He sets them down, and in his face I see relief. I tell him that something is horribly wrong, and he tries to explain what happened. I can't believe that he intends for me to stay here. I wonder if he is real. He begins quizzing me on things that only he and I would know. He asks me about my board scores, the paint colors we recently chose and the pair of condors we spotted while hiking in the Andes the day before he proposed—a blessing on our union. Somehow he reaches me and I begin to trust him. He tells me that my bowel was injured during the cesarean section and that I almost died. I think he is exaggerating, but then he tells me that I went into septic shock and had emergency surgery, during which I had several episodes when I was pulse-

less and needed chest compressions. I have been on a ventilator for five days.

He tells me about everyone who has visited, the people who are praying for me and what a miracle it is that I survived. As he finishes, a small cry emerges from where the infant carrier rests. I watch with curiosity as Kirk reaches in, lifts up the

Even as we planned for the future, I found myself preoccupied with the possibility of my premature death. I had a sense of vulnerability, an awareness that our lives could change in an instant.

baby and proudly reintroduces me to our son. Frank looks just like his brother.

Healing

The first weeks are incredibly hard. I am jealous of every person who walks into my room and walks back out. They have jobs and go home to their families. I wonder what is left for me. With the help of therapists, I regain the strength to sit, stand and walk. I take pride when I am able to do a lap around the unit and quickly advance to two. I transition from a walker to a cane. The nurses cheer me on, and I dream of the day when I will be able to care for my children. After two and a half weeks, I am discharged to home. I continue to get stronger, and with the help of family and friends, gently ease back into motherhood.

With time, I regain my energy, interview for residencies and complete my remaining rotations. On March 15, I am thrilled to learn that I have matched into psychiatry at the University of Minnesota. Still, I worry about the possibility that my patients might be injured as a result of my care. I wonder how I will cope with being on the other side of harm.

Graduating

The day before my graduation ceremony, a massive blizzard moves through Iowa and southern Minnesota. When my dad calls to tell me he and my mother will not be able to come because of the weather, I am both relieved that they will be safe and

disappointed. I call the rest of my family and tell them not to come as well.

Outside a small town in central Iowa, my sister is driving to a doctor's appointment. She slides on an icy bridge and veers into an oncoming vehicle. Although she and her 2-year-old son escape with relatively minor injuries, the driver of the

other car does not survive. I feel a deep sense of loss for his family; I worry about the emotional impact on my sister. The accident fuels my fear over the many ways in which harm can happen.

That night, my 3-year-old develops a high fever and is the sickest we have ever seen him. It becomes apparent that Kirk will need to stay home with Sam the next day. I decide that I need to be with my family and notify the school that I am unable to attend the ceremony. There is something about graduation that I am dreading anyway. It no longer feels relevant.

Kirk and I begin hatching a plan for a mock ceremony in our home. He will welcome me into the profession, I will read the oath, Sam will honor me with his Fisher Price stethoscope and Frank will be a witness. The school graciously agrees to loan me an academic hood for this makeshift event. I will be hooded in the place where we exchanged our wedding vows nearly four years earlier.

The day of graduation, Kirk is practicing a buoyant rendition of his commencement speech to Frank's squeals of approval. As I eavesdrop on his rehearsal, he congratulates "the class of 2013" on their accomplishments including surviving after being brought to the brink of death. He reassures the class that their ability to face adversity—and be made stronger by it—will serve them well in their careers. ●

As the real class of 2013 gathers for a group photo at the State Theater in Minneapolis, I am carrying Sam around our pediatrician's waiting room in an effort to distract him. I stop to glance at the photos of the physicians in the practice. Sam asks me where my picture is, and I tell him that I'm not a doctor yet.

Despite a temperature of 104.8, Sam seems OK, and I leave the clinic thankful for our pediatrician, who took a break from his lunch to see us. From the doctor's office, we make our way toward the theater to pick up my hood. I arrive in the lobby as the last of my classmates heads down the aisle to "Pomp and Circumstance." One of the event organizers leads me down a side corridor that opens onto stage right, where I wait while he goes in search of the hood they have reserved. From here, I can see the faces of my 220 classmates. I am hit by a wave of sadness that I am not standing with this tremendous group of people. But something seems familiar about the scene. It occurs to me that it is exactly how I imagined my graduation: that I would be there, but

not really. The event organizer hands me the hood. I thank him and make my way back to the rear of the theater. As I cross the lobby, I hear the opening speaker say that graduating from medical school makes you a member of a special group. I walk out into the rain where my husband and sleeping children are waiting in the car.

We go home and tuck Sam in bed. Kirk lays down to rest. As I am cleaning, I turn to find that Frank has just pulled himself to standing for the first time. I am shocked that he is doing this just a week after starting to sit and crawl. I exclaim in excitement for him and he smiles from ear to ear. I contemplate all of the milestones that he will have in his life and anticipate the joy of watching him grow and develop.

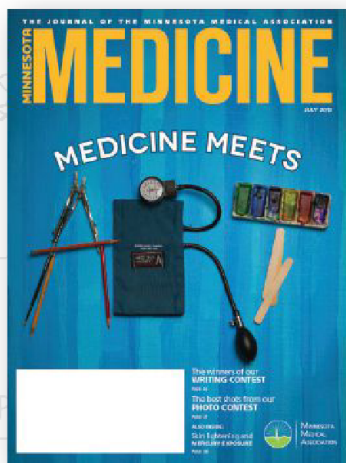
It occurs to me that medical school was not the end after all but the beginning of the next phase in my journey. I consider the years of training that prepared the nurses and doctors who saved my life, and I am incredibly grateful for their dedication. I admire the courage of the people

who critically examined the sequence of events that led up to me coding and their commitment to creating a safer system of care. I recognize that in medicine the potential for harm will always exist but that if I am overwhelmed by this, I will not be able to function as a healer.

As I applaud Frank for his big accomplishment, he waves his arms wildly and then flings his body backwards. He hits the floor hard and wails with shock and anger. I scoop him up, simultaneously bouncing, patting and rubbing. I tell him that it's OK, that these things happen. He blinks at me through his tears. It gets easier, I reassure him. Standing. It gets easier. **MM**

Marianne Bernadino is a resident in psychiatry at the University of Minnesota.

This essay received honorable mention in *Minnesota Medicine's* writing contest. It is dedicated in fond memory to Dr. Ted Thompson, director of clinical education at the University of Minnesota Medical School, in appreciation of his wisdom and encouragement.



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2013 ANNUAL MEETING PREVIEW

Is there life after the House of Delegates?

BY DAN HAUSER

Maine did it in 2003. Oregon did it last year. Is Minnesota next in line? The “it” refers to dissolving the state medical association’s House of Delegates (HOD). It’s a thorny topic, and passions run high on both sides of the debate whether it’s in Oregon, Maine, Minnesota or a half dozen other states where medical associations are currently considering such a change.

Each organization is trying to find ways to stay relevant to members. And although they have approached that goal from different angles, they are reaching a similar conclusion—in order to attract a younger, more diverse membership, they need to embrace new strategies to get input from a majority of the membership.

In Minnesota, the HOD, the Board of Trustees and a handful of members

have been debating governance for the past three years. Some conclusion should be reached on September 21 at the 2013 MMA Annual Meeting in Brooklyn Park,

Some organizations are doing away with mechanisms like the House of Delegates, in which a small percentage of members elect officials and make policy, and embracing new strategies to get input from a majority of the membership.

when the House votes on whether it will replace itself with a policy council that will meet at least two times a year (one being at an all-member annual meeting).

Those opposed to dissolution recognize that the HOD is not working optimally but contend it just needs to be strengthened and improved.

Proponents argue that the HOD is beyond repair. They point to participation, which has been decreasing over the past decade, and note that those who do participate are getting older and don’t accurately reflect the diversity of the MMA’s membership.

These are all familiar refrains to leaders from other state associations. The Oregon Medical Association (OMA) began examining its governance five years ago. As OMA leaders traveled around their state,

2013 ANNUAL MEETING PREVIEW

they found that 24 out of 36 counties had no functioning county medical society to elect delegates. They heard from members, time and time again, that the House was a barrier to participation; it was unappealing to members.

They ended up overhauling the OMA bylaws and establishing the OMA Board of Trustees as the policy-making body. This decision resulted in an opportunity to review and set policy more than once a year and the transformation of what used to be the House gathering into a general meeting for all members.

“With strong physician leaders at the helm, supported by committed board members from across the state, the Oregon Medical Association took on the challenge to change its governance structure in order to do what’s in the best interest of the organization—ensure we remain relevant,” says Joanne Bryson, executive vice president and CEO of OMA.

The Maine Medical Association did away with its House of Delegates in 2003 and replaced it with a general membership meeting held once a year. “The reaction to the change has been overwhelmingly favorable and our attendance at the meeting has improved,” says Gordon Smith, executive vice president. “We can still consider resolutions at the meeting, but since 2012 the resolutions are advisory only to our 25-member board of directors.”

In addition to Minnesota, state medical associations in California, Pennsylvania, Tennessee, Virginia, Washington, Kansas and Ohio are also debating whether to dissolve their House of Delegates.

If the HOD does vote itself out of existence, it does not necessarily mean it’s gone for good, however. If the new governance structure is adopted, the MMA will create a formal process to review whether the change is working. The process would result in a report being presented within three years to the Board of Trustees.

Hearing all voices

While most of the focus (and debate) has been around the possible dissolution of the MMA’s House of Delegates, there’s another issue in play—whether to open up the election of MMA leaders to all members.

Currently, only delegates are allowed to vote for president, board members and AMA delegates. With the number of delegates decreasing over the past decade, fewer and fewer members have had a hand in deciding MMA leadership. Thus, it has been proposed that the MMA implement an electronic process so that all members can vote for these positions.

If the measure passes, the MMA will create a nominating committee that will review and vet candidates. During each election cycle, Component Medical Societies (CMSs) will be able to nominate one candidate for trustee, consistent with the requirements of the MMA bylaws and the principles/guidelines adopted by the MMA board. All nominations must be received prior to the review of all candidates by the committee.

The nominating committee also may nominate one or more additional candidates for each available office.

In addition, the MMA’s Leadership Effectiveness and Development committee will create campaign guidelines addressing:

- Candidate distribution of information regarding their candidacy, credentials and reason(s) for running for office
- How candidates will be labeled on the ballot
- Distribution of email addresses for candidate use

If approved, the first all-member electronic elections will take place in the fall of 2014.

PHOTO BY STEVE WEWERKA



Governance changes in a nutshell

- Reduce the size of the Board of Trustees from 33 to 12 to 14 (approved in 2012; full implementation by 2015)
- Hold policy forums on timely issues across the state (approved and in progress)
- Use listening sessions to hear from members in all settings (approved and in progress)
- Dissolve the House of Delegates and replace it with an all-member annual meeting to discuss policy
- Create a 40-member Policy Council to advise the Board of Trustees
- Implement electronic all-member elections of president, trustees and AMA delegates

2013 ANNUAL MEETING PREVIEW



PHOTO BY STEVE WEWERKA

House and its procedures. The MMA Board of Trustees, on the other hand, has put forth a resolution that recommends dissolving the House.

Governance is not the only topic to be considered, though. Others include:

- The future of several CMSs. Park Region Medical Society, East Central Minnesota Medical Society and Mower County Medical Society have proposed dissolving. Plus, in southwestern Minnesota, several CMSs have proposed merging. They include: the Blue Earth County Medical Society, the Blue Earth

2013 resolutions: A seismic shift

Change is afoot for this year's Annual Meeting. Of the resolutions submitted to the House of Delegates, more than a quarter of them deal with how the MMA will govern itself in the future.

Twenty-eight resolutions were submitted. Six were initially rejected, referred to the Board of Trustees for consideration or reaffirmed by a resolution review committee made up of eight members. Registered delegates had the opportunity to vote whether to keep these resolutions in early August and voted to bring several back. In the end, 26 resolutions will be considered by the House.

The bulk of the resolutions were generated by the Twin Cities Medical Society (TCMS), the state's largest component medical society (CMS), and nearly half of those deal with governance. Several of the TCMS resolutions seek to maintain and modify the

Valley Medical Society, Camp Release District Medical Society, Lyon-Lincoln Medical Society, Mid-Minnesota Medical Society and the Southwestern Minnesota Medical Society.

- The Minnesota Academy of Family Physicians has put forward two resolutions asking the MMA to study the cost implications and administrative burdens associated with providing quality-improvement data.
- The MMA's Prescription Opioid Management Advisory Task Force has submitted a resolution seeking to embed the state's Prescription Monitoring Program (PMP) into electronic health records so it's easier for physicians to access.

Comedian to perform at president's dinner

This year's Annual Meeting won't be all debate and seriousness. Nationally known comedian Bob Stromberg of "Triple Espresso" fame will entertain those attending the president's inaugural dinner on September 20.

Originally from Pennsylvania, Stromberg now calls Minnesota home. For more than 30 years, he has entertained audiences of all ages with his unique style of clean comedy. For more information, visit his website at www.bobstromberg.com.

The 2013 Annual Meeting takes place September 20-21 at the Minneapolis Marriott Northwest in Brooklyn Park. For more information, visit www.mnmed.org/AbouttheMMA/2013AnnualMeeting.



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News briefs



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Appeals court makes physician-friendly ruling in legal guardian case

A Minnesota Court of Appeals reversed a district court's decision and ruled in late July that a guardian can authorize removal of a ward's life support without court approval. The ruling regarded the case of *The Guardianship of Jeffers A. Tschumy*.

Earlier this year, the MMA submitted an amicus brief supporting the argument that legal guardians have the inherent power to make medical decisions on behalf of their wards, including the decision to decline medical care and to terminate life support. The MMA urged the Court of Appeals to reject the district court's assertion that all guardians must obtain a court order before authorizing "end of life" care for their wards.

"This is an important ruling from the Court of Appeals," says Teresa Knoedler, J.D., the MMA's policy counsel. "Medical decisions are best made by family and guardians in conjunction with physicians and other providers. This ruling keeps that decision-making out of the courts in most circumstances. It's a good outcome for Minnesota physicians."



National expert to speak at primary care summit in November

Scott Shipman, M.D., M.P.H., director of Primary Care Affairs and Workforce Analysis at the Association of American Medical Colleges, will be the keynote speaker at the MMA's Primary Care Physician Workforce Expansion Summit

November 12 in Minneapolis.

"The summit is aimed at identifying and sharing strategies for increasing Minnesota's primary care physician workforce," says

Juliana Milhofer, an MMA policy analyst who is helping organize the event.

The MMA formed a task force earlier this year in an effort to address the state's primary care physician shortage. Between 2000 and 2030, the percentage of Minnesota's population age 65 and older is expected to increase from 12 to 24 percent. And in January, when the Affordable Care Act kicks into full gear, more Minnesotans will find themselves in the health insurance pool. Meanwhile, primary care physicians in Minnesota are getting older and closer to retirement. In 2011, more than a third were age 55 or older.

"This is a very serious issue," says MMA President Dan Maddox, M.D. "Figuring out how to address the shortage is a critical priority for the MMA. The number of patients is growing, while the number of physician is decreasing. That adds up to trouble for any of us who will need care in the future."

The summit will be held from 4 to 8 p.m. at the Ramada Plaza Minneapolis, 1330 Industrial Boulevard, N.E. For more information on the summit, contact Milhofer at 612-362-3735 or email her at jmilhofer@mnmed.org.

MMA celebrates its 160th anniversary in July

In July, the Minnesota Medical Association turned 160 years old. On July 23, 1853, John H. Murphy, M.D., and 10 young physicians gathered in St. Paul for the first-ever medical profession convention in Minnesota. This convention was the formation of the Minnesota Medical Society, which in 1903 changed its name to the Minnesota Medical Association.

"I can't imagine those 11 physicians knew what they were starting back in 1853, but I'm sure they would be proud of how their creation turned out," says MMA President Dan Maddox, M.D. The MMA now has more than 10,000 members and continues to work on behalf of Minnesota physicians and their patients.

Resident program on employment contracts set for October

The MMA will host an informational session/social event on employment contracts for Minnesota residents on October 17 at 6:30 at Rojo Mexican Grill, 1602 West End Boulevard, in St. Louis Park.

This is an excellent opportunity for residents to receive advice from legal experts as well as representatives from large health care provider organizations and independent practices.

For more information, contact Kathleen Baumbach (kbaumbach@mnmed.org), MMA's manager of physician outreach, at 612-362-3729.



News briefs

(continued from previous page)

Member physicians testify at immunization hearing

Two MMA member physicians testified before an administrative law judge in June in favor of proposed changes to Minnesota's school and child care immunization law.



PHOTO BY AMY WALTERS/ISTOCKPHOTO/THINKSTOCK

Both Laurel Ries, M.D., chair of MMA's Public Health committee, and Robert Jacobson, M.D., a Mayo Clinic physician who is president of the MN Chapter of the American Academy of Pediatrics, spoke on behalf of the proposed rule changes.

The changes, which would take effect in September 2014, include:

- requiring children enrolling in child care and school-based early childhood programs to be vaccinated for hepatitis A and B
- requiring secondary students to get a meningococcal vaccination beginning in seventh grade
- replacing the current seventh-grade tetanus-diphtheria vaccine with one that also includes pertussis (Tdap).

In addition, the timing of the polio vaccine and DTaP vaccine would be changed to match current medically acceptable standards, and the age for the first varicella (chickenpox) immunization would be changed from 18 months to 15 months for children enrolling in child care and school-based early childhood programs.

"Ensuring that Minnesota's children are being vaccinated against serious and often life-threatening disease is good medicine, cost-effective medicine, and essential for the health of the public," Ries testified.

The changes would bring Minnesota in line with the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recommendations.

MMA supports changes to how sunlamps are classified

In late June, the MMA offered its full support for a U.S. Food and Drug Administration (FDA) proposal to reclassify sunlamps used in artificial tanning facilities to better protect the public from the dangers of artificial tanning.

The FDA categorizes devices in three ways based upon the risk they pose to health. Currently, sunlamps are listed as a Class I device, the category used for such items as tongue depressors and bandages. The proposal before the FDA is to reclassify sunlamps as a Class II device.

Under the new classification, tanning bed manufacturers would be required to affix labels to the devices noting that there are clear risks to their use, that users should get regular cancer screenings and that sunlamps are not recommended for use by youths.

In the letter, MMA President Dan Maddox, M.D., encouraged the FDA "to take further actions in the future to completely restrict access of minors to artificial tanning facilities." Such an effort would mirror legislation that the MMA will advocate for in 2014—the complete banning of access to artificial tanning facilities by minors.

Research has shown that exposure to the UV radiation emitted by artificial tanning devices increases one's risk for developing melanoma by 75 percent. Each year, more than 12,000 Americans die from skin cancer, 9,000 of whom have melanoma. Melanoma rates are rising dramatically across the country, and in Minnesota, the incidence of melanoma among women ages 20 to 49 has doubled since 1995.



PHOTO BY SANTIAGO/ISTOCKPHOTO/THINKSTOCK



Terry Ruane



Kathleen Baumbach



Dave Renner



Janet Silversmith



Dave Thorson, M.D.



Lyle Swenson, M.D.

MMA in action

Terry Ruane, the MMA's director of membership, marketing and communications, **Brian Strub**, an MMA manager of physician outreach, and **Dave Renner**, MMA director of state and federal legislation, attended at the American Association of Medical Society Executives annual meeting in St. Louis in mid-July. The event included a number of educational programs on issues affecting medical societies and physicians.

Renner also attended the AMA State Legislative Strategy Conference in Chicago in early August. This meeting of state medical and specialty society government affairs staff included a discussion on state legislative issues related to health reform, scope of practice, public health and quality improvement. In addition, Renner participated in the AMA Advocacy Resource Center's Executive Committee meeting. Renner serves as vice chair of the committee.

Renner, **Eric Dick**, the MMA's manager of state legislative affairs, and MMA Board Chair **Dave Thorson**, M.D., convened a meeting of several specialty society leaders and lobbyists in July to discuss legislation that could expand the scope of practice for advance practice registered nurses (APRNs). The meeting included representatives of family medicine, anesthesiology, psychiatry and pain medicine.

In mid-July, Immediate Past President **Lyle Swenson**, M.D., TCMS President **Edwin Bogonko**, M.D., and Strub participated in a listening session with the physicians of Metro Urology.

Kathleen Baumbach, an MMA manager of physician outreach, attended Honoring Choices Minnesota's fourth annual Sharing the Experience Conference in Minneapolis in mid-July.

In July, Baumbach and Strub met with MMA Board member **Fatima Jiwa**, M.B.Ch.B., to discuss member outreach to pediatricians, physicians with young children and women in medicine.

In late July, Strub and **Nancy Bauer** of the Twin Cities Medical Society, met with **Kevin Brown**, D.O., of Hennepin County Medical Center's Neurology & Specialty Clinic in Chaska, to discuss the role of delegates to the Annual Meeting, resolutions and the ways physicians can have an impact with the MMA and TCMS.

Janet Silversmith, MMA director of policy, was the featured speaker at a general session during the Minnesota Medical Group Management Association summer conference at Breezy Point Resort in late July. Her talk was titled "The Affordable Care Act: T - 6 Months."

In early August, Strub attended the University of Minnesota's Medical School orientation. The MMA and TCMS co-sponsored a lunch-and-learn event to welcome new medical students.

Upcoming MMA events

Hippocrates Cafe Celebrate the creative side of medicine

6:30 p.m.

September 19

Mill City Clinic, Minneapolis

MMA Annual Meeting

September 20-21

Minneapolis Marriott Northwest, Brooklyn Park

What You Need to Know about Employment Contracts

6:30 p.m.

October 17

Rojo Mexican Grill, St. Louis Park

Minnesota Community Measurement Data Portal (webinar)

7:30-9 a.m.

October 31

Primary Care Physician Workforce Expansion Summit

4 to 8 p.m.

November 12

Ramada Plaza Minneapolis

The 2014 Patient Experience Measure (webinar)

7:30-9 a.m.

November 21

Visit www.mnmed.org for more information and to register for each event.

Big Data, big influence

Why our collective data is a social determinant of health.

BY EDWARD P. EHLINGER, M.D., M.S.P.H.

Who owns the Earth? By definition, it is a public good. It is the “commons,” the natural resource available to all, that helps sustain every one of us. Yet, for centuries, the Earth has been arbitrarily partitioned, with groups of people claiming ownership over vast areas and resources. We have further divided and subdivided it so that some relatively small groups and individuals now claim pieces of it as their own.

The Earth’s resources are often extracted, harvested, harnessed and used for the benefit of all—for food, shelter, clothing, security and quality of life. But sometimes those resources are used for private gain, rather than the public good. When that happens, some people benefit disproportionately.

Power and money are generally the levers used to gain control over our natural resources. They are also the levers used to gain control over our socioeconomic resources—the social, economic, educational, physical and health care systems that form the environment in which we are born, grow, live, work, age and receive care.¹ We refer to these complex, integrated and overlapping socioeconomic systems as the social determinants of health, as they have a huge impact on our overall well-being. Although our socioeconomic

resources can be used for the benefit of many, often they are not, and thus we have unfair and avoidable differences in health status among and within countries.²

Big Data and health

Big Data has emerged as a new and powerful force that is rapidly and dramatically transforming our world. The term refers to the massive and complex datasets now being generated, along with our ever-expanding capacity to analyze their content and extract and use information.³ Big Data is expanding and modifying our understanding of every aspect of our world and giving us the ability to educate, inform, influence, monitor, track, assess and direct people in ways that were once only imagined.

Big Data has a particularly profound impact on health. In fact, it might be one of the most important social determinants of health because of its overwhelming influence on every aspect of our lives.

The advent of Big Data has allowed us to rapidly decode human DNA, track and prevent disease, predict human behavior, monitor physiological systems, find treatments for cancer, foil terrorists, improve airline safety, build self-driving vehicles and personalize marketing efforts.⁴ Yet there is a downside. As more data are

collected in multiple ways from multiple sources, our privacy is eroding. As anyone who uses a credit card, a cell phone or the Internet knows, personal information is already widely shared, often without one’s knowledge or consent.

The impact, both positive and negative, of Big Data is only going to grow, as the amount of data we generate grows. Google’s executive chairman Eric Schmidt said at the 2010 Technomy conference: “From the dawn of civilization until 2003, humankind generated five exabytes of data. Now we produce five exabytes every two days ... and the pace is accelerating.” Big Data will affect everyone on the planet.

With improved health outcomes as a goal, Big Data can be a powerfully positive force. It can be useful in determining the effectiveness of current treatments for all sorts of injuries and diseases. It can provide clues to the causes of infections, cancers and noncommunicable diseases, which can lead to new cures.⁵ It also can improve health care by linking electronic health records with vital records, disease surveillance systems, social media, and housing, environment, transportation, employment, finance and education data. Such integration will allow treatment of individuals to be informed by a better

understanding of the physical and social environment in which they live.

In the field of public and population health, the potential benefits of Big Data are innumerable. One example is crowd-sourcing, which may one day enable us to identify infectious disease outbreaks at an early stage, when interventions might mitigate their severity. Linking public health datasets with health records also could help identify issues that affect the health of community members such as environmental triggers for asthma or the density and location of tobacco advertising. It also could help in the development of public policies that promote healthy behaviors. Combined, these efforts could lead to more than \$300 billion in health care savings, according to McKinsey and Co.⁶

If profit, rather than health, is the goal, Big Data could be used to alter clinical practice in ways that benefit one health care entity or one device manufacturer or pharmaceutical company over others. Similarly, it could allow health plans or insurance companies to target outreach efforts and services to populations based on economic rather than health-improvement goals. We are already seeing Big Data being used to encourage and support unhealthy behaviors such as the consumption of sugar-sweetened beverages and to market products such as menthol cigarettes to minority populations.

Private good or public commodity?

Because of its power, Big Data can influence the direction of our health care system and the health of our communities. Beyond that, it could influence the course of our entire society, depending on how it is used.

This raises multiple questions: Is Big Data part of the “commons”? Is it a public good or a private commodity? Who owns it? Who controls it? Who decides what to collect and analyze? Who decides how to use it? Who is responsible for evaluating its impact?

Obviously, these are rhetorical questions designed to stimulate an overdue conversation. If Big Data is considered

part of the commons, broad community input and involvement will be needed to determine how it could be harnessed to help society more effectively address disparities and guide us toward health equity. If it becomes a private commodity, Big Data most likely will be controlled by those with power and money and used to promote their vested interests. This could lead to even greater inequities.

As we learn more about Big Data, we probably will reach an understanding that it can be both a public good and a private commodity. Like all the social determinants of health, it embodies aspects of both. Our challenge will be to ensure a balance between broad community interests and the more narrow interests of private entities when it comes to influencing the health of our society. The stakes are high because whoever owns Big Data may not own the Earth, but they certainly will be a powerful force in determining the well-being of its inhabitants for the foreseeable future. **MM**

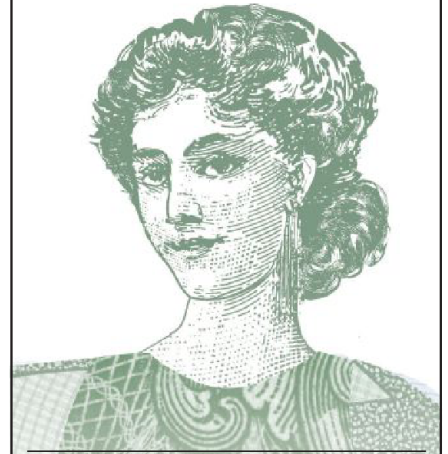
Edward Ehlinger is Minnesota’s Commissioner of Health.

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Health care's digital divide

Minnesota's large hospital systems may be well on their way to meeting goals for electronic health record adoption, but rural and critical access hospitals are being left behind.

BY PAUL KLEEBERG, M.D.

Minnesota has been a leader both in adopting health information technology¹ and using it to provide high-quality care at a low cost.² The Minnesota Legislature has been an advocate for the use of electronic health record (EHR) systems in hospitals and clinics. In 2004, it established the Minnesota eHealth Advisory Committee to provide recommendations related to the adoption of EHRs and other health information technology.³ Based on the committee's recommendations, in 2008 the Legislature mandated that health care providers in the state use interoperable EHR systems by 2015.⁴

The federal government has also driven this. In 2009, Congress passed the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the Recovery Act, requiring providers and hospitals nationwide to adopt and use EHR technology to meet specific goals (termed "meaningful use") by 2015. To achieve this, the law provided a mixture of incentives and penalties to drive adoption.⁵ The use of health information technology has grown significantly throughout the United States since passage of the HITECH Act. In fact, between 2008 and 2012, EHR system adoption more than

doubled in office practices and more than quadrupled in hospitals.⁶

These gains have been impressive, but they have not been evenly distributed. Surveys conducted in 2012 showed that 64 percent of the 131 Minnesota hospitals that responded had a "basic EHR." Of the 86 rural and critical access hospitals (CAHs) that were included only 47 percent had one.^{7,8} A basic EHR system is one that offers the following functions: patient history and demographics, patient problem lists, physician clinical notes, a comprehensive list of patients' medications and allergies, computerized orders for prescriptions, and the ability to view laboratory and imaging results electronically.

Large urban systems see benefits

Large health systems in metropolitan areas have a number of advantages when it comes to health information technology. First, they have greater access to resources and skilled temporary staff. Larger organizations are able to afford more expensive and elaborate systems that have been refined and redesigned to meet the needs of integrated systems that have inpatient and ambulatory facilities. Often they have access to information technology experts who can customize the system to meet their unique needs. Finally, since many of

these facilities had EHR systems in place prior to the federal government's incentive program and were already doing many of the things required to earn an incentive, they were able to use those additional dollars to further customize and enhance their systems to meet their quality objectives.

A systematic review of the literature published in 2006 sheds light on this. Reviewers who looked at the impact of EHRs on the quality, efficiency and cost of medical care found that 25 percent of the 257 studies that met the inclusion criteria were from four academic medical centers. These institutions had been using their own internally developed systems for a number of years, and they were the only ones in the study that showed quality and efficiency benefits.⁹ This demonstrated two things: First, that it takes time for a facility to see the benefits of using an EHR, and second, that local development and enhancement are necessary to create a system that meets the needs of a facility.

That large systems have been the ones to realize the benefits of EHR systems was evident at the Minnesota eHealth Summit in June of this year. Representatives from two such systems talked about the benefits of using EHRs.^{10,11} Both have large IT staffs, which helped design and implement their EHRs. Both used a mature product and

customized it for their needs. One had been using its EHR for a number of years and was able to show significant benefits.¹⁰ This system had gone paperless in its clinics in 2004 and in its main hospital in 2006.

Small rural hospitals face challenges

Rural and critical access hospitals find themselves in a much different situation. These facilities do not have the same resources at their disposal that large urban hospitals have. Many of them have limited IT staff, making it difficult to customize their EHR system. In addition, the EHR systems designed for these smaller facilities are typically not as mature as the ones used by large systems. Many started out as billing and materials management systems, pharmacy systems, nursing documentation systems and order entry systems designed more for pharmacists who order by vial or tablet than for physicians who order by dose. Order sets, which make electronic order entry easier and are commonly used in large facilities, are often missing in the systems used at smaller hospitals because of the physician and staff time it takes to develop them. To add to the challenge, some of these EHR systems lack a robust physician documentation component, making it impossible for the hospital to give up paper charts altogether. Having to manage patient care using both electronic and paper records is inefficient and increases the chance for error.

Many of these hospitals have asked their EHR vendor for an ambulatory component, thinking it would provide a seamless interface between hospital and outpatient setting. But often, the interface is not seamless, and these products are difficult to use. Because of that, physicians may not see their benefits.

To add to the challenge, physicians practicing in ambulatory clinics affiliated with rural hospital or CAH were excluded from the federal incentive program when it began. Most of these physicians do not use Medicare part B billing, which was a requirement for participation in the pro-

gram. This May, the Centers for Medicaid and Medicare Services announced that some physicians who bill through critical access hospitals will become eligible for the incentive dollars, if they meet certain criteria;¹² but this may be too little too late to get these physicians to adopt EHR systems. A recent *Health Affairs* article states the problem this way: “Rural hospitals have made substantial progress, with one in eight of them acquiring at least a basic [EHR] system in 2012 alone.... However, the gap between urban and rural hospitals remains.”¹³

In our travels to Minnesota and North Dakota CAHs, we’ve seen evidence of the rural-urban technology divide. We’ve seen physicians who work in these facilities struggle to use their EHR, and it was easy to understand why they were unhappy. The products were a generation behind those being used in large facilities.

Vendors who build products for these small hospitals also struggle. For one thing, they are using all their resources to keep up with the certification requirements for meaningful use and have had little time or resources left to refine and improve their products. Second, they are trying to meet their clients’ upgrade and installation demands in order to keep pace with meaningful use. Consequently, many small hospitals have found themselves on long waiting lists for EHR installation.

Closing the rural-urban gap

Office-based physicians in both rural and urban settings appear to have been able to adopt EHR systems and use them effectively.¹⁴ In Minnesota, 67 percent of all office-based providers and 66 percent of primary care providers had a basic EHR in 2012.^{7,15}

One reason may be because there are a number of good EHR products on the market for ambulatory practices. The American Academy of Family Physicians regularly rates systems and has found that many score very highly in physician satisfaction.¹⁶ Some of those require minimal maintenance as well.

A national study found the biggest relative increase in the EHR adoption rate

was among older physicians and those working in solo practices and community health centers—groups that historically had low adoption rates.¹⁴ Although small practices continue to lag behind larger ones, the gap has closed significantly. The authors attributed that to the work of the HIT regional extension centers, which were created to help primary care providers with adoption and use of EHR systems.

Although the extension centers were also asked to assist rural hospitals and CAHs, funding for those facilities came later and has not been adequate to support the needs of hospitals. Consequently, many extension centers decided not to work with rural hospitals and CAHs. (Minnesota’s extension center, REACH, has worked with 95 percent of the state’s rural hospitals and CAHs.)

Some small rural hospitals, through strong leadership and a bold vision, have been very successful at gaining physician and staff buy-in and now use their EHR system effectively. Others have been able to achieve meaningful use by leveraging their nursing, pharmacy and IT staff (with minimal physician participation)—an approach that will become more challenging to maintain as the meaningful use requirements become more demanding. The vendors who serve these facilities are working hard to enhance their products and have made significant progress.

But a big concern remains for the rural hospitals and CAHs. Unlike many of the larger facilities that already had EHRs in place, these facilities, which were frequently short on capital, used any meaningful use incentives they received to assist with the initial purchase and installation of their EHR system as opposed to enhancing it.

In the future, rural facilities are going to need assistance as they continue to adopt, enhance and optimize their use of EHR systems. Most started later than their urban counterparts and do not have the same support mechanisms available to them. The HIT regional extension centers can be of significant assistance to these hospitals;^{6,13} however, their contracts are set to expire in February of 2014. If we

do not figure out a mechanism to provide support and technical assistance to these facilities, the digital divide will only grow wider and the quality, efficiency and safety of health care in our rural communities will fall behind. **MM**

Paul Kleeberg is chief medical information officer for Stratis Health and clinical director for the Regional Extension Assistance Center for HIT that serves Minnesota and North Dakota.

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Minnesota Clinics' Adoption, Use and Exchange of Electronic Health Information

BY KAREN SODERBERG, M.S., AND MARTY LAVENTURE, PH.D., M.P.H.

In 2007, Minnesota passed a law requiring all health care providers in the state to implement an interoperable electronic health record (EHR) system by January 1, 2015. Since then, the Minnesota Department of Health has been monitoring progress each year by surveying hospitals, clinics and other health and health care facilities about their EHR use. This article summarizes findings from the 2013 survey of ambulatory clinics. Those results show Minnesota clinics are well on the way to achieving the state's goals for using EHRs to exchange information: 87% of clinics have adopted EHRs, 80% routinely use medication guides and alerts, and 36% exchange health information with unaffiliated settings.

Electronic health record (EHR) systems enable physicians in a variety of settings to access information that can help them deliver care that leads to better outcomes, is less expensive and leaves patients satisfied.¹ The information gleaned from EHRs is also enabling researchers to better understand illness and treatment and health care administrators to identify inefficiencies and drivers of cost.^{2,3}

In 2007, Minnesota enacted legislation that requires all health care providers in the state to implement an interoperable EHR system by January 1, 2015.⁴ Since 2010, the Minnesota Department

of Health's Office of Health Information Technology has conducted surveys of health and health care facilities in the state about their adoption and use of any type of EHR system.⁵ Those surveys have shown that almost all hospitals, clinical labs, pharmacies and local health departments have adopted an EHR or EHR-like product (Table 1).

This article presents the findings of the latest survey, which focused on EHR use in clinics. It also identifies emerging issues related to the use of EHRs.

The Health Information Technology Survey

The 2013 survey was sent to 1,623 ambulatory clinics (defined as any location where primary or specialty care ambulatory services are provided for a fee by one or more physician). It was administered online between February 15 and March 15, 2013, and consisted of 72 questions. The response rate was 79%, with 1,286 clinics responding.

The survey found nearly nine in 10 (87%) ambulatory clinics had adopted an EHR, representing 1,114 clinics (Table 1). Nationally, 38% of clinic-based physicians reported using an EHR.⁶

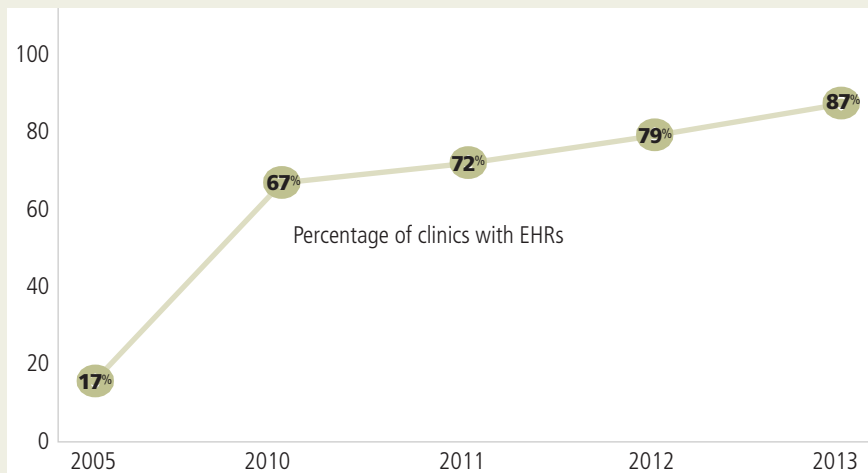
Currently, there is no significant difference between the EHR adoption rates in urban and rural clinics. However, specialty care clinics have a lower implementation rate than primary care clinics, with 83% currently using an EHR or in the process of installing one, compared with 93% of primary care clinics. EHR adoption rates among Minnesota's clinics have increased over time and are expected to continue to increase. Figure 1 shows that since the first clinic survey in 2010, the EHR adoption rate increased from 67% to 87%. As

TABLE 1

Adoption of Electronic Health Record Systems and Related Technology in Minnesota

TYPE OF FACILITY	PERCENT WITH EHRS OR EHR-LIKE SYSTEMS	NUMBER ADOPTING/ NUMBER RESPONDING	YEAR OF ASSESSMENT
Clinics	87%	1,114/1,286	2013
Hospitals	96%	130/136	2012
Local health departments	94%	67/71	2012
Clinical labs	97%	133/137	2011
Nursing homes	69%	217/316	2011
Chiropractic offices	25%	69/277	2011

FIGURE 1
Trends in Adoption of Electronic Health Record Systems among Minnesota Clinics



of 2013, another 9% of clinics report that they are planning to implement an EHR within the next three years. Earlier data on EHR adoption is limited; a 2005 survey of a subset of adult primary care clinics estimated the adoption rate at 17%.

Effective Use of EHRs

The real value of an EHR system is realized when it is used to support workflow and clinical decision-making, gather information for quality-reporting initiatives, and improve the health of individuals and populations. Effective use of EHRs means that the system has tools such as e-prescribing and clinical decision support,

and that staff are adequately trained to use them.

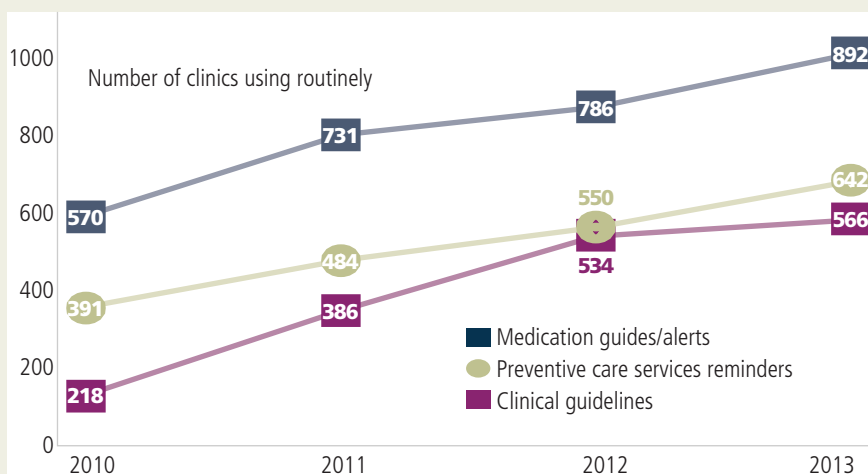
The clinic survey measures the use of several tools and functionalities. For this analysis, three clinical decision support (CDS) tools are highlighted: medication guides/alerts, preventive care reminders and clinical guidelines (Figure 2). Four out of five primary and specialty care clinics (892) routinely use medication guides and alerts. More than half (642) are routinely using preventive care reminders, and about half (566) are routinely using clinical guidelines. Use of all three tools has increased substantially over time. Furthermore, there is evidence that physicians

and other providers are using multiple tools, with 57% of clinics reporting that their providers use three or more of the following CDS tools: automated reminders for missing labs and tests; chronic disease care plans and flow sheets; clinical guidelines based on patient problem list, gender and age; high-tech diagnostic imaging decision support tools; medication guides/alerts; patient-specific or condition-specific reminders; reminders of preventive care services that are due.

Common reasons why providers do not use CDS tools include too many false alarms, lack of resources to build the tools and the need to redesign workflow.

Another indicator of effective use is electronic prescribing or e-prescribing—secure bidirectional electronic information exchange between prescribers, dispensers (pharmacies), pharmacy benefit managers and health plans, either directly or through an intermediary network.⁷ Minnesota has seen a notable increase in the rate of pharmacies using e-prescribing, from 57% in December of 2008 to 95% in April of 2013; currently, nearly 1,000 pharmacies in the state are using e-prescribing. Of the 69 pharmacies that are not, 36 are chain and 33 are independent.⁸ An estimated 80% of new and renewal prescriptions in Minnesota are now e-prescribed.⁹ Common barriers to e-prescribing are the technical inability to e-prescribe controlled substances and pharmacies being unable to receive electronic prescriptions.

FIGURE 2
Clinic Trends in Use of Clinical Decision-Support Tools, Minnesota



Health Information Exchange

Health information exchange is the secure electronic exchange of clinical information between organizations using nationally recognized standards.¹⁰ The goal is to make information available when and where it is needed, thus improving the quality and safety of care. In Minnesota, a number of efforts are underway to help achieve the secure electronic exchange of clinical information. Currently, most of the exchange is happening between hospitals and clinics that are owned by the same health system or that are affiliated with one another. Figure 3 shows that more than half (54%) of clinics are exchanging

information with affiliated hospitals or clinics, but a little more than one-third (36%) are exchanging with unaffiliated hospitals or clinics. Common challenges for exchanging information include limited capacity of others to exchange, lack of technical support or expertise, competing priorities, and cost and privacy concerns.

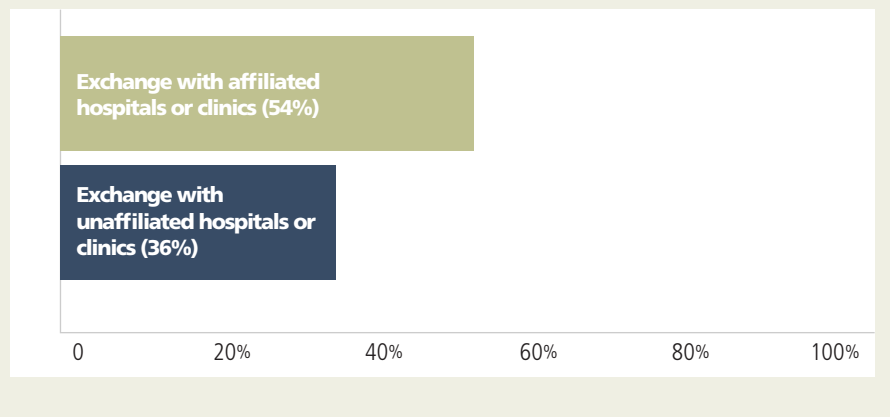
Discussion

This research shows that Minnesota's ambulatory clinics have made great strides toward implementation and effective use of EHR systems. This has been driven in part by key national and state actions. The American Recovery and Reinvestment Act of 2009 authorized \$20 billion in funding to develop health information technology infrastructure to promote adoption and use of EHRs.¹¹ As of May 2013, organizations in Minnesota have received more than \$270 million in incentive payments to implement EHR systems.¹² Before these federal incentive dollars became available, policymakers in Minnesota recognized that more effective use of health information technology—including timely exchange of information—was needed to improve the quality and safety of care and to help control costs. The Department of Health recently published guidance that describes Minnesota's law, who is affected, what kind of information should be exchanged, privacy and security requirements, and how organizations can go about exchanging information.¹³ The health department will continue to support implementation guidance for providers across the continuum of care.

Over time, EHR systems are being used more effectively. Minnesota has had great success with e-prescribing following the state's 2011 e-prescribing mandate.¹⁴ Because of its high rate of e-prescribing adoption, Minnesota has consistently ranked at or near the top of Surescripts' Safe-Rx Ranking.¹⁵ There is still room for improvement, however, and barriers to interoperability need to be addressed. Some EHR systems have issues that may inhibit optimal utilization such as excessive alerts, poor functionality and features that don't

FIGURE 3

Minnesota Clinics' Exchange of Health Information with Hospitals and Clinics, 2013



apply to a clinic's practice; as technology evolves these issues should diminish.

Ongoing training will be needed both for the existing workforce and for new hires. Findings from this study show that health informatics and health information technology-related skills are needed to optimize use of EHRs and address changes in workflow. Clinics need staff who can customize and/or maintain an EHR, who have solid computer skills, and who are trained in health informatics.

Patient privacy and security continue to be a concern. In 2012, the Legislature directed the Minnesota Department of Health to study patient consent practices. Key recommendations from this study focus both on work practices and technology. They include the need to help providers develop best practices and standards for monitoring records in order to make sure privacy is not breached and information is not compromised, and to educate patients about how their information is protected.¹⁶

An emerging issue is consumer engagement—encouraging patients to access and use their personal health information, and identifying best practices for providers to involve patients in their health. Providers can support the concept of “patients as partners” by encouraging patients to register and use their personal health information, and by providing educational materials through the EHR that are tailored to the patient's condition. More than half (57%) of the ambulatory clinics in Min-

nesota offer an online portal for patients to access their EHR.

EHRs are also important to health care reform efforts at both the state and national level. The expansion of Medicaid eligibility in Minnesota will bring more people onto the health insurance rolls, including some who have complex health care needs and a transient lifestyle. Having an accessible medical record will allow physicians and other providers to review these patients' health histories and provide them with consistent care, even if they have never been seen in that clinic. Minnesota received a \$45 million grant from the Centers for Medicare and Medicaid Services to test the Minnesota Accountable Health Model, which is designed to expand the state's current Medicaid ACO demonstrations and provide more integrated, less fragmented care.¹⁷ Effective use of EHRs, including timely and secure health information exchange among multiple providers, will be essential to achieving the goals of this model.

Conclusion

More and more health care providers are embracing EHR systems and related technologies. Although more work is needed to achieve interoperability, Minnesota's clinics are well on the way to meeting the state's goals for using EHR technology to exchange information. Much of the progress to date has resulted from collaboration within the health care community. ➔

Health care providers will benefit by continuing to work together to overcome technical barriers and push for better tools and systems. When this happens, they will be well-positioned to optimize patient care and outcomes, and engage patients as partners in their care. **MM**

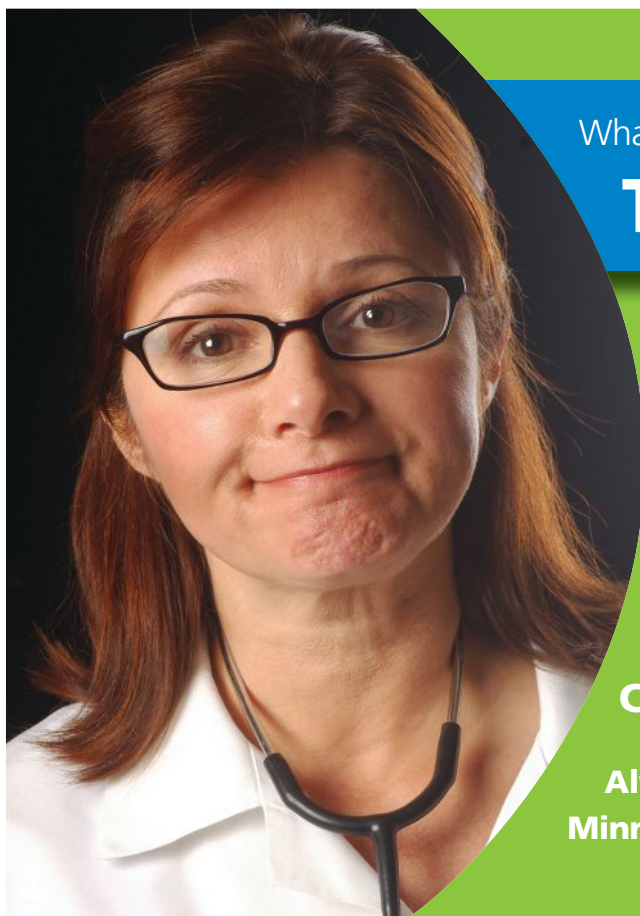
Karen Soderberg is the HIT assessment and evaluation coordinator in the Minnesota Department of Health's Office of Health Information Technology. Martin LaVenture is director of the Office of Health Information Technology.

The authors would like to thank Minnesota Community Measurement and the Health Economics Program and Office of Health Information Technology at the Minnesota Department of Health, Division of Health Policy.

Information about EHR adoption and information exchange in other health care settings is available at www.health.state.mn.us/e-health/assessment.html.

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2009 H1N1 Vaccination in Minnesota

An Evaluation by ZIP Code

BY MIRIAM HALSTEAD MUSCOPLAT, M.P.H., MARGARET RODDY, M.P.H., ELIZABETH PARILLA, M.P.H.,
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According to Minnesota Immunization Information Connection (MIIC) data, 23% of Minnesotans were vaccinated against 2009 pandemic H1N1 influenza. We analyzed 2009 H1N1 vaccination data at the ZIP code level to learn more about who received the vaccine between 2009 and 2010. We found significant differences in H1N1 vaccination rates by percentage of residents living below the family poverty line, percentage of non-Caucasian residents in a ZIP code and median family income. When stratified by urban or rural location, median family income was significantly associated with vaccination rate only in urban settings; the percentage of non-Caucasians living in an area was significant only in rural settings. In both urban and rural settings, most H1N1 vaccinations were given in a private facility, although the proportion was much higher in urban ZIP codes (81.5%) than rural ZIP codes (53.2%, $P < 0.0001$). Further research is needed to find out why vaccination rates were associated with increasing median family income in urban areas and why in rural areas, people living in ZIP codes with a higher percentage of non-Caucasian residents were more likely to be vaccinated after controlling for poverty and median income.

The 2009 H1N1 virus was the first to cause pandemic influenza in more than 30 years. The Centers for Disease Control and Prevention (CDC) estimates that between 43 million and 89 million cases occurred in the United States between April 2009 and March 13, 2010.¹ During that time, there were an estimated 274,000 hospitalizations and 12,470 deaths related to the infection.¹ In Minnesota, the Department of Health reported 1,824 laboratory-confirmed hospitalized cases of 2009 H1N1 influenza; in addition, the state saw 63 confirmed deaths caused by the virus.²

Once H1N1 influenza was identified as a pandemic threat, the federal government began working with manufacturers to develop a vaccine. In July 2009, the national Advisory Committee on Immunization Practices (ACIP) developed a list of recommended target groups for vaccination including pregnant women, caretakers

of young children, health care workers, people between the ages of 6 months and 24 years, and nonelderly adults with underlying medical conditions. Approximately 159 million people in the United States and 2.4 million in Minnesota fell into these categories. The ACIP also noted that if vaccine supplies were unexpectedly restricted, the following groups should have priority: pregnant women, people who live or work with children younger than 6 months of age, health care workers with direct exposure to infected patients or the virus, children between 6 months and 4 years of age, and children 5 to 18 years of age who have underlying risk factors. An estimated 700,000 Minnesotans fell into these categories.³

H1N1 vaccine production was protracted compared with seasonal influenza vaccine production because the selected virus strain grew slowly in chicken eggs, which delayed release of the vaccine.

When the vaccine became available, distribution was managed by the federal government with state and local public health departments determining which sites received doses. The first doses of H1N1 vaccine became available in late September 2009 in the nasal spray formulation (LAIV, Live Attenuated Influenza Vaccine); the injectable formulation (TIV, trivalent inactivated vaccine) became available in October. During the 2009-2010 flu season, more than 120 million doses of H1N1 vaccine were distributed in the United States.⁴

Minnesota received its first batch of the H1N1 vaccine on October 1, 2009. Initial doses were given to physicians and others who worked with medically fragile children. Between mid-October and late November, only a small amount of vaccine was available and health department officials recommended that the subset of the target groups identified by the ACIP (pregnant women, individuals who live or

work with children younger than 6 months of age, health care workers with direct exposure to infected patients or the virus, children between 6 months and 4 years of age, and children 5 to 18 years of age who have underlying risk factors) receive those limited doses. On November 30, the vaccine was made available to all of the target groups. On December 16, the Department of Health issued a statement indicating that providers could make the vaccine available to everyone, as long as they had adequate supply. In total, 2,475,000 doses of 2009 H1N1 vaccine were distributed to clinics throughout the state.

This study sought to identify who was vaccinated in Minnesota and what demographic and socioeconomic factors may have played a role in their receiving the vaccine. This information may be useful in planning for future pandemics.

Methods

Immunization rates for 2009 H1N1 were obtained from the Minnesota Immunization Information Connection (MIIC), a web-based immunization database. Providers interested in administering the 2009 H1N1 vaccine were required to pre-register with the Department of Health and enter information about vaccine recipients into MIIC within two weeks of vaccine administration. Even with the two-week grace period, information about many of the recipients was not entered until much later. All doses entered through December 1, 2010, were included in the study. The study population included all individuals older than 6 months of age who had at least one 2009 H1N1 influenza vaccination recorded in MIIC. Children younger than 6 months were excluded from the analysis because the vaccine was not licensed for this age group.

Definition of Variables

We used census data for median household income, percentage of residents in a particular ZIP code with incomes below the federal poverty level, and percentage of persons residing in a ZIP code who were not Caucasian. Data were catego-

TABLE 1

Vaccination Rates by Age and Geographic Distribution of Minnesota's Population

AGE	% OF POPULATION	% VACCINATED
6 mos to 4 years	6.7%	41.2%
5 to 19 years	22.5%	28.0%
20 to 24 years	6.6%	13.9%
25 to 49 years	37.8%	16.2%
50 to 64 years	14.4%	32.8%
65+ years	12.1%	33.6%
<i>Geographic setting</i>		
Urban	25.5%	22.6%
Rural	74.5%	23.0%

Source: Population characteristics from Census 2000 data, vaccination rates from MIIC

rized into approximate quartiles based on distribution. Median family income was categorized as less than \$35,000, \$35,000 to \$40,000, \$40,000 to \$50,000 and more than \$50,000 a year. Percentage of residents living below the federal poverty line was categorized into less than 3%, 3% to 5%, 5% to 8% and more than 8%. Percentage of non-Caucasian residents was categorized as less than 1%, 1% to 2%, 2% to 5%, and more than 5%. ZIP code-level vaccination rates were calculated using 2000 census data ZIP code population estimates for the denominator.

Rural or urban designation was established using Rural-Urban Commuting Area Codes (RUCA), a classification scheme that uses census urbanized area and urban cluster definitions in conjunction with commuting characteristics.⁵ ZIP codes were classified as either urban or rural using RUCA codes.⁵

Analysis

Data cleaning and analysis were done using SAS 9.2 and SAS Enterprise Guide 4. Descriptive statistics were presented to describe the study population and determine vaccination coverage. Chi-square tests were used to identify associations between categorized ZIP code-level H1N1 vaccination rates and ZIP code-level independent variables (urban or rural location, median family income, family poverty rate and

For more information on the statistical methodology used in this study, contact Miriam Muscoplat at miriam.muscoplat@state.mn.us.

minority status). Generalized linear models were used to further explore the relationships between urban or rural location, median family income, family poverty rate and minority status with ZIP code-level H1N1 vaccination rates.

Results

According to the CDC's Behavioral Risk Factor Surveillance System (BRFSS), Minnesota ranked eighth in the nation in terms of the percentage of all eligible residents vaccinated against 2009 H1N1 influenza.⁶ Minnesota was first in vaccine coverage (47%) for persons ages 25 to 64 years with medical conditions that put them at higher risk for influenza-related complications.⁶ Minnesota also led other states in the region (Illinois, Indiana, Michigan, Ohio and Wisconsin) for H1N1 vaccination coverage. For example, Minnesota vaccinated 41% of those in the initial ACIP target group compared with 33% for the region and 33% for the country.⁶ MIIC data showed 23% of eligible people in Minnesota had received at least one dose as of June 22, 2009.

Census 2000 and MIIC data were used to describe statewide population characteristics (age and geographic setting) and vaccination status (Table 1). When data were evaluated at the ZIP code level, there were significant differences in H1N1 vaccination rates based on the percentage of residents living below the family poverty line ($P<0.0001$), the percentage of non-Caucasians ($P=0.0023$) and median family income ($P<0.0001$) (Table 2). There was no statistical difference in the rates of urban versus rural residents ($P=0.189$).

As shown in Table 3, of those vaccinated against 2009 H1N1 ($n=1,221,617$), 27.4% were vaccinated prior to November 30, 2009, when the strictest recommendations were in place. Between November

30 and December 16, 2009, 17.9% were vaccinated, and 54.7% were vaccinated after December 16, 2009, when all of the target group recommendations were lifted. Of those living in an urban setting, 22.6% were vaccinated against 2009 H1N1 whereas 23.0% of those living in a rural setting were vaccinated (Table 1). Private providers in urban areas administered a significantly larger proportion of 2009 H1N1 vaccine than private providers in rural areas (81.5% vs. 53.2%, $P<0.0001$, Table 4).

Location-stratified models identified that associations between H1N1 vaccination rates and family poverty, minority status and median income differed by urban or rural location. In urban locations, higher median family income was

significantly associated with increased vaccination rates ($P=0.0017^*$); whereas other socioeconomic status indicators such as poverty and minority status were not significantly associated with vaccination rates. In rural locations, minority status was significantly associated with higher vaccination rates ($P=0.032^*$), higher median family income was marginally associated with higher H1N1 vaccination rates ($P = 0.064^*$), but poverty was not significantly associated with H1N1 vaccination rates.

* data not shown

TABLE 2

ZIP Code-Level Analysis of Population Characteristics and H1N1 Vaccination Rate

	ZIP CODES WITH VACCINATION RATES <15%	ZIP CODES WITH VACCINATION RATES BETWEEN 15 TO <20%	ZIP CODES WITH VACCINATION RATES BETWEEN 20 TO 25%	ZIP CODES WITH VACCINATION RATES ABOVE 25%	TOTAL	CHI-SQUARE P-VALUE
<i>Of residents below poverty line</i>						
<3.0%	21 (10.1%)	37 (17.9%)	73 (35.3%)	76 (36.7%)	207	
3.0 to <5.0%	31 (15.6%)	39 (19.6%)	78 (39.2%)	51 (25.6%)	199	
5.0 to 8.0%	53 (21.5%)	66 (26.7%)	76 (30.8%)	52 (21.1%)	247	
>8.0%	64 (29.9%)	65 (30.4%)	43 (20.1%)	42 (19.6%)	214	
TOTAL	169	207	270	221	867	<0.0001
<i>Of non-Caucasian residents</i>						
<1.0%	37 (30.8%)	20 (16.7%)	38 (31.7%)	25 (20.8%)	120	
1.0 to <2.0%	43 (18.8%)	69 (30.1%)	57 (24.9%)	60 (26.2%)	229	
2.0 to 5.0%	59 (19.8%)	70 (23.5%)	98 (32.9%)	71 (23.8%)	298	
>5.0%	30 (13.6%)	48 (21.8%)	77 (35.0%)	65 (29.5%)	220	
TOTAL	169	207	270	221	867	0.0023
<i>Median family income</i>						
<\$35,000	80 (29.9%)	80 (29.9%)	59 (22.0%)	49 (18.3%)	268	
\$35,000 to <40,000	56 (23.9%)	65 (27.8%)	60 (25.6%)	53 (22.6%)	234	
\$40,000 to \$50,000	28 (13.9%)	43 (21.3%)	81 (40.1%)	50 (24.8%)	202	
>\$50,000	5 (3.1%)	19 (11.7%)	70 (42.9%)	69 (42.3%)	163	
TOTAL	169	207	270	221	867	<0.0001
<i>Urban/rural area</i>						
Urban	64 (23.3%)	66 (24.0%)	84 (30.5%)	61 (22.2%)	275	
Rural	104 (17.7%)	140 (23.9%)	184 (31.3%)	159 (27.1%)	587	
TOTAL	168	206	268	220	862	0.1893

Discussion

Minnesota has a history of high rates of vaccination for seasonal influenza for both adults and children.⁷⁻⁹ In April 2010, the CDC published research that found a correlation between seasonal influenza coverage and H1N1 coverage among children (r=0.72) and adults (r=0.72).⁸ The authors concluded that these strong correlations suggest factors such as the effectiveness of state and local seasonal influenza vaccination campaigns might partly explain the variation in H1N1 vaccination rates among states.

One of the ways Minnesota’s H1N1 vaccine campaign differed from those of other states was its tiered-approach, first targeting high-risk groups identified by the ACIP. Good compliance with Department of Health recommendations was evident early on in the campaign as the majority of individuals vaccinated prior to November 5 were younger than five years of age. Conversely, more than 75% of per-

sons 25 years of age and older waited until after December 16, 2009, when the health department indicated the general public could be vaccinated.

Communication played an important role in ensuring that members of high-risk groups would be the first to receive the vaccination and making sure there was enough supply before expanding to other groups. The health department maintained consistent recommendations and communicated them to providers (primarily by email) and through weekly conference calls with local public health agencies. Feedback from local providers about vaccine usage and availability was critical to state decision makers responsible for expanding the recommendations. Asking certain segments of the population to wait for immunization was a departure from what had been done during previous flu seasons. In particular, it was highly unusual to ask persons older than 65 years of age to wait for their vaccine. It is possible that Minnesota’s staged approach created

a demand for vaccine that outlasted the demand experienced by other parts of the country. This may have helped increase coverage.

According to MIIC data, 23.0% of eligible Minnesotans received at least one dose of H1N1 vaccine. The rate of H1N1 immunization was similar in urban and rural settings (22.6% vs. 23.0%, respectively). In both urban and rural communities, the majority of H1N1 vaccinations were given in private settings (clinics, hospitals, nursing homes, long-term care facilities, pharmacies, etc.), although the percentage of people who received the vaccine in those settings was much higher in urban ZIP codes than rural ones (81.5% vs. 53.2%, respectively). This difference in where people in urban and rural areas received their vaccines underscores the need to tailor pandemic planning to the realities of local populations and infrastructure.

TABLE 3

2009 H1N1 Vaccination Coverage by Date of First Dose and Age at Vaccination

DATE OF FIRST H1N1 VACCINATION	AGE AT FIRST H1N1 VACCINATION			TOTAL
	< 5 YEARS	5-24 YEARS	≥25 YEARS	
Before November 30, 2009	94,704 (57.1%)	106,902 (34.0%)	132,700 (17.9%)	334,306 (27.4%)
November 30, 2009 to December 16, 2009	27,294 (16.5%)	84,242 (26.8%)	107,503 (14.5%)	219,039 (17.9%)
After December 16, 2009	43,924 (6.6%)	123,208 (18.4%)	501,140 (75.0%)	668,272 (54.7%)
	165,922	314,352	741,343	1,221,617

TABLE 4

Type of Organization Providing 2009 H1N1 Vaccination by Urban or Rural Setting

TYPE OF PROVIDER ORGANIZATION	URBAN	RURAL	TOTAL
Tribal/IHS	2,989 (0.3%)	8,149 (2.0%)	11,138 (0.8%)
Public health/community vaccinators	163,416 (18.0%)	186,680 (44.7%)	350,096 (26.4%)
Correctional facilities	1,720 (0.2%)	867 (0.2%)	2,587 (0.2%)
Clinics, hospitals, nursing homes, long-term care facilities, pharmacies, etc.*	738,880 (81.5%)	222,097 (53.2%)	960,977 (72.5%)
Total	907,005	417,793	1,324,798

*Significant difference when compared with all other providers.

Rural/Urban Status and H1N1 Vaccination

Our study did not find a significant difference between H1N1 vaccination rates in urban and rural settings in the unadjusted analysis (Table 2). However, in a multiple regression analysis, two distinct models emerged to describe the factors associated with receipt of H1N1 vaccine in various settings. In urban settings, ZIP codes with higher median income levels predicted H1N1 vaccination after adjusting for poverty and minority status. In rural settings, people living in ZIP codes with a higher percentage of non-Caucasian residents were more likely to be vaccinated after controlling for poverty and median income.

Income/Economics and H1N1 Vaccination

The relationship between family income and seasonal influenza vaccination has been documented in the scientific literature. Linn et al. found influenza vaccination rates increased with household income and education level in their study of 2008 influenza vaccination.¹⁰ The fact that H1N1 vaccine was available at no cost to everyone makes interpretation of this finding more challenging. A study published in 2011 by Galarce et al. found no statistical difference in H1N1 vaccine uptake between those living above and below the federal poverty level.¹¹ As noted earlier, the majority of H1N1 vaccines (81.5%) administered in urban communities in Minnesota were given in private facilities. It is likely that persons who receive care in private clinics and other facilities have higher median incomes and had less difficulty accessing the H1N1 vaccine, particularly in urban areas.

Race/Ethnicity and H1N1 Vaccination

Our finding that rural ZIP codes with higher percentages of minority residents had higher mean vaccination rates differs from the results of most previous studies. Many have found just the opposite, that non-Hispanic whites have a higher rate of influenza vaccination compared with

members of other racial and ethnic minority groups.^{10,12-15} Frew et al. found low pediatric influenza vaccination acceptance among minority parents.¹⁶ And Galarce found that blacks were the racial or ethnic group least likely to believe the H1N1 vaccine was safe.¹¹ Unfortunately, our ability to examine the relationship between vaccine rates and race/ethnicity is limited because the data are not available in MIIC.

Several reasons may explain the success in vaccinating members of vulnerable and minority populations in rural Minnesota. For one thing, rural areas have more public health clinics per capita than urban areas. In addition, the population in Minnesota's rural areas is less diverse, as these areas have fewer residents who are members of racial and ethnic minorities than urban areas. This can make outreach to them easier. Also the fact the Tribal or Indian Health Service clinics in those areas vaccinated more individuals than the Tribal and Indian Health Service clinics in urban parts of Minnesota may help explain the success (Table 4, 2.0% vs. 0.3%, respectively). According to Census 2000 data, 53.2% of Native Americans in Minnesota live in rural ZIP codes.⁵

Limitations

Our study had several limitations. First, ZIP code census data represent an average of all individuals living within a geographic area and may not reflect the racial and economic characteristics of all of its residents. Second, although the most recent data were used, the ZIP code level census data came from the 2000 census. In the nine years between census 2000 and the 2009 H1N1 pandemic, the racial and economic makeup of geographic areas may have changed. Census data were used as the denominator to determine vaccination rate, as MIIC may overestimate the population younger than 18 years of age and underestimate those older than 18 who received the vaccine. MIIC rates are calculations rather than estimates, and they are often lower than those from the National Immunization Survey or the BRFSS. They also are influenced by provider participation in the registry.

Although provider participation is quite high in Minnesota (85% to 90%), not all providers report all shots given.

Conclusion

H1N1 vaccination rates seemed to be influenced by minority status, family income level and urban/rural location. It is not clear why minority status in rural areas was associated with increased immunization rates. Further research is needed to determine if the difference is due to the make-up of the minority populations or if other socioeconomic factors are responsible. Increased H1N1 vaccination rates were associated with higher median income in urban areas. This may be because families with higher median incomes in those areas were more likely to have access to health care. Again, further research is needed to explain this finding. Although a centralized system of vaccine distribution that relied heavily on the private sector worked well in Minnesota during the 2009 H1N1 influenza pandemic, work is needed to make sure the coverage gaps that existed are addressed when planning for a future pandemic. **MM**

Miriam Halstead Muscoplat, Margaret Roddy, Elizabeth Parilla, Karen White and Kristen Ehresmann are with the Minnesota Department of Health. Cynthia S. Davey is with the Biostatistical Design and Analysis Center at the University of Minnesota. Laura Fleege was with the Minnesota Department of Health.

The biostatistical components described were supported by Grant Number UL1RR024150 from the National Center for Research Resources, National Institutes of Health (NIH). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

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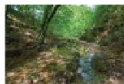
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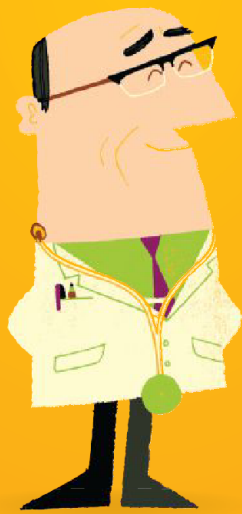
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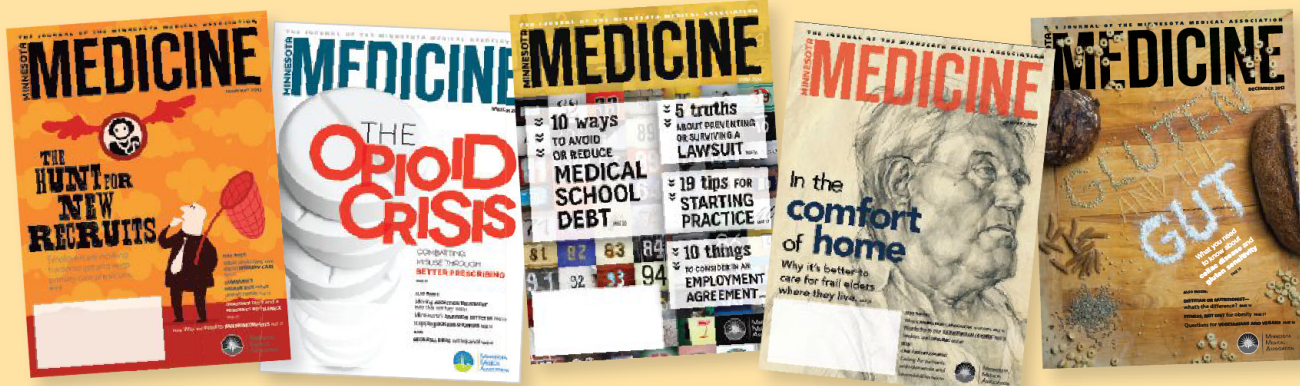
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PAGING STEVE JOBS ...

Can someone build a better EHR?

BY JON HALLBERG, M.D.

One year ago, I made the switch from one electronic health record (EHR) system to another. I had been using the old EHR for nearly nine years and had grown comfortable with it. Although it wasn't perfect and needed some serious upgrades, it got the job done and I knew its limitations. But the system we were using was different from the one our partner hospital was using. It no longer made sense to continue with two different EHRs. We *had* to be on the same electronic page.

My clinic was among the last cluster of clinics in our group to make the switch. Although theoretically many of the glitches and kinks had been worked out of the system before we made the change, we still heard grumbling about the difficult, painful process of going from the old EHR system to the new one. Despite that, I went into the process with an open mind.

Last August, I attended my first instructional session on the new system. From the moment I logged on and read that I was “jumping to hyperspace,” my open mind narrowed. When my homepage popped up for the first time, I stared at the screen. My eyes darted from three rows of multi-colored tabs at the top to more tabs and columns of words in a small font size along the left-hand side. I tried to make sense of this visual mess, but there was no logical place for my eyes to fall.

As we started interacting with the system (ordering lab tests, documenting encounters), it became clear there were multiple ways of doing the same thing. Nothing seemed intuitive or logical. My



frustration and cynicism grew. I didn't want to dislike (or hate) the new system, despite everything I'd heard, but I began to resent it—deeply. It felt like I was in an arranged marriage with no hope of learning to love my new life-partner. I was rapidly falling into a kind of e-depression.

A year later, I've made peace with this system. For a guy who really doesn't know how to type quickly or correctly (I regret blowing off that summer school typing class), I've developed some finger memory. I know where to look, what to click, how to code and link and task and review. But it's still painful, and I spend much more time on my computer than before—a common complaint, regardless of which EHR system one uses. Caring for patients, it seems, has become a combination of court reporting (with someone constantly typing at a keyboard or clicking a mouse during an encounter) and the carnival game Whac-A-Mole (where the object is to hit a “mole” on the head with a hammer every time it pops up through a random hole—or in our case, clicking off tasks as they constantly and randomly appear in our virtual in-baskets).

It felt like I was in an arranged marriage with no hope of learning to love my new life-partner. I was rapidly falling into a kind of e-depression.

There *has* to be a better way. Surely someone somewhere is capable of creating a method for documenting and coding and billing that isn't so cumbersome and time-consuming. Which leads me to ask: Where is the Steve Jobs of the EHR world? Where is that person who knows what we want before *we* know what we want? That person who understands simplicity and elegance and knows where to cut and pare? That person who's maniacal about doing the right thing—and getting it right before a product is released? That person who knows the value of combining art and science into the DNA of a product or company, creating something both useful *and* beautiful? I have to believe—I *want* to believe—that someone somewhere is cooking up something insanely great, that someone understands what it means—what it *truly* means—to “think different” in the world of electronic health records. **MM**

Jon Hallberg is medical director of University of Minnesota Physicians' Mill City Clinic in Minneapolis.

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