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WMJ

volume 110 · no. 4 · august 2011

Education & Work

finding the right balance for student success

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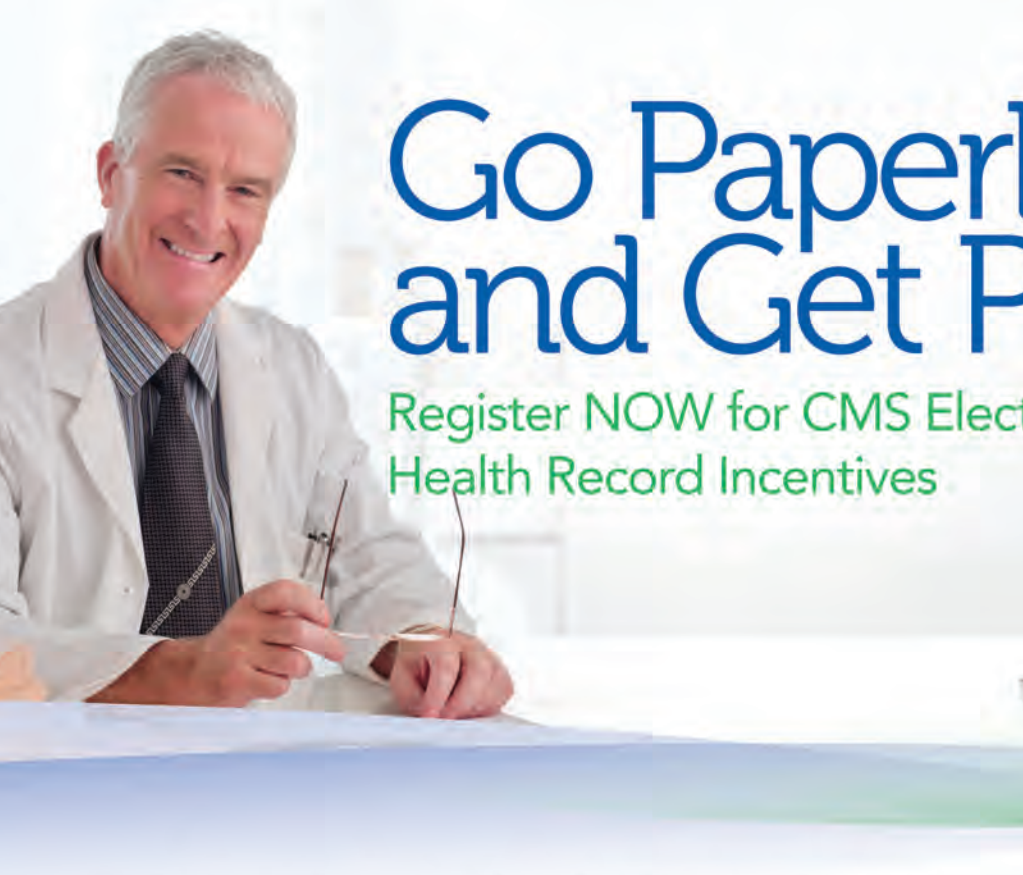

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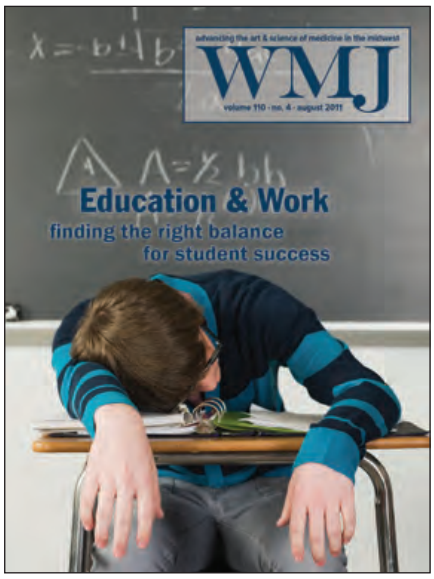
Volume 110, no. 4 • August 2011

WMJ



COVER THEME
Education & Work: finding the right balance for student success

As the school year gets under way throughout the Midwest, many students work to juggle academics and jobs—some with more success than others. A study in this issue of *WMJ* examines the effect working can have on student health, performance, and safety.

Cover design by Mary Kay Adams-Edgette.

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

advancing the art & science of medicine in the midwest

YOUR PROFESSION

The *WMJ* (ISSN 1098-1861) is published by the Wisconsin Medical Society and is devoted to the interests of the medical profession and health care in the Midwest. The managing editor is responsible for overseeing the production, business operation and contents of the *WMJ*. The editorial board, chaired by the medical editor, solicits and peer reviews all scientific articles; it does not screen public health, socioeconomic, or organizational articles. All articles published herein, including commentaries, letters to the editor and editorials represent the views of the authors, for which neither *WMJ* nor the Wisconsin Medical Society take responsibility, unless clearly stated. Advertising content is the responsibility advertiser and does not imply an endorsement or sponsorship by *WMJ* or the Wisconsin Medical Society and its affiliates unless specified. *WMJ* is indexed in Index Medicus, Hospital Literature Index, and Cambridge Scientific Abstracts.

Send manuscripts to *WMJ*, 330 E Lakeside St, Madison, WI 53715. Instructions to authors are available at www.wmjonline.org, call 866.442.3800, or e-mail wmj@wismed.org.

SUBSCRIPTION RATES
Members: included in membership dues. Non-members: $149. Current year single copies, $25 each. Previous years' single copies, when available, $12 each.

Periodical postage paid in Madison, Wis, and additional mailing offices.

Published every other month, beginning in February. Acceptance for mailing at special rate of postage provided for in Section 1103, Act of October 3, 1917. Authorized August 7, 1918.

Address all correspondence to *WMJ*, PO Box 1109, Madison, WI 53701. Street address: 330 E Lakeside St, Madison, WI 53715; e-mail: WMJ@wismed.org

POSTMASTER
Send address changes to: WMJ, PO Box 1109, Madison, WI 53701

ISSN 1098-1861
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DULERA is indicated for the treatment of asthma in patients 12 years of age and older.

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DULERA is NOT indicated for the relief of acute bronchospasm.

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Selected Important Safety Information about DULERA

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA), such as formoterol, one of the active ingredients in DULERA, increase the risk of asthma-related death. Data from a large placebo-controlled U.S. study that compared the safety of another LABA (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of the LABA, including formoterol. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients.

When treating patients with asthma, prescribe DULERA only for patients with asthma not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid, or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue DULERA) if possible without loss of asthma control, and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use DULERA for patients whose asthma is adequately controlled on low or medium dose inhaled corticosteroids.

Please read Brief Summary of the Prescribing Information, including Boxed Warning about asthma-related death, on following pages.

DULERA is indicated for the treatment of asthma in patients 12 years of age and older.
DULERA is NOT indicated for the relief of acute bronchospasm.

Consider DULERA

IN A CLINICAL STUDY WITH DULERA 100 mcg/5 mcg*

- Patients experienced significant improvement in lung function (FEV_1 AUC [0-12 hr]) at Week 12 (co-primary endpoint) that was maintained through Week 26 (versus patients on mometasone furoate 100 mcg).[1]
- Significantly fewer patients experienced clinically judged deterioration in asthma or reductions in lung function† through Week 26 (versus patients on formoterol fumarate 5 mcg).[1]
- Patients experienced significant reduction versus patients on placebo in total SABA use and in proportion of nights with nocturnal awakenings.[1]
- Metered-dose inhaler comes in 2 dosage strengths with an integrated numeric dose counter.

Selected Important Safety Information about DULERA

- DULERA is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. DULERA is contraindicated in patients with known hypersensitivity to any of the ingredients in DULERA.
- DULERA is NOT a rescue medication and does NOT replace fast-acting inhalers to treat acute symptoms. Increasing use of inhaled, short-acting $beta_2$-agonists is a marker for deteriorating asthma. In this situation, the patient requires immediate re-evaluation with reassessment of the treatment regimen.
- Patients using DULERA should not use additional formoterol or other long-acting inhaled $beta_2$-agonists for any reason.
- Oropharyngeal candidiasis may occur. If candidiasis develops, it should be treated with appropriate antifungal therapy, but at times therapy with DULERA may need to be interrupted. Advise patients to rinse the mouth after inhalation.
- DULERA should be used with caution in patients with tuberculosis, fungal, bacterial, viral (including chickenpox or measles), or parasitic infections; or ocular herpes simplex infections because of the potential for worsening of these infections. A more serious or even fatal course of chickenpox or measles can occur in susceptible patients.
- Particular care is needed for patients who are transferred from systemically active corticosteroids to DULERA. Deaths due to adrenal insufficiency have occurred in asthmatic patients during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids.
- Hypercorticism and adrenal suppression may occur with very high dosages of DULERA or at the regular dosage in susceptible individuals. Patients treated with DULERA should be observed carefully for any evidence of systemic corticosteroid effects. If such changes occur, discontinue DULERA slowly.
- Caution should be exercised when considering the coadministration of DULERA with long-term ketoconazole and other known strong CYP3A4 inhibitors, or in patients being treated with MAO inhibitors or tricyclic antidepressants.
- Discontinue DULERA and institute alternative therapy if paradoxical bronchospasm occurs.
- Excessive beta-adrenergic stimulation has been associated with central nervous system and cardiovascular effects. DULERA should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.
- Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids, including mometasone furoate, a component of DULERA.

Reference: 1. Nathan RA, Nolte H, Pearlman DS; for P04334 Study Investigators. Twenty-six-week efficacy and safety study of mometasone furoate/formoterol 200/10 µg combination treatment in patients with persistent asthma previously receiving medium-dose inhaled corticosteroids. *Allergy Asthma Proc.* 2010;31(4):269-279.

Please read Brief Summary of the Prescribing Information, including Boxed Warning about asthma-related death, on following pages.

*In a 26-week, placebo-controlled study of 781 patients 12 years of age and older comparing DULERA 100 mcg/5 mcg (n=191), mometasone furoate 100 mcg (n=192), formoterol fumarate 5 mcg (n=202), and placebo (n=196), each administered as 2 inhalations twice daily by metered-dose inhalation aerosols. All other maintenance therapies were discontinued. This study included a 2- to 3-week run-in period with mometasone furoate 100 mcg, 2 inhalations twice daily. Patients had persistent asthma that was not well controlled on a medium dose of ICS prior to randomization. All treatment groups were balanced with regard to baseline characteristics.[1]

The co-primary endpoints were FEV_1 AUC (0-12 hr) and clinically judged deterioration in asthma or reductions in lung function.[1]

†Deteriorations in asthma (any one of these asthma events)[1]:

- FEV_1 decrease of 20%
- PEF decrease of 30% on 2 or more consecutive days
- Emergency treatment, hospitalization, or treatment with systemic corticosteroids or other asthma medications not allowed per protocol

AUC=area under the curve; FEV_1=forced expiratory volume in 1 second; ICS=inhaled corticosteroid; PEF=peak expiratory flow; SABA=short-acting $beta_2$-adrenergic agonist.

Patients with major risk factors for decreased BMD should be monitored and treated with established standards of care.

- Inhaled corticosteroids, including DULERA, may cause a reduction in growth velocity when administered in pediatric patients.
- Glaucoma, increased intraocular pressure, and cataracts have been reported following the use of long-term inhaled corticosteroids, including mometasone furoate, a component of DULERA.
- DULERA, like other medications containing sympathomimetic amines, should be used with caution in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually responsive to sympathomimetic amines. Doses of the related $beta_2$-agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.
- Be alert to hypokalemia and hyperglycemia as $beta_2$-agonist medications such as DULERA have the potential to produce adverse cardiovascular effects.
- The most common treatment-emergent adverse events reported in ≥3% of patients and more common than placebo included nasopharyngitis, sinusitis, and headache.
- Dysphonia was reported in a longer-term treatment trial at an incidence of 5% in patients receiving DULERA 100 mcg/5 mcg and 3.8% in patients receiving DULERA 200 mcg/5 mcg.

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DULERA®

(mometasone furoate and formoterol fumarate dihydrate) Inhalation Aerosol

BRIEF SUMMARY (For full Prescribing Information, see package insert.)

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA), such as formoterol, one of the active ingredients in DULERA, increase the risk of asthma-related death. Data from a large placebo-controlled U.S. study that compared the safety of another long-acting beta$_2$-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of the LABA, including formoterol. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, DULERA should only be used for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue DULERA) if possible without loss of asthma control, and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use DULERA for patients whose asthma is adequately controlled on low or medium dose inhaled corticosteroids. ***[See Warnings and Precautions (5.1)]***

1 INDICATIONS AND USAGE

1.1 Treatment of Asthma

DULERA is indicated for the treatment of asthma in patients 12 years of age and older.

Long-acting beta$_2$-adrenergic agonists, such as formoterol, one of the active ingredients in DULERA, increase the risk of asthma-related death. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients *[see Warnings and Precautions (5.1)]*. Therefore, when treating patients with asthma, DULERA should only be used for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue DULERA) if possible without loss of asthma control, and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use DULERA for patients whose asthma is adequately controlled on low or medium dose inhaled corticosteroids.

Important Limitation of Use

- DULERA is NOT indicated for the relief of acute bronchospasm.

4 CONTRAINDICATIONS

4.1 Status Asthmaticus

DULERA is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.

4.2 Hypersensitivity

DULERA is contraindicated in patients with known hypersensitivity to mometasone furoate, formoterol fumarate, or any of the ingredients in DULERA *[see Warnings and Precautions (5.10)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Asthma-Related Death

Long-acting beta$_2$-adrenergic agonists, such as formoterol, one of the active ingredients in DULERA, increase the risk of asthma-related death. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, physicians should only prescribe DULERA for patients with asthma not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue DULERA) if possible without loss of asthma control, and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use DULERA for patients whose asthma is adequately controlled on low or medium dose inhaled corticosteroids.

A 28-week, placebo-controlled US study comparing the safety of salmeterol with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in patients receiving salmeterol (13/13,176 in patients treated with salmeterol vs. 3/13,179 in patients treated with placebo; RR 4.37, 95% CI 1.25, 15.34). This finding with salmeterol is considered a class effect of the LABAs, including formoterol, one of the active ingredients in DULERA. No study adequate to determine whether the rate of asthma-related death is increased with DULERA has been conducted.

Clinical studies with formoterol suggested a higher incidence of serious asthma exacerbations in patients who received formoterol fumarate than in those who received placebo. The sizes of these studies were not adequate to precisely quantify the differences in serious asthma exacerbation rates between treatment groups.

5.2 Deterioration of Disease and Acute Episodes

DULERA should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of asthma. DULERA has not been studied in patients with acutely deteriorating asthma. The initiation of DULERA in this setting is not appropriate.

Increasing use of inhaled, short-acting beta$_2$-agonists is a marker of deteriorating asthma. In this situation, the patient requires immediate re-evaluation with reassessment of the treatment regimen, giving special consideration to the possible need for replacing the current strength of DULERA with a higher strength, adding additional inhaled corticosteroid, or initiating systemic corticosteroids. Patients should not use more than 2 inhalations twice daily (morning and evening) of DULERA.

DULERA is not indicated for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. An inhaled, short-acting beta$_2$-agonist, not DULERA, should be used to relieve acute symptoms such as shortness of breath. When prescribing DULERA, the physician must also provide the patient with an inhaled, short-acting beta$_2$-agonist (e.g., albuterol) for treatment of acute symptoms, despite regular twice-daily (morning and evening) use of DULERA.

When beginning treatment with DULERA, patients who have been taking oral or inhaled, short-acting beta$_2$-agonists on a regular basis (e.g., 4 times a day) should be instructed to discontinue the regular use of these drugs.

5.3 Excessive Use of DULERA and Use with Other Long-Acting Beta$_2$-Agonists

As with other inhaled drugs containing beta$_2$-adrenergic agents, DULERA should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medications containing long-acting beta$_2$-agonists, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using DULERA should not use an additional long-acting beta$_2$-agonist (e.g., salmeterol, formoterol fumarate, arformoterol tartrate) for any reason, including prevention of exercise-induced bronchospasm (EIB) or the treatment of asthma.

5.4 Local Effects

In clinical trials, the development of localized infections of the mouth and pharynx with *Candida albicans* have occurred in patients treated with DULERA. If oropharyngeal candidiasis develops, it should be treated with appropriate local or systemic (i.e., oral) antifungal therapy while remaining on treatment with DULERA therapy, but at times therapy with DULERA may need to be interrupted. Advise patients to rinse the mouth after inhalation of DULERA.

5.5 Immunosuppression

Persons who are using drugs that suppress the immune system are more susceptible to infections than healthy individuals.

Chickenpox and measles, for example, can have a more serious or even fatal course in susceptible children or adults using corticosteroids. In such children or adults who have not had these diseases or who are not properly immunized, particular care should be taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affect the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered.

DULERA should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract, untreated systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

5.6 Transferring Patients from Systemic Corticosteroid Therapy

Particular care is needed for patients who are transferred from systemically active corticosteroids to DULERA because deaths due to adrenal insufficiency have occurred in asthmatic patients during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. After withdrawal from systemic corticosteroids, a number of months are required for recovery of hypothalamic-pituitary-adrenal (HPA) function.

Patients who have been previously maintained on 20 mg or more per day of prednisone (or its equivalent) may be most susceptible, particularly when their systemic corticosteroids have been almost completely withdrawn. During this period of HPA suppression, patients may exhibit signs and symptoms of adrenal insufficiency when exposed to trauma, surgery, or infection (particularly gastroenteritis) or other conditions associated with severe electrolyte loss. Although DULERA may improve control of asthma symptoms during these episodes, in

recommended doses it supplies less than normal physiological amounts of corticosteroid systemically and does NOT provide the mineralocorticoid activity necessary for coping with these emergencies.

During periods of stress or severe asthma attack, patients who have been withdrawn from systemic corticosteroids should be instructed to resume oral corticosteroids (in large doses) immediately and to contact their physicians for further instruction. These patients should also be instructed to carry a medical identification card indicating that they may need supplementary systemic corticosteroids during periods of stress or severe asthma attack.

Patients requiring systemic corticosteroids should be weaned slowly from systemic corticosteroid use after transferring to DULERA. Lung function (FEV_1 or PEF), beta-agonist use, and asthma symptoms should be carefully monitored during withdrawal of systemic corticosteroids. In addition to monitoring asthma signs and symptoms, patients should be observed for signs and symptoms of adrenal insufficiency such as fatigue, lassitude, weakness, nausea and vomiting, and hypotension.

Transfer of patients from systemic corticosteroid therapy to DULERA may unmask allergic conditions previously suppressed by the systemic corticosteroid therapy, e.g., rhinitis, conjunctivitis, eczema, arthritis, and eosinophilic conditions.

During withdrawal from oral corticosteroids, some patients may experience symptoms of systemically active corticosteroid withdrawal, e.g., joint and/or muscular pain, lassitude, and depression, despite maintenance or even improvement of respiratory function.

5.7 Hypercorticism and Adrenal Suppression

Mometasone furoate, a component of DULERA, will often help control asthma symptoms with less suppression of HPA function than therapeutically equivalent oral doses of prednisone. Since mometasone furoate is absorbed into the circulation and can be systemically active at higher doses, the beneficial effects of DULERA in minimizing HPA dysfunction may be expected only when recommended dosages are not exceeded and individual patients are titrated to the lowest effective dose.

Because of the possibility of systemic absorption of inhaled corticosteroids, patients treated with DULERA should be observed carefully for any evidence of systemic corticosteroid effects. Particular care should be taken in observing patients postoperatively or during periods of stress for evidence of inadequate adrenal response.

It is possible that systemic corticosteroid effects such as hypercorticism and adrenal suppression (including adrenal crisis) may appear in a small number of patients, particularly when mometasone furoate is administered at higher than recommended doses over prolonged periods of time. If such effects occur, the dosage of DULERA should be reduced slowly, consistent with accepted procedures for reducing systemic corticosteroids and for management of asthma symptoms.

5.8 Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors

Caution should be exercised when considering the coadministration of DULERA with ketoconazole, and other known strong CYP3A4 inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, telithromycin) because adverse effects related to increased systemic exposure to mometasone furoate may occur *[see Drug Interactions (7.1) and Clinical Pharmacology (12.3)]*.

5.9 Paradoxical Bronchospasm and Upper Airway Symptoms

DULERA may produce inhalation induced bronchospasm with an immediate increase in wheezing after dosing that may be life-threatening. If inhalation induced bronchospasm occurs, it should be treated immediately with an inhaled, short-acting inhaled bronchodilator. DULERA should be discontinued immediately and alternative therapy instituted.

5.10 Immediate Hypersensitivity Reactions

Immediate hypersensitivity reactions may occur after administration of DULERA, as demonstrated by cases of urticaria, flushing, allergic dermatitis, and bronchospasm.

5.11 Cardiovascular and Central Nervous System Effects

Excessive beta-adrenergic stimulation has been associated with seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, palpitation, nausea, dizziness, fatigue, malaise, and insomnia. Therefore, DULERA should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Formoterol fumarate, a component of DULERA, can produce a clinically significant cardiovascular effect in some patients as measured by pulse rate, blood pressure, and/or symptoms. Although such effects are uncommon after administration of DULERA at recommended doses, if they occur, the drug may need to be discontinued. In addition, beta-agonists have been reported to produce ECG changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression. The clinical significance of these findings is unknown. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.

5.12 Reduction in Bone Mineral Density

Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids, including mometasone furoate, one of the components of DULERA. The clinical significance of small changes in BMD with regard to long-term outcomes, such as fracture, is unknown. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants and corticosteroids) should be monitored and treated with established standards of care.

In a 2-year double-blind study in 103 male and female asthma patients 18 to 50 years of age previously maintained on bronchodilator therapy (Baseline FEV_1 85%-88% predicted), treatment with mometasone furoate dry powder inhaler 200 mcg twice daily resulted in significant reductions in lumbar spine (LS) BMD at the end of the treatment period compared to placebo. The mean change from Baseline to Endpoint in the lumbar spine BMD was -0.015 (-1.43%) for the mometasone furoate group compared to 0.002 (0.25%) for the placebo group. In another 2-year double-blind study in 87 male and female asthma patients 18 to 50 years of age previously maintained on bronchodilator therapy (Baseline FEV_1 82%-83% predicted), treatment with mometasone furoate 400 mcg twice daily demonstrated no statistically significant changes in lumbar spine BMD at the end of the treatment period compared to placebo. The mean change from Baseline to Endpoint in the lumbar spine BMD was -0.018 (-1.57%) for the mometasone furoate group compared to -0.006 (-0.43%) for the placebo group.

5.13 Effect on Growth

Orally inhaled corticosteroids, including DULERA, may cause a reduction in growth velocity when administered to pediatric patients. Monitor the growth of pediatric patients receiving DULERA routinely (e.g., via stadiometry). To minimize the systemic effects of orally inhaled corticosteroids, including DULERA, titrate each patient's dose to the lowest dosage that effectively controls his/her symptoms *[see Use in Specific Populations (8.4)]*.

5.14 Glaucoma and Cataracts

Glaucoma, increased intraocular pressure, and cataracts have been reported following the use of long-term administration of inhaled corticosteroids, including mometasone furoate, a component of DULERA. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts *[see Adverse Reactions (6)]*.

5.15 Coexisting Conditions

DULERA, like other medications containing sympathomimetic amines, should be used with caution in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually responsive to sympathomimetic amines. Doses of the related $beta_2$-agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

5.16 Hypokalemia and Hyperglycemia

$Beta_2$-agonist medications may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. Clinically significant changes in blood glucose and/or serum potassium were seen infrequently during clinical studies with DULERA at recommended doses.

6 ADVERSE REACTIONS

Long-acting $beta_2$-adrenergic agonists, such as formoterol, one of the active ingredients in DULERA, increase the risk of asthma-related death. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Data from a large placebo-controlled US trial that compared the safety of another long-acting $beta_2$-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol *[see Warnings and Precautions (5.1)]*.

Systemic and local corticosteroid use may result in the following:

- *Candida albicans* infection *[see Warnings and Precautions (5.4)]*
- Immunosuppression *[see Warnings and Precautions (5.5)]*
- Hypercorticism and adrenal suppression *[see Warnings and Precautions (5.7)]*
- Growth effects in pediatrics *[see Warnings and Precautions (5.13)]*
- Glaucoma and cataracts *[see Warnings and Precautions (5.14)]*

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.

6.1 Clinical Trials Experience

The safety data described below is based on 3 clinical trials which randomized 1913 patients 12 years of age and older with asthma, including 679 patients exposed to DULERA for 12 to 26 weeks and 271 patients exposed for 1 year. DULERA was studied in two placebo- and active-controlled trials (n=781 and n=728, respectively) and in a long term 52-week safety trial (n=404). In the 12 to 26-week clinical trials, the population was 12 to 84 years of age, 41% male and 59% female; 73% Caucasians, 27% non-Caucasians. Patients received two inhalations twice daily of DULERA (100 mcg/5 mcg or 200 mcg/5 mcg), mometasone furoate MDI (100 mcg or 200 mcg), formoterol MDI (5 mcg) or placebo. In the long term 52-week active-comparator safety trial, the population was 12 years to 75 years of age with asthma, 37% male and 63% female, 47% Caucasians, 53% non-Caucasians and received two inhalations twice daily of DULERA 100 mcg/5 mcg or 200 mcg/5 mcg, or an active comparator.

The incidence of treatment emergent adverse reactions associated with DULERA in Table 2 below is based upon pooled data from 2 clinical trials 12 to 26-week in duration in patients 12 years and older treated with two inhalations twice daily of DULERA (100 mcg/5 mcg or 200 mcg/5 mcg), mometasone furoate MDI (100 mcg or 200 mcg), formoterol MDI (5mcg) or placebo.

Table 2: Treatment-emergent adverse reactions in DULERA groups occurring at an incidence of ≥3% and more commonly than placebo

Adverse Reactions	DULERA*		Mometasone Furoate*		Formoterol*	Placebo*
	100 mcg/ 5 mcg n=424 n (%)	200 mcg/ 5 mcg n=255 n (%)	100 mcg n=192 n (%)	200 mcg n=240 n (%)	5 mcg n=202 n (%)	n=196 n (%)
Nasopharyngitis	20 (4.7)	12 (4.7)	15 (7.8)	13 (5.4)	13 (6.4)	7 (3.6)
Sinusitis	14 (3.3)	5 (2.0)	6 (3.1)	4 (1.7)	7 (3.5)	2 (1.0)
Headache	19 (4.5)	5 (2.0)	10 (5.2)	8 (3.3)	6 (3.0)	7 (3.6)
Average Duration of Exposure (days)	116	81	165	79	131	138

*All treatments were administered as two inhalations twice daily.

Oral candidiasis has been reported in clinical trials at an incidence of 0.7% in patients using DULERA 100 mcg/5 mcg, 0.8 % in patients using DULERA 200 mcg/5 mcg and 0.5 % in the placebo group.

Long Term Clinical Trial Experience

In a long term safety trial in patients 12 years and older treated for 52 weeks with DULERA 100 mcg/5 mcg (n=141), DULERA 200 mcg/5 mcg (n=130) or an active comparator (n=133), safety outcomes in general were similar to those observed in the shorter 12 to 26 week controlled trials. No asthma-related deaths were observed. Dysphonia was observed at a higher frequency in the longer term treatment trial at a reported incidence of 7/141 (5%) patients receiving DULERA 100 mcg/5 mcg and 5/130 (3.8%) patients receiving DULERA 200 mcg/5 mcg. No clinically significant changes in blood chemistry, hematology, or ECG were observed.

7 DRUG INTERACTIONS

In clinical trials, concurrent administration of DULERA and other drugs, such as short-acting beta$_2$-agonist and intranasal corticosteroids have not resulted in an increased frequency of adverse drug reactions. No formal drug interaction studies have been performed with DULERA. The drug interactions of the combination are expected to reflect those of the individual components.

7.1 Inhibitors of Cytochrome P450 3A4

The main route of metabolism of corticosteroids, including mometasone furoate, a component of DULERA, is via cytochrome P450 (CYP) isoenzyme 3A4 (CYP3A4). After oral administration of ketoconazole, a strong inhibitor of CYP3A4, the mean plasma concentration of orally inhaled mometasone furoate increased. Concomitant administration of CYP3A4 inhibitors may inhibit the metabolism of, and increase the systemic exposure to, mometasone furoate. Caution should be exercised when considering the coadministration of DULERA with long-term ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, telithromycin) *[see Warnings and Precautions (5.8) and Clinical Pharmacology (12.3)]*.

7.2 Adrenergic agents

If additional adrenergic drugs are to be administered by any route, they should be used with caution because the pharmacologically predictable sympathetic effects of formoterol, a component of DULERA, may be potentiated.

7.3 Xanthine derivatives

Concomitant treatment with xanthine derivatives may potentiate any hypokalemic effect of formoterol, a component of DULERA.

7.4 Diuretics

Concomitant treatment with diuretics may potentiate the possible hypokalemic effect of adrenergic agonists. The ECG changes and/or hypokalemia that may result from the administration of non-potassium sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the coadministration of DULERA with non-potassium sparing diuretics.

7.5 Monoamine oxidase inhibitors, tricyclic antidepressants, and drugs known to prolong the QTc interval

DULERA should be administered with caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval or within 2 weeks of discontinuation of such agents, because the action of formoterol, a component of DULERA, on the cardiovascular system may be potentiated by these agents. Drugs that are known to prolong the QTc interval have an increased risk of ventricular arrhythmias.

7.6 Beta-adrenergic receptor antagonists

Beta-adrenergic receptor antagonists (beta-blockers) and formoterol may inhibit the effect of each other when administered concurrently. Beta-blockers not only block the therapeutic effects of beta$_2$-agonists, such as formoterol, a component of DULERA, but may produce severe bronchospasm in patients with asthma. Therefore, patients with asthma should not normally be treated with beta-blockers. However, under certain circumstances, e.g., as prophylaxis after myocardial infarction, there may be no acceptable alternatives to the use of beta-blockers in patients with asthma. In this setting, cardioselective beta-blockers could be considered, although they should be administered with caution.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

DULERA: Teratogenic Effects: Pregnancy Category C

There are no adequate and well-controlled studies of DULERA, mometasone furoate only or formoterol fumarate only in pregnant women. Animal reproduction studies of mometasone furoate and formoterol in mice, rats, and/or rabbits revealed evidence of teratogenicity as well as other developmental toxic effects. Because animal reproduction studies are not always predictive of human response, DULERA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Mometasone Furoate: Teratogenic Effects

When administered to pregnant mice, rats, and rabbits, mometasone furoate increased fetal malformations and decreased fetal growth (measured by lower fetal weights and/or delayed ossification). Dystocia and related complications were also observed when mometasone furoate was administered to rats late in gestation. However, experience with oral corticosteroids suggests that rodents are more prone to teratogenic effects from corticosteroid exposure than humans.

In a mouse reproduction study, subcutaneous mometasone furoate produced cleft palate at approximately one-third of the maximum recommended daily human dose (MRHD) on a mcg/m^2 basis and decreased fetal survival at approximately 1 time the MRHD. No toxicity was observed at approximately one-tenth of the MRHD on a mcg/m^2 basis.

In a rat reproduction study, mometasone furoate produced umbilical hernia at topical dermal doses approximately 6 times the MRHD on a mcg/m^2 basis and delays in ossification at approximately 3 times the MRHD on a mcg/m^2 basis.

In another study, rats received subcutaneous doses of mometasone furoate throughout pregnancy or late in gestation. Treated animals had prolonged and difficult labor, fewer live births, lower birth weight, and reduced early pup survival at a dose that was approximately 8 times the MRHD on an area under the curve (AUC) basis. Similar effects were not observed at approximately 4 times MRHD on an AUC basis.

In rabbits, mometasone furoate caused multiple malformations (e.g., flexed front paws, gallbladder agenesis, umbilical hernia, hydrocephaly) at topical dermal doses approximately 3 times the MRHD on a mcg/m^2 basis. In an oral study, mometasone furoate increased resorptions and caused cleft palate and/or head malformations (hydrocephaly and domed head) at a dose less than the MRHD based on AUC. At a dose approximately 2 times the MRHD based on AUC, most litters were aborted or resorbed *[see Nonclinical Toxicology (13.2)]*.

Nonteratogenic Effects:

Hypoadrenalism may occur in infants born to women receiving corticosteroids during pregnancy. Infants born to mothers taking substantial corticosteroid doses during pregnancy should be monitored for signs of hypoadrenalism.

Formoterol Fumarate: Teratogenic Effects

Formoterol fumarate administered throughout organogenesis did not cause malformations in rats or rabbits following oral administration. When given to rats throughout organogenesis, oral doses of approximately 80 times the MRHD on a mcg/m^2 basis and above delayed ossification of the fetus, and doses of approximately 2,400 times the MRHD on a mcg/m^2 basis and above decreased fetal weight. Formoterol fumarate has been shown to cause stillbirth and neonatal mortality at oral doses of approximately 2,400 times the MRHD on a mcg/m^2 basis and above in rats receiving the drug during the late stage of pregnancy. These effects, however, were not produced at a dose of approximately 80 times the MRHD on a mcg/m^2 basis.

In another testing laboratory, formoterol was shown to be teratogenic in rats and rabbits. Umbilical hernia, a malformation, was observed in rat fetuses at oral doses approximately 1,200 times and greater than the MRHD on a mcg/m^2 basis. Brachygnathia, a skeletal malformation, was observed in rat fetuses at an oral dose approximately 6,100 times the MRHD on a mcg/m^2 basis. In another study in rats, no teratogenic effects were seen at inhalation doses up to approximately 500 times the MRHD on a mcg/m^2 basis. Subcapsular cysts on the liver were observed in rabbit fetuses at an oral dose approximately 49,000 times the MRHD on a mcg/m^2 basis. No teratogenic effects were observed at oral doses up to approximately 3,000 times the MRHD on a mcg/m^2 basis *[see Nonclinical Toxicology (13.2)]*.

8.2 Labor and Delivery

There are no adequate and well-controlled human studies that have studied the effects of DULERA during labor and delivery.

Because beta-agonists may potentially interfere with uterine contractility, DULERA should be used during labor only if the potential benefit justifies the potential risk *[see Nonclinical Toxicology (13.2)]*.

8.3 Nursing Mothers

DULERA: It is not known whether DULERA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when DULERA is administered to a nursing woman.

Since there are no data from well-controlled human studies on the use of DULERA on nursing mothers, based on data for the individual components, a decision should be made whether to discontinue nursing or to discontinue DULERA, taking into account the importance of DULERA to the mother.

Mometasone Furoate: It is not known if mometasone furoate is excreted in human milk. However, other corticosteroids are excreted in human milk.

Formoterol Fumarate: In reproductive studies in rats, formoterol was excreted in the milk. It is not known whether formoterol is excreted in human milk.

8.4 Pediatric Use

The safety and effectiveness of DULERA have been established in patients 12 years of age and older in 3 clinical trials up to 52 weeks in duration. In the 3 clinical trials, 101 patients 12 to 17 years of age were treated with DULERA. Patients in this age-group demonstrated efficacy results similar to those observed in patients 18 years of age and older. There were no obvious differences in the type or frequency of adverse drug reactions reported in this age group compared to patients 18 years of age and older. Similar efficacy and safety results were

observed in an additional 22 patients 12 to 17 years of age who were treated with DULERA in another clinical trial. The safety and efficacy of DULERA have not been established in children less than 12 years of age.

Controlled clinical studies have shown that inhaled corticosteroids may cause a reduction in growth velocity in pediatric patients. In these studies, the mean reduction in growth velocity was approximately 1 cm per year (range 0.3 to 1.8 per year) and appears to depend upon dose and duration of exposure. This effect was observed in the absence of laboratory evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression, suggesting that growth velocity is a more sensitive indicator of systemic corticosteroid exposure in pediatric patients than some commonly used tests of HPA axis function. The long-term effects of this reduction in growth velocity associated with orally inhaled corticosteroids, including the impact on final adult height, are unknown. The potential for "catch up" growth following discontinuation of treatment with orally inhaled corticosteroids has not been adequately studied.

The growth of children and adolescents receiving orally inhaled corticosteroids, including DULERA, should be monitored routinely (e.g., via stadiometry). If a child or adolescent on any corticosteroid appears to have growth suppression, the possibility that he/she is particularly sensitive to this effect should be considered. The potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the risks associated with alternative therapies. To minimize the systemic effects of orally inhaled corticosteroids, including DULERA, each patient should be titrated to his/her lowest effective dose *[see Dosage and Administration (2.2)]*.

8.5 Geriatric Use

A total of 77 patients 65 years of age and older (of which 11 were 75 years and older) have been treated with DULERA in 3 clinical trials up to 52 weeks in duration. Similar efficacy and safety results were observed in an additional 28 patients 65 years of age and older who were treated with DULERA in another clinical trial. No overall differences in safety or effectiveness were observed between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out. As with other products containing $beta_2$-agonists, special caution should be observed when using DULERA in geriatric patients who have concomitant cardiovascular disease that could be adversely affected by $beta_2$-agonists. Based on available data for DULERA or its active components, no adjustment of dosage of DULERA in geriatric patients is warranted.

8.6 Hepatic Impairment

Concentrations of mometasone furoate appear to increase with severity of hepatic impairment *[see Clinical Pharmacology (12.3)]*.

10 OVERDOSAGE

10.1 Signs and Symptoms

DULERA: DULERA contains both mometasone furoate and formoterol fumarate; therefore, the risks associated with overdosage for the individual components described below apply to DULERA.

Mometasone Furoate: Chronic overdosage may result in signs/symptoms of hypercorticism *[see Warnings and Precautions (5.7)]*. Single oral doses up to 8000 mcg of mometasone furoate have been studied on human volunteers with no adverse reactions reported.

Formoterol Fumarate: The expected signs and symptoms with overdosage of formoterol are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the following signs and symptoms: angina, hypertension or hypotension, tachycardia, with rates up to 200 beats/min., arrhythmias, nervousness, headache, tremor, seizures, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, hypokalemia, hyperglycemia, and insomnia. Metabolic acidosis may also occur. Cardiac arrest and even death may be associated with an overdose of formoterol.

The minimum acute lethal inhalation dose of formoterol fumarate in rats is 156 mg/kg (approximately 63,000 times the MRHD on a mcg/m^2 basis). The median lethal oral doses in Chinese hamsters, rats, and mice provide even higher multiples of the MRHD.

10.2 Treatment

DULERA: Treatment of overdosage consists of discontinuation of DULERA together with institution of appropriate symptomatic and/or supportive therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdosage of DULERA. Cardiac monitoring is recommended in cases of overdosage.

Manufactured by 3M Health Care Ltd.,
Loughborough, United Kingdom.
Manufactured for Schering Corporation, a subsidiary of
MERCK & CO., INC.
Whitehouse Station, NJ 08889 USA.

6/10 **32704107T-JBS**

Advance Directives: Society President Encouraging Completion of Health Care POAs

One of my goals as president of the Wisconsin Medical Society (Society) is to increase awareness about the importance of advance care planning.

According to statistics from the State Bar of Wisconsin, an estimated 80% of Wisconsin residents—including 50% of those with severe or terminal illnesses—have not completed an advance directive to document their preferences about issues surrounding end-of-life decisions.[1] I believe that—through physician leadership—we can do better.

The Society and I are polling physicians and medical students as to whether or not they have completed their own health care power of attorney. The good news is that with over 1900 responses so far, 61% of the 1165 physicians who responded have completed a health care POA; and an additional 26% indicate they plan to do so in the next 12 months. That's in contrast to 150 of 442 medical students who responded that they have filled one out.

I discussed this initiative at the recent AMA Annual Meeting, and I am urging other states to join this effort. I am asking physicians and other health care professionals who have not completed the survey to do so. It is available online at http://WMS.informz.net/survistapro/s.asp?id=6530. Additionally, the Society can also assist other state medical societies and specialty societies who wish to survey their members. E-mail communications@wismed.org for more information. Hopefully, the data we gather can be used to encourage all of us to express our health care wishes.

Hopefully, the data we gather can be used in our outreach efforts to encourage colleagues and patients to complete an advance directive. I believe it's essential that everyone have a conversation with their loved ones about their health care wishes, so that in the event they are unable to speak for themselves their wishes will be clear.

George M. Lange, MD, FACP
President, Wisconsin Medical Society

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General Practice in Northern Wisconsin

Joseph P. Cox, MD

Editor's note: The following is excerpted from *WMJ*, Volume 3, April 1905, pp. 643-647.

I had an experience, on entering the profession, of working for nothing for so many years in charitable hospitals, that when I finally swung my shingle to the breezes of Northern Wisconsin, and a victim strayed into the office, I felt almost as if I were a thief to accept any pay from him. It took me a great many years to get up courage enough to demand a decent fee, and I presume several of us (if the truth were only known) have been in the same boat.

From the time we enter the profession we are told (if we have a good preceptor) that our calling is a humanitarian one, that we would have many years of starvation, and that we must have an ambition to enter the profession only for the good we can do. These are the teachings I received, and I have no doubt the majority of you received the same. But when a man has served his term of service, when he has worked his way through school by the sweat of his brow, as I have done, when he has worked for nothing, and as our friend Ole Oleson would say "eaten himself" for many years, he should then demand good pay. The popular impression that obtains among the people is that we are willing to do almost anything to secure experience. In this respect there are more idiots in general practice than in any other calling I know of. I feel this when I look back years ago when I was driving through Sawyer and Washburn Counties day and night, running 2 to 4 horses to death, flattering myself that I was making an enormous amount of money, wearing myself out, breaking myself down—and I did break down as you all will do if you follow my example—and what was the result? I was spending all I made and collected from those who did pay me to take care of those who did not pay. I was so busy that I could not pay proper attention to my family. Frequently a doctor's family is the most neglected family in the community, and yet, we own them as much attention as other families receive—otherwise a woman who marries a doctor is a very foolish woman.

I think, after we have reached a certain point, after we have studied as we should do and gotten in touch with medical literature, after we are equipped with ripe experience, then we should put on the brake and say to ourselves: I do not want to do so much work, but must do better work and for that work I must be paid.

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Doctor Cox was from Spooner, Wis.

Education and Work

John J. Frey, III, MD, Medical Editor

When I turned 12, my father had one of his "young man" talks with me—not the one I had expected; that would come later. He wanted to know which of the two papers in town I would like to deliver. I was looking for a third option but that was not one of my choices: either the *Sentinel* in the morning or the *Journal* in the evening. My father had helped support his family in the Depression by delivering papers and he wanted me to have the experience of responsibility and money. I opted for the morning paper so that I could participate in extracurriculars after school. Getting up at 4 AM in winter in Wisconsin to carry papers was not the exercise in character-building my father had hoped for, but I learned a lot about myself and about people that I haven't forgotten. I suspect many readers have had similar experiences during their education.

The article by Zierold and colleagues[1] should give us all pause about the mixed benefits and risks of combining education and work. Many of us are unaware of the impressive commitment that secondary education in Wisconsin has made to School-Sponsored Work. It is part of the fabric of almost all high schools in the state, and a very large number of students engage in school-based work like counseling, school-sponsored apprenticeships, and service learning. Many of us who have adolescent patients or have high school-age children can see the value of linking classroom work to direct applications of learning to situations like working with younger children, watching and participating in apprenticeships, and learning manual and thinking skills with school-sponsored community projects. They do help young people learn responsibility, leadership, and teamwork.

But Zierold and colleagues, in an extensive review of statewide data, show the effects of "work" on 3 cohorts of students—those who engage in school-sponsored work only, those who add a paid job to school-sponsored work, and those who opt only for paid work. When looking at the number of students who had one job in addition to school-sponsored work compared to those who had more than one, they found that the risk of injury to those with multiple jobs was significantly higher than those with only one. The types of jobs were similar in the two groups, but the risk of adverse health issues was higher. It makes sense: young people who work late (and many of the two-job students did) tend to be more tired, a bit less careful, and exposed to more opportunities for injury. Concerns that increased work would adversely affect school performance on the whole were not supported in their study.

This study should support questions about work outside of school as an essential part of adolescent physical exams, be they for sports, other activities, or urgent care visits. If students are working multiple jobs, our responsibility to them is to counsel them about the dangers of loss of concentration or the safety training that should be a part of their job. Many students work, like my father, not by choice but by necessity, particularly young people from families that are being stressed dramatically by the Great Recession. We have a responsibility to counsel them to be mindful of dangers inherent in their work. We also have a responsibility when such students consider a career in medicine to put their whole lives, not just their scholastic achievements, into the mix.

Getting up at 4 AM in winter in Wisconsin to carry papers was not the exercise in character-building my father had hoped for, but I learned a lot about myself and about people that I haven't forgotten.

Cayley's thoughtful review[2] of a number of structured formats for clinical teaching demonstrates that more effective teaching can be learned. "Natural" teachers may have interpersonal and critical-thinking gifts that most of us don't, but we can become learner-centered and talented teachers if we use tested methods, like those Cayley describes, until we do them naturally. Perhaps the most crucial component for

teaching—just as in patient care—is to ask the learner if what we did was helpful and how it might be improved. Feedback is good for teachers and for doctors.

If we need another study to demonstrate that there is a Brobdingnagian problem of a skewed physician workforce that currently is unable to meet demand and access and, with the Affordable Care Act, will cripple the US health system with increasing cost and decreasing quality, then we haven't been reading journals and newspapers for the past decade. Rieselbach and colleagues elaborate on their previous work to propose an alliance between academic health centers, primary care residency training, and the increasing number of community health centers that might change education in primary care internal medicine and pediatrics.[3] Ironically, their proposal comes at a time when the federal government and states are cutting insurance for low-income patients. No one, not even community health centers, can survive with a majority of uninsured patients.

Case reports, particularly if they are well done as the two in this issue are,[4,5] continue to be a valuable addition to the medical literature. An unusual presentation of a common problem or an unusual or unsuspected problem often finds us looking to see whether there is a case report on the subject. The discussion in a well-done case report is a mini-review of the subject and points us to other sources of reading.

This issue contains the collection of abstracts from the Wisconsin Chapter of the American College of Physicians[6] and offers insight into the many clinical and management dilemmas younger physicians face. This compendium has become a favorite addition to the *WMJ* over the years.

Finally, we publish, on occasion, excerpts of articles from the *Wisconsin Medical Journal* from a century ago. The *WMJ* is one of the oldest continuously publishing journals of any kind in the United States, having just celebrated our 109th birthday. If physicians today wonder if things have changed, much has, but, as this wonderful 106-year-old treatise on rural practice by Dr Cox from Spooner explains it, much about practice has not. Enjoy it.

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Expanded Community Health Center – Academic Medical Center Partnerships

Richard E. Rieselbach, MD; Patrick L. Remington, MD, MPH; Marc K. Drezner, MD; Robert N. Golden, MD

The nation has taken the first step on the difficult journey to health care reform via enactment of the Patient Protection and Affordable Care Act (ACA) of 2010. Skepticism regarding the achievement of affordable care has fueled concern regarding the impact of this legislation on national health care costs. Additional concerns relate to its focus on improving access to medical care with few incentives to improve health outcomes in the population.

We propose expansion of partnerships between community health centers (CHCs) and academic medical centers (AMCs). This could lead to more affordable care and better outcomes for many of the estimated 32 million people who will acquire health insurance or Medicaid eligibility as of 2014 and are likely to be cared for by CHCs. The model we propose—the Community Health and Academic Medical Centers Partnership (CHAMP)—would build upon a long history of collaboration between CHCs and AMCs,[1] as documented in a recently conducted survey.[2]

A major expansion of these collaborative relationships is now possible. Enactment of the ACA, with its support for primary care and teaching health centers (THCs), holds great potential for CHAMPS to have substantial impact in facilitating the further development of CHCs as a key component of a reformed health care delivery system that emphasizes cost control and improved outcomes.

Federally qualified CHCs are a nationwide system of non-profit health care clinics. Their characteristics and growing importance recently have been described in detail.[3,4] Future ACA funding will enable CHCs to serve nearly 20 million new patients by 2015, while adding an estimated 15,000 new providers[4]. This expansion, however, may be severely curtailed by the current difficulty in recruiting primary care physicians.[3]

We describe herein how the THC provides the foundation for the CHAMP, by serving as the community academic home for AMC primary care faculty who perform patient care, teaching, and health services research. The ACA provides funding for both CHC primary care residents and for these faculty who could pursue innovations in 4 critical areas:

- health professional training and outreach education
- cost containment
- health services research
- health promotion and disease prevention

Health Professional Training and Outreach Education

Essential to the CHAMP is a link between primary care graduate medical education and care for patients in CHCs. This can be achieved by CHAMPs through development of THCs in CHCs that are committed to establishing a patient-centered medical home practice environment and electronic medical records, as recently described.[5] Family medicine, primary care general internal medicine, and pediatric residents would receive their final year of training in these settings and subsequently have the incentive of National Health Services Corps debt repayment to practice in CHCs. Primary care residents trained in this setting would immediately increase the clinical capacity of these CHCs and ultimately expand the primary care work force for all CHCs. Once established, the CHAMP setting would be excellent for training medical, dental, and allied health students.

CHAMP faculty would conduct continuing medical education directed toward all CHC physicians in the region. This would include encouraging these physicians to use objective evidence, comparative effectiveness, and outcomes data as the basis for medical decision making. Academic detailing, which would provide evidence-based prescribing information from faculty as opposed to the pharmaceutical industry, would be an additional important program.[6] These outreach activities could be carried out by personal contact with CHAMP faculty, as well as via electronic and published communication.

Cost Containment

Programs leading to cost containment that could be pursued effectively by CHAMPs include the following:

- The previously described initiative in Graduate Medical Education, which would provide rapid cost-effective expansion in the number of patients served by THCs due to its physician multiplier effect, and ultimately facilitate expansion of all CHCs by increasing their number of primary care physicians.
- The CHAMP Medicaid ACO.[7] This novel health care delivery model for Medicaid would combine the subspecialist expertise, medical technology, and inpatient

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care of local academic medical centers with the primary care expertise of CHCs. It would use an emerging group of CHCs known as Teaching Health Centers (THCs) to create a distinctive form of Accountable Care Organization (ACO). By combining the best elements of AMCs and CHCs, these CHAMP ACOs could deliver high-quality, cost-effective care to low-income Americans. Eleven potential sources of savings that could be produced by this model have been described recently.[7]

- Development and implementation of electronic consultation and physician point-of-care decision support tools for CHC physicians. This would enhance their cost-effectiveness by decreasing dependence on costly subspecialty consultations. Electronic communication with AMC subspecialists prior to actual referral would help provide the coordination of primary and specialty care services necessary for improvement of outcomes.
- Outreach educational activities involving academic detailing and dissemination of comparative effectiveness research findings.

Community Health Services Research

Creating a CHAMP would establish "academic centers" in the community, which could provide the setting to launch community-based research that could determine and tackle the existent roadblocks to high-quality care. CHAMPs could develop and validate strategies that would allow all CHCs to better organize, manage, finance, and deliver high-quality care, reduce medical errors, and improve medication adherence and patient safety.

AMC faculty in CHCs, in addition to their teaching role, could partner with other health care providers in the CHCs and with community organizations to develop research studies that are understood and welcomed by community members. The CHC faculty also could collaborate with appropriate faculty at their home institutions, thereby expanding the range of investigations possible, with support from NIH clinical translational sciences award grants (eg, type 2 community collaborative or community health sciences grants).

Health Promotion and Disease Prevention

The current health insurance system in the United States rewards providers for delivering more care, with few rewards for preventive care. In contrast, CHCs have a longstanding track record of high quality preventive services. The proposed CHAMPs would build upon this tradition by encouraging evidence-based clinical preventive services for all CHC patients. CHAMPs could build integrated health information systems that would assure high levels of preventive service.

CHAMPs could also provide health care providers with more opportunities to participate as an active member of the new "public health system" envisioned in a recent Institute of Medicine report.[8] This new system goes beyond the traditional focus on governmental public health departments to include health care organizations and academia, as well as employers, the media, and community organizations. The establishment of CHAMPs would take 1 small step and begin to translate this theoretical public health system into reality by providing a setting to engage other community organizations in population health improvement efforts that extend beyond the borders of the clinic and into the community.

Discussion

CHCs currently provide extremely cost-effective care with predicted CHC generated savings of $316 billion over the next decade. Those CHCs participating in CHAMPs would greatly increase their clinical capacity (and thereby their capacity to generate savings) through the addition of third year primary care residents. The ultimate resulting increase in CHC primary care physicians would provide expanded access in all CHCs—key to the transformation necessary to promote affordable health care. The innovations we propose herein require rigorous study via well-designed pilot programs in order to validate their efficacy.

Feasibility of CHAMP development has been facilitated by several ACA provisions. Included are substantial authorizations for CHC construction and programmatic support, resident and faculty funding via support for THCs and section 747 of Title VII, and physician debt repayment that will facilitate resident and faculty recruitment.[4] Additionally, pilot programs of the new Center for Medicaid and Medicare Innovation are a potential source of support for research.[9]

Many of our 131 AMCs are in a position to pursue this type of partnership with CHCs. Establishing CHAMPs would increase the proportion of physicians practicing in health professions shortage areas—1 of the measures used to rank the "social mission" of ranking US medical schools.[10] This collaborative achievement of more affordable care and better health outcomes would greatly facilitate the challenging journey to healthcare reform.

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Students Enrolled in School-Sponsored Work Programs: The Effect of Multiple Jobs on Workplace Safety and School-Based Behaviors

Kristina M. Zierold, PhD; Savi Appana, MS; Henry A. Anderson, MD

ABSTRACT

Background: Throughout the United States, over 70% of public schools with 12th grade offer school-sponsored work (SSW) programs for credit; 60% offer job-shadowing programs for students. Wisconsin offers a variety of work-based learning programs for students, including, but not limited to, job shadowing, internships, co-op education, and youth apprenticeship programs. No research has compared workplace injury and school-based behaviors in students enrolled in SSW programs who work only 1 job compared with those who work multiple jobs.

Methods: A total of 6810 students in the 5 public health regions in Wisconsin responded to an anonymous questionnaire that was administered in 2003. The questionnaire asked about employment, injury, characteristics of injury, and school-based behaviors and performance.

Results: A total of 3411 high school students aged 14 to 18 reported they were employed during the school year. Among the working students, 13.5% were enrolled in a SSW program. Of the SSW students, 44% worked multiple jobs. SSW students who worked multiple jobs were more likely to do hazardous job tasks, to work after 11 PM, to work over 40 hours per week, to have a near-miss incident, to have a coworker injured, and to be injured at work.

Conclusions: SSW students who are working multiple jobs are violating labor laws that put their safety and their school performance at risk. The responsibilities of employers and schools have to be addressed to ensure that SSW students are abiding by labor laws when working multiple jobs.

INTRODUCTION

In 1994, the federal government passed the School-To-Work Opportunities Act (the Act) to create a work-based learning program that was modeled after the concept of an apprenticeship. The program was designed to integrate school-based instruction with structured on-the-job training. The Act was passed to provide an opportunity to improve the skills that working youth would need in the changing job market.[1] It pointed to a "lack of a comprehensive and coherent system to help youths acquire the knowledge, skills, abilities, and information about and access to the labor market that are necessary to make an effective transition from school to work or further education."[2] The Act supported the notion that the work-based learning approach, which should integrate theoretical instruction with structured on-the-job training, combined with school-based learning would be very effective in engaging student interest, enhancing skill acquisition, developing positive work attitudes, and preparing youth for high-skill, high-wage careers.[2]

While the Act allowed states to determine their own form of school-sponsored work (SSW) programs, 3 categories were required to be included within the SSW programs: (1) school-based activities, which encompass classroom instruction focused on workplace experiences; (2) work-based activities, which include structured training and work experiences outside school-time instruction, such as job shadowing, internship, apprenticeship, and mentoring; and (3) connecting activities, which involve efforts to help the schools and employers maintain bonds between school-based and work-based activities.[3] In an assessment of high schools providing SSW programs, 94% of schools offered 6 or more school-based activities, such as career counseling and job site visits, and 46% offered 6 or more work-based activities, such as curriculum changes that build on work experience. Eighty-two percent of teachers reported being involved in connecting activities, such as attending professional meetings with themes related to SSW programs.[4] Schools located in urban areas and schools with more minority students and teachers

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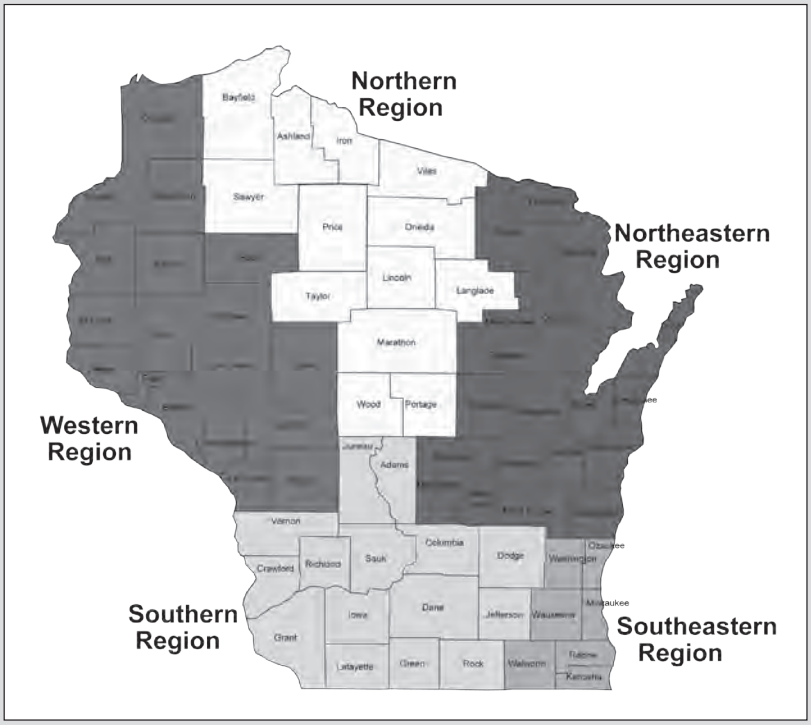

Figure 1. Five Public Health Regions in Wisconsin.

have more SSW activities compared with other schools.

Although federal support for the Act officially ended in 2001, the US Department of Education reported in 2004 that 71.8% of public schools with 12th grade offered work-based learning programs for credit and 60% of schools offered job-shadowing programs.[5]

Wisconsin often is considered a model for work-based learning programs. It was the first state in the United States to establish a comprehensive youth apprenticeship program; this program was 1 of 4 programs used as a model by the federal government to develop the Act in 1994.[6] Wisconsin offers a wide variety of work-based learning programs, including service learning, job shadowing, internships, cooperative education, employability skills certificate, cooperative education skills certificate, youth apprenticeship, school-based enterprise, and youth leadership. In-depth description of these work-based learning programs can be found in the *Wisconsin Work-Based Learning Guide*.[7] Each program has requirements for students, teachers, and the participating partners. Grade requirements are different among the programs. For example, a student in middle school can participate in job shadowing, whereas only juniors and seniors can participate in the youth apprenticeship program. Each of these programs is meant to let students experience different types of jobs and help them learn and apply skills important for working.

Limited research has been conducted to assess SSW programs,[4,8,9,10] and most of it is limited to a description of the types of programs offered and the demographic characteristics of the schools and students. To date, no studies have investigated the occurrence of injury and academic performance among students enrolled in SSW programs; nor has the effect of multiple jobs been investigated. Therefore, in this study, we compared work-related injury and school performance and behaviors among students who only worked in a SSW job and students who worked in a SSW job plus other jobs.

METHODS

Data Collection

The data for this study came from a survey of Wisconsin high school students. In 2003, the Wisconsin Division of Public Health conducted a survey of high school youth throughout the state regarding work, injury, and school performance.

To ensure the schools were representative of youth throughout the state, the school districts were selected from Wisconsin's 5 public health regions, which are determined by the Wisconsin Department of Health and Family Services. They are the northern region, the northeastern region, the western region, the southern region, and the southeastern region, each of which encompasses a number of counties (Figure 1). Students in this study were classified into groups based on whether (1) the student was not employed (non-working), (2) the student was employed and enrolled in a SSW program (SSW) or (3) the student was employed but not enrolled in a SSW program (other-working).

The original project, which involved the collection of the data from the high school students, was considered "exempt" by the Institutional Review Board affiliated with the Wisconsin Division of Public Health because the questionnaire was anonymous and no personal identifiers were collected from the students. The secondary analysis evaluating SSW programs was also considered "exempt" by the Institutional Review Board of the University of Louisville because the data contained no identifiers.

Statistical Methods

Multiple outcomes relating to work and school were analyzed using chi-square methods and logistic regression. Initially, summary statistics (frequency counts and percents) were calculated along with *P*-values from chi-square tests comparing SSW students with 1 job vs SSW students with multiple jobs for demographic characteristics, working characteristics, injury characteristics, and school performance outcomes. Next, crude odds ratios (OR) were estimated using the univariate logistic regression models to assess the association between the number of jobs held and the various outcomes of interest. Finally, 3 multivariable logistic regression (MVLR) models were fit to select work-related and school performance outcomes that provided estimates for adjusted odds ratios (AORs) and their 95% confidence intervals (CI). The first MVLR model was adjusted for age, gender, and race, and was fit on all the work-related and school outcomes. The second MVLR model was fit for work-related outcomes and was adjusted for age, gender, race, hours worked per week, how late student worked, informed of legal rights and responsibilities, received safety training, performed a dangerous task, and had a near miss. The third MVLR model was fit for school performance outcomes and was adjusted for age, gender, race, hours worked per week, how late student worked, injured at work, cut/skipped classes, absent from school, expect to graduate, GPA, and time spent on homework in and out of school. All statistical analyses were performed using SAS 9.2 (SAS Institute Inc., Cary, North Carolina). All statistical tests were made at the alpha equal 0.05 level.

RESULTS

A total of 6810 questionnaires were completed and returned, which covered student work during the 2002-2003 school year. Data from 6519 surveys meeting the following exclusion criteria was used: (1) age <14 or age >18, and (2) missing or invalid group data. After applying the exclusion criteria and only considering SSW students, the data consisted of 461 SSW students. Two hundred fifty of those students held only 1 job, 204 held multiple jobs, and 7 had missing information on number of jobs held.

Description of the Population

Overall, 3411 high school students aged 14 to 18 reported they were employed during the school year. Among those working students, 461 (13.5%) reported they were enrolled in a SSW program when they completed the questionnaire; 204 (44%) held multiple jobs. Table 1 reports the demographics and work characteristics for the SSW students, stratified by number of jobs. No significant differences exist in age, gender, type of school district, and how many days worked before

Table 1. Demographic and Work Characteristics of SSW Students (N=461)

Characteristic	Levels	Worked 1 Job (n=250)	Worked >1 Job (n=204)	*P*-value
Age	14	8 (3%)	7 (3%)	0.63
	15	31 (12%)	17 (8%)	
	16	49 (20%)	42 (21%)	
	17	86 (34%)	67 (33%)	
	18	76 (30%)	71 (35%)	
Gender	NR	2 (1%)	2 (1%)	0.816
	Male	109 (44%)	91 (45%)	
	Female	139 (56%)	111 (54%)	
Race	NR	3 (1%)	7 (3%)	0.043
	White	161 (64%)	140 (69%)	
	African-American	43 (17%)	17 (8%)	
	Hispanic	17 (7%)	12 (6%)	
	Other	26 (10%)	28 (14%)	
Type of School District	Rural	19 (8%)	26 (13%)	0.297
	Small Town	12 (5%)	10 (5%)	
	Medium City	197 (79%)	154 (75%)	
	Large City	22 (9%)	14 (7%)	
How late do you work?	NR	30 (12%)	15 (7%)	0.024
	Before 7 PM	95 (38%)	63 (31%)	
	Between 7 PM and 11 PM	116 (46%)	108 (53%)	
	After 11 PM	9 (4%)	18 (9%)	
How many days do you work before 8 AM?	NR	21 (8%)	13 (6%)	0.501
	Never	156 (62%)	120 (59%)	
	1 day	15 (6%)	16 (8%)	
	2 or more days	58 (23%)	55 (27%)	
Number of hours worked per week	NR	2 (1%)	0 (0%)	0.058
	< 5	38 (15%)	31 (15%)	
	6 - 10	44 (18%)	33 (16%)	
	11 - 16	59 (24%)	36 (18%)	
	17 - 22	56 (22%)	44 (22%)	
	23 - 40	47 (19%)	46 (23%)	
	> 40	4 (2%)	14 (7%)	
Asked to perform a dangerous task	NR	10 (4%)	5 (2%)	0.012
	Yes	19 (8%)	31 (15%)	
	No	221 (88%)	168 (82%)	
Had a near-miss incident	NR	17 (7%)	8 (4%)	0.013
	Yes	37 (15%)	50 (25%)	
	No	196 (78%)	146 (72%)	
Injured at work	NR	16 (6%)	7 (3%)	0.003
	Yes	36 (14%)	53 (26%)	
	No	198 (79%)	144 (71%)	
Received safety training	NR	8 (3%)	4 (2%)	0.928
	Yes	180 (72%)	148 (73%)	
	No	62 (25%)	52 (25%)	
Informed of legal rights and responsibilities	NR	7 (3%)	4 (2%)	0.15
	Yes	207 (83%)	160 (78%)	
	No	36 (14%)	40 (20%)	

NR = no record.

Table 2. Jobs and Tasks Reported by SSW Students, Stratified by Number of Jobs[a]

Types of jobs and tasks	SSW students				
	Worked 1 job (n=250)		Worked >1 job (n=204)		*P*-value
	N	%	N	%	
Animal care	11	4.4	18	8.8	0.057
Harvesting/planting	6	2.4	11	5.4	0.095
Babysitting/childcare	56	22.4	63	30.9	0.041
Cashier/waitperson	84	33.6	82	40.2	0.147
Dishwashing	40	16.0	40	19.6	0.317
Sales person	29	11.6	48	23.5	0.001
Cleaning tables/floors/rooms	57	22.8	61	29.9	0.087
Stocking shelves	41	16.4	56	27.5	0.004
Cooking/frying	39	15.6	38	18.6	0.397
Other food preparation	34	13.6	36	17.6	0.241
Department store	19	7.6	26	12.7	0.071
Tree/shrub trimming or cutting	2	0.80	11	5.4	0.004
Hardware store	5	2.0	11	5.4	0.514
Carpentry	8	3.2	18	8.8	0.011
Gas station	1	0.4	8	3.9	0.008
Construction	5	2.0	19	9.3	0.001
Lawn mowing	15	6.0	21	10.3	0.092
Roofing	6	2.4	17	8.3	0.005
Painting	11	4.4	17	8.3	0.086
Manufacturing	4	1.6	9	4.4	0.076
Lumber yard	—	—	7	3.4	0.035
Hospital/nursing home/clinic	19	7.6	15	7.4	0.936
Nursing assistant/working with patients	16	6.4	16	7.8	0.562
Hotel/motel/resort	11	4.4	13	6.4	0.345
Newspaper/magazine delivery	2	0.8	7	3.4	0.048
Office assistant/receptionist	22	8.8	26	12.7	0.179
Driver/courier/delivery person	7	2.8	10	4.9	0.242
Other	43	17.2	40	19.6	0.511

[a]Students could choose multiple jobs or tasks.

8 AM, between SSW students working 1 job vs multiple jobs. However, students enrolled in SSW programs who worked only 1 job were more likely to be either Black or Hispanic (24% vs 14%, $P=0.043$). SSW students who worked multiple jobs were more likely to report working after 11 PM (9% vs 4%, $P=0.024$) compared with SSW students who worked only 1 job. On a similar note, SSW students who worked multiple jobs were more likely to work over 40 hours per week (7% vs 2%, $P=0.058$); however, this result does not reach statistical significance.

There were large significant differences in the percent that reported an injury and related outcomes between SSW students with multiple jobs and SSW students with 1 job. Students working multiple jobs were more likely to have been injured at work (26% vs 14%, $P=0.003$), be asked to perform a dangerous task (15% vs 8%, $P=0.012$), and have a near-miss incident where they were almost injured (25% vs 15%, $P=0.013$). There were no significant differences between the groups regarding students receiving safety training and being informed of legal rights.

Jobs and Tasks Worked

Table 2 presents the jobs and tasks reported by the SSW students, stratified by number of jobs. Among all SSW students, the jobs/tasks most commonly reported included cashier/waitperson, cleaning tables/floors/rooms, and babysitting/childcare. There were some differences in the profiles of the students. SSW students who held multiple jobs were more likely to report working in babysitting/childcare (30.9% vs 22.4%, $P=0.041$), sales (23.5% vs 11.6%, $P=0.001$), stocking shelves (27.5 % vs 16.4%, $P=0.004$), tree/shrub trimming or cutting (5.4% vs 0.80%, $P=0.004$), carpentry (8.8% vs 3.2%, $P=0.011$), gas station (3.9% vs 0.4%, $P=0.008$), construction (9.3% vs 2.0%, $P=0.001$), roofing (8.3% vs 2.4%, $P=0.005$), lumber yard (3.4% vs 0%, $P=0.035$), animal care (8.8% vs 4.4%, $P=0.057$), and newspaper/magazine delivery (3.4% vs 0.8%, $P=0.048$).

Injuries

There were differences in injuries of the SSW students who worked 1 job vs SSW students who worked multiple jobs. Among the SSW students who worked 1 job, 36 students (14%) reported being injured, and 60 injuries were reported. The most common injuries were cuts (33%), burns (22%), and bruises (13%). Broken bones, crushed body parts, and sprained muscles accounted for 13% of the reported injuries. Among the 36 injured students, the majority were injured by contact with hot grease or fluids (23%), contact with a knife or sharp object (19%), and falls from ladders, stairs, or flat surfaces (17%).

When evaluating the percent of students injured by job and tasks, the percentage ranged from a low of 0% to a high of 50%. The jobs and tasks with the greatest percentage of students injured included roofing (50%), lawn mowing (31%), driver/courier/delivery person (29%), and other food preparation (28%).

Among the SSW students who worked multiple jobs, 53 students (26%) reported being injured and 108 injuries were

reported. The most common types of injuries reported were the same types of injuries as those reported in the single job group; however, there was a much higher percentage (25%) of reported broken bones, crushed body parts, and sprained muscles in the SSW students who held multiple jobs. Among the SSW students who worked multiple jobs and were injured, the majority were injured by falls from ladders, stairs and flat surfaces (17%), contact with hot grease or fluids (12%), and carrying or lifting an object (11%).

When evaluating the percent of students injured by job and tasks, the percentage ranged from a low of 18% to a high of 71%. The jobs and tasks with the greatest percentage of students injured included roofing (71%), driver/courier/delivery person (60%), construction (58%), manufacturing (56%), and carpentry (56%).

Table 3. School Characteristics of SSW Students (N=461)

Characteristic	Levels	Worked 1 Job (n=250)	Worked >1 Job (n=204)	*P*-value
Late for school	NR	28 (11%)	18 (9%)	0.892
	< 3 times	128 (51%)	106 (52%)	
	≥ 3 times	94 (38%)	80 (39%)	
Cut/skipped classes	NR	28 (11%)	16 (8%)	0.002
	< 3 times	152 (61%)	100 (49%)	
	≥ 3 times	70 (28%)	88 (43%)	
Unexcused absence	NR	29 (12%)	16 (8%)	0.17
	< 3 times	129 (52%)	97 (48%)	
	≥ 3 times	92 (37%)	91 (45%)	
Time spent on homework IN school	NR	29 (12%)	17 (8%)	0.509
	> 90 minutes	14 (6%)	15 (7%)	
	≤ 90 minutes	207 (83%)	172 (84%)	
Time spent on homework OUT of school	NR	27 (11%)	17 (8%)	0.092
	> 120 minutes	10 (4%)	16 (8%)	
	≤ 120 minutes	213 (85%)	171 (84%)	
GPA > 2.0	NR	32 (13%)	18 (9%)	0.597
	GPA ≤ 2.0	40 (16%)	38 (19%)	
	GPA > 2.0	178 (71%)	148 (73%)	
Expect to graduate	NR	31 (12%)	18 (9%)	0.028
	No	10 (4%)	19 (9%)	
	Yes	209 (84%)	167 (82%)	
Parents prevented child from working because of grades	NR	31 (12%)	21 (10%)	0.587
	Yes	155 (62%)	134 (66%)	
	No	64 (26%)	49 (24%)	
Parents prevented child from working because of safety and health	NR	32 (13%)	20 (10%)	0.048
	Yes	184 (74%)	141 (69%)	
	No	34 (14%)	43 (21%)	

School Performance and Behavior

Table 3 reports the school performance and behavioral characteristics of the SSW students, stratified by number of jobs. SSW students with multiple jobs were more likely to cut/skip classes 3 or more times (43% vs 28%, $P = 0.002$), expect not to graduate (9% vs 4%, $P = 0.028$), and have parents/guardians who would not prevent them from working if their job was dangerous to their safety and health (21% vs 14%, $P = 0.048$).

Logistic Regression Findings

Table 4 presents the odds ratios and adjusted odds ratios (AOR) for the outcomes of interest. When adjusting for race, age, and gender, compared with SSW students who worked multiple jobs, SSW students who worked only 1 job were significantly less likely to be injured at work (AOR = 0.43, 95% CI = 0.26 - 0.72), have a near-miss incident at work (AOR = 0.54, 95% CI = 0.33 - 0.89), and cut or skip school 3 or more times (AOR = 0.55, 95% CI = 0.36 - 0.84). While not significant at the $P = 0.05$ level, students who worked 1 job were less likely to perform a dangerous task (AOR = 0.54, 95% CI = 0.29 - 1.01), more likely to spend time on homework outside of school (AOR = 2.05, 95% CI = 0.90 - 4.70), and more likely to expect to graduate from high school (AOR = 2.16, 95% CI = 0.94 - 4.97).

When adjusting for the additional variables described in the methods section, SSW students who worked 1 job were less likely to be injured at work (AOR = 0.64, 95% CI = 0.34 - 1.20), have a near-miss incident (AOR = 0.64 95% CI = 0.37,-1.11), perform a dangerous task (AOR = 0.62, 95% CI = 0.30 - 1.29), and cut or skip school 3 or more times (AOR = 0.65, 95% CI = 0.40-1.08), although these findings were not statistically significant.

DISCUSSION

This study is the first to evaluate the effect of multiple jobs on students enrolled in SSW programs. SSW programs were developed with the idea of preparing youth for transitioning into the workforce upon high school graduation. These programs combine school-based activities with work-based activities so that youth are trained with the skills necessary to succeed in the workplace. In this study, we compared injury and school performance among students who worked only in the SSW job (54%) and students who worked in the SSW job plus

Table 4. Outcome Comparison of SSW Students Working 1 Job vs. SSW Students Working Multiple Jobs

Injury Outcomes of Interest	Unadjusted OR (95% CI) 1 Job vs >1 Job	Adjusted OR[a] (95% CI) 1 Job vs >1 Job	Adjusted OR[b] (95% CI) 1 Job vs >1 Job
Informed of legal rights and responsibilities	1.44 (0.88, 2.36), 0.151	1.43 (0.85, 2.42), 0.174	0.97 (0.51, 1.87), 0.937
Received safety training	1.02 (0.66, 1.56), 0.928	1.11 (0.71, 1.72), 0.651	0.90 (0.53, 1.53), 0.690
Performed a dangerous task	0.47 (0.25, 0.85), 0.013	0.54 (0.29, 1.01), 0.055	0.62 (0.30, 1.29), 0.201
Near-miss incident	0.55 (0.34, 0.89), 0.014	0.54 (0.33, 0.89), 0.015	0.64 (0.37, 1.11), 0.112
Injured at work	0.49 (0.31, 0.79), 0.004	0.43 (0.26, 0.72), 0.001	0.64 (0.34, 1.20), 0.165
Injury affected normal activity (>3 days)	0.81 (0.33, 1.98), 0.642	0.60 (0.22, 1.63), 0.320	1.42 (0.26, 7.67), 0.686
School Performance Outcomes of Interest	**Unadjusted OR (95% CI) 1 Job vs >1 Job**	**Adjusted OR[a] (95% CI) 1 Job vs >1 Job**	**Adjusted OR[c] (95% CI) 1 Job vs >1 Job**
Cut/skipped classes (3 or more times)	0.52 (0.35, 0.78), 0.002	0.55 (0.36, 0.84), 0.005	0.65 (0.40, 1.08), 0.094
Absent from school (3 or more times)	0.76 (0.51, 1.12), 0.170	0.74 (0.50, 1.11), 0.148	1.00 (0.62, 1.61), 0.993
Expect to graduate	2.38 (1.08, 5.25), 0.032	2.16 (0.94, 4.97), 0.071	0.91 (0.31, 2.63), 0.860
Time spent on homework in school (≤ 90 mins)	1.29 (0.61, 2.75), 0.510	1.40 (0.65, 3.03), 0.395	1.03 (0.40, 2.67), 0.949
Time spent on homework outside of school(≤ 120 mins)	1.99 (0.88, 4.50), 0.097	2.05 (0.90, 4.70), 0.089	2.20 (0.79, 6.16), 0.132
GPA > 2.0	1.14 (0.70, 1.87), 0.597	1.20 (0.72, 2.01), 0.485	1.00 (0.55, 1.82), 0.991

Referent Group = teens with one job
[a] Adjusted for age, gender, and race.
[b] Adjusted for age, gender, race, hours worked per week, how late at night worked, and the injury outcome variables.
[c] Adjusted for age, gender, race, hours worked per week, how late at night worked, and the school performance variables.
Abbreviation: OR = odds ratio.

other jobs (44%). This study was undertaken because there is limited information regarding SSW programs, and the majority of information available is description of demographic profiles of the schools involved in such programs. No research has evaluated the health and safety of students in SSW programs nor looked at the school performance outcomes of students in SSW programs.

Clearly, students who are working multiple jobs are more likely to be in circumstances that are potentially harmful to themselves and their school performance. In our study, students working multiple jobs were more likely to work over 40 hours per week, more likely to work after 11 PM during the school week, more likely to be asked to do a dangerous task, and more likely to report having a near-miss incident at work. When controlling for the differences in work characteristics between SSW students with 1 job and SSW students with multiple jobs, those students working multiple jobs were 1.6 times more likely to be injured compared to those working 1 job. While this is not a statistically significant finding, the elevated odds ratio does indicate that working multiple jobs has an effect on work-related injury.

Additional explanations for the difference in injury can be found by looking at the job profiles of students working only the SSW job compared with students working multiple jobs. Many of the jobs considered more hazardous on the list are being worked by students who work multiple jobs. For example, compare multiple vs 1 job: construction (9.3% versus 2%), tree/shrub trimming or cutting (5.4% vs 0.80%), roofing (8.3% vs 2.4%), and carpentry (8.8% vs 3.2%).

Based on the concept of SSW programs where an apprenticeship model is used, we would expect that students enrolled in the program receive occupational safety and health training, which would include information regarding child labor laws. While more than 70% of both SSW groups reported receiving safety training, and greater than 75% reported being informed of their legal rights, SSW students working multiple jobs were violating various labor laws that put their safety at risk. The question that arises then, is who is responsible for ensuring that labor laws regarding the number of hours worked per week, night-time hours worked, and jobs being done are followed by SSW students? Do we expect that employers are solely responsible or do the schools have a role in protecting students who take part in SSW programs, even in multiple jobs? Or should we expect a combination of school and employer responsibility?

The *Wisconsin Work-Based Learning Guide* clearly defines the roles of both students and employers in SSW programs. For employers, for example, it is mandated that they abide by federal child labor laws; ensure that any work performed under the label of hazardous occupation shall be under the direct and close supervision of a qualified and experienced person; ensure that the work of a youth apprentice, or any other student learner, in any occupation labeled as hazardous should be periodic and of short duration; and ensure that all safety instruction will be provided and understood by the youth apprentice.[7] This guide discusses the SSW jobs, but for SSW students working multiple jobs, where is the assurance that labor laws are being followed once the student leaves the SSW job and goes to work at another job?

In this study, parents of students who worked multiple jobs were less likely to prevent their children from working if the job affected their safety and health. This points to the fact that parents of teens cannot be relied on to ensure that labor laws are being followed and that youth are safe at work. Parents may not know labor laws, may not be informed of what the teen is doing at work, or simply may not care. Either way, protection of young workers must come from elsewhere.

In addition to workplace safety, many of the academic performance outcomes were worse for students who worked multiple jobs. For example, among students working multiple jobs, 9% did not expect to graduate, 43% cut or skipped classes 3 or more times, and 45% had 3 or more unexcused absences. This is in sharp contrast with students who worked 1 job, where 4% did not expect to graduate, 28% cut or skipped classes 3 or more times, and 37% had 3 or more unexcused absences. While the SSW program promotes work experience, it also needs to promote academic performance so that youth learn and graduate. The Act clearly states that its purpose is "to help all students attain high academic and occupational standards" and "to motivate all youths, including low-achieving youths, school dropouts, and youths with disabilities, to stay in or return to school or a classroom setting."[2] Allowing students to slip by because they are in work programs does not benefit the student or the employer, particularly in an ever-changing economy where job stability is not certain. A high school education is needed so that youth have the opportunity to transition jobs or return to education in the future.

This study did have some limitations. There may be selection bias, as this study was conducted with students in 1 state. There was a wide variety of schools selected to participate in the study; however, because Wisconsin was a model for the federal School-To-Work Opportunities Act, it may have some SSW programs available to students that other states do not. Because we did not focus specifically on the type of SSW program and focused only on the overall participation, we believe that the bias is limited. Another limitation of the data is that we cannot specifically determine what jobs or tasks were associated with a reported injury. During the survey, students selected multiple jobs and tasks, and there is no possible way of deciphering which job or task led to the reported injury. However, we are able to evaluate the jobs and tasks and compare the profiles to evaluate whether SSW students working multiple jobs were greatly different than SSW students working 1 job. Furthermore, we presented the jobs and tasks with the highest percentage of injuries for both working groups. An additional limitation of this study is that the SSW data was collected in 2003 but not analyzed until 2009. While the majority of teens predominately work in the service sector, there may be some differences of jobs or work characteristics in 2011, due to the change in the economic climate. Additionally, there may have been some changes to the SSW programs. The final limitation of this study may be that the minority population in Wisconsin is small compared to many other states. In 2009, the minority population made up 10.6% of Wisconsin.[11]

This study has shed light on students in SSW programs, clearly noting that many SSW students are employed in multiple jobs. Because many SSW students are working multiple jobs and suffering injury and some poorer school outcomes, compared to SSW students working a single job, we must concern ourselves with the importance of labor laws, safety and health, and school performance for these students. Much more research is needed to understand both work-related safety and the education of students working multiple jobs who are part of the SSW programs.

Funding/Support: This study was funded by NIOSH grant R03OH008957–"Safety and Injury Among Teens Enrolled in School-To-Work Apprentice Programs."

Financial Disclosure: None declared.

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Effective Clinical Education: Strategies for Teaching Medical Students and Residents in the Office

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ABSTRACT

Problem: Educating medical students and residents in the office presents the challenges of providing quality medical care, maintaining efficiency, and incorporating meaningful education for learners. Numerous teaching strategies to address these challenges have been described in the medical educational literature, but only a few teaching strategies have been evaluated for their impact on education and office practice.

Methods: Literature on the impact of office-based teaching strategies on educational outcomes and on office efficiency was selected from a Pub Med search, from review of references in retrieved articles, and from the author's personal files.

Results: Two teaching strategies, "one-minute preceptor" (OMP) and "SNAPPS," have been shown to improve educational processes and outcomes. Two additional strategies, "Aunt Minnie" pattern recognition and "activated demonstration," show promise but have not been fully evaluated. None of these strategies has been shown to improve office efficiency.

Conclusions: OMP and SNAPPS are strategies that can be used in office precepting to improve educational processes and outcomes, while pattern recognition and activated demonstration show promise but need further assessment. Additional areas of research also are suggested.

INTRODUCTION

Educating medical students and residents in the office setting presents the simultaneous challenges of providing quality medical care, maintaining efficiency, and incorporating meaningful education for learners. A recent literature review identified several common barriers that often impede effective clinical teaching, including time constraints, inadequate institutional financial support, lack of access to educational specialists, and lack of access to appropriate educational space and resources.[1] Furthermore, research has demonstrated that physicians who precept medical students typically spend a significant amount of extra time teaching, consequently seeing fewer patients and losing income.[2]

A study of clinical preceptors found that 3 factors commonly influence which patients are selected by preceptors for teaching encounters with medical students: the potential influence of teaching on the doctor-patient relationship, the educational value for the student, and considerations of time and efficiency.[3]

The impact of teaching on the doctor-patient relationship can be influenced by whether a patient is established and returning for follow-up, and perhaps more likely to want only a known and trusted physician, or new and perhaps more likely to provide an opportunity for the learner to have a "fresh start" on a clinical problem. The educational potential in patient visits may be related to the opportunity for the learner to have a "fresh start" on a new clinical problem or diagnosis, or the opportunity for the learner to "shadow" in multiple visits to maximize exposure to patients and diagnoses. Time for and efficiency of teaching is influenced by patient volume for the clinical day and the balance between visits for follow-up of established problems vs visits for new or undiagnosed complaints.

Numerous models or strategies for clinical teaching have been described in the medical education literature. This article reviews 4 specific clinical teaching strategies and the evidence for their impact on educational outcomes or office efficiency. Literature for this review was selected based on the results of a Pub Med search on the terms "medical student" and "precepting," review of references in retrieved articles, and the author's personal files.

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CME available. See page 203 for more information.

"One-Minute Precepting"—Education Using the 5 "Microskills"

The "one-minute preceptor" (OMP) strategy, first described in the early 1990s, recommends 5 key steps or "microskills" for an effective teaching encounter (Table 1).[4] First, "getting a commitment," with questions such as "What do you want to do?" or "If I weren't here, what would you do for the patient?" is designed to encourage the learner's processing and synthesis of information obtained from the patient. Second, "probing for supporting evidence" with questions such as "What factors did you consider in making that decision?" or "Were there other options you considered and discarded?" is meant to help the preceptor understand the learner's fund of knowledge, analytic processes, and areas for further learning. Third, "teaching general rules applicable to the case at hand," with a "mini-lecture" or suggested reading, is recommended to help the learner understand application of general medical reasoning and principles to individual cases. The fourth and fifth steps, "reinforcing what was done right" and "correcting mistakes," involve providing descriptive, case-specific and behavior-focused feedback to the learner.[4]

In a study comparing the OMP model with "traditional models of ambulatory teaching," 116 preceptors (primarily representing internal or family medicine) in 7 different faculty development programs watched videotaped teaching encounters of both OMP and traditional precepting. Those preceptors watching the OMP encounters were equally or better able to diagnose the patient's medical problem compared to preceptors who watched encounters using a traditional teaching model. Preceptors watching videotapes of the OMP model also rated students' abilities higher on history taking and physical examination, presentations, clinical reasoning, and fund of knowledge. Preceptors watching tapes of OMP precepting also rated themselves as more confident in evaluating students' abilities.[5] The same study also found that preceptors using the OMP model tended to provide more emphasis on disease-specific teaching and focused more on higher-order thinking rather than on general disease processes.[6] A second study by the same investigators, in which 164 third- and fourth-year medical students viewed traditional or OMP teaching encounters, found students rated OMP more effective than traditional teaching.[7]

In a study of residents with inpatient teaching responsibilities, 28 residents who received a 1-hour lunchtime training session on OMP were compared with 29 control residents. The residents trained in OMP were rated more highly afterward by their students on measures of "asking for a commitment," "providing feedback," and "motivating me to do outside reading." However, there was no difference between the 2 groups in students' ratings of their "overall teaching effectiveness."[8] A separate investigation using quantitative analysis of audiotaped teaching encounters found that after participation in a set of three 90-minute faculty development seminars on the OMP model, faculty preceptors improved in the specificity of their feedback to students.[9]

Table 1. One-Minute Precepting (OMP)[4]

1. Get a commitment
2. Probe for supporting evidence
3. Teach general rules
4. Reinforce what was done right
5. Correct mistakes

Table 2. SNAPPS[10]

1. Summarize relevant history and physical findings
2. Narrow the differential: Likely? Relevant?
3. Analyze the differential
4. Probe the preceptor
5. Plan patient management
6. Select a case-related learning issue

SNAPPS—Learner-Led Education

The SNAPPS strategy was developed based on cognitive learning and reflective practice theory. This approach emphasizes active learning and casts the precepting encounter as a learner-led experience. The SNAPPS acronym derives from the 6 steps of the process (Table 2). First, the student is asked to Summerize, generally in 3 minutes or less, the relevant history and physical findings. Second, the student is asked to Narrow the differential diagnosis or possible interventions to the 2 or 3 most relevant and likely possibilities. Commitment to an initial decision on the part of the student, prior to preceptor input, is a key part of this teaching strategy. Third, the learner should Analyze the differential by comparing and contrasting the possible explanations. This allows the learner to verbalize thought processes. Fourth, the learner is asked to Probe the preceptor by asking about uncertainties, difficulties, or other approaches. This allows the preceptor insight into the learner's thought process and knowledge base, and teaches the student to see the preceptor as a knowledge resource. Fifth, to Plan management of the patient, the learner initiates a discussion with the preceptor by attempting either a brief management plan or suggesting specific interventions and then further refining these with preceptor input. Lastly, the learner is asked to Select a case-related issue for self-directed learning and reading, with preceptor input as needed to help focus the question or select learning resources.[10]

The 1 evaluation of SNAPPS that has been published compared preceptors trained in SNAPPS to preceptors given no specific educational instructions or just general instruction on feedback. This study found that students working with SNAPPS-trained preceptors were more concise in their summa-

Table 3. "Aunt Minnie"[12,13]

1. Student presents the chief complaint and the presumptive diagnosis
2. Student begins a write-up and preceptor evaluates the patient
3. Preceptor discusses case with student
4. Preceptor reviews and signs medical record

Table 4. Activated Demonstration[17]

1. Assess student's relevant knowledge
2. Determine what the student should learn from the skill demonstration
3. Guidance for student participation during skill demonstration
4. Demonstrate the clinical skill
5. Discuss learning points with the student
6. Set an agenda for future learning opportunities

ries, presented more than twice as many diagnostic possibilities, and justified their diagnostic possibilities more often. SNAPPS students also performed better at contrasting hypotheses, expressing uncertainties, initiating discussion of management, and identifying learning topics.[11]

"Aunt Minnie"—The Value of Pattern Recognition

Most clinical teaching methods focus on a critical-thinking discussion between student and preceptor, and at least a brief exploration of diagnostic or management options. In contrast, the "Aunt Minnie" approach has been described as a way to educationally employ the value of pattern recognition in clinical practice. So named for the principle that "If the lady across the street walks like your Aunt Minnie and dresses like your Aunt Minnie, she probably is your Aunt Minnie," this approach has been advocated as actually representing the typical approach applied by most clinicians for common ambulatory problems. One approach to teaching "Aunt Minnie" pattern recognition is: (1) the student evaluates the patient then presents to the preceptor the chief complaint and the presumptive diagnosis, (2) the student begins a write-up and the preceptor evaluates the patient, (3) the preceptor discusses the case with the student, (4) the preceptor reviews and signs the medical record (Table 3).[12,13]

While the use of pattern recognition has been studied most thoroughly in radiology education, there has been only limited investigation of pattern-recognition education in clinical medicine. One study found that pattern-recognition could be used reliably in developing an end-of-rotation test for surgical clerkship students.[14] Another study compared instruction in clinical reasoning to "leaving students to their own intuitions regarding how best to approach new cases." The investigators found that instruction to students to use familiarity-driven pattern recognition combined with careful consideration of the presenting features led to improved diagnostic accuracy.[15] Finally, a study comparing medical students' diagnostic pattern recognition and clinical data interpretation found that pattern recognition improved more quickly than data interpretation across all 4 years of medical school.[16] While none of these studies specifically assessed the proposed "Aunt Minnie" model of precepting described above, they do suggest a role for pattern recognition in medical education, which may bear further investigation.

Activated Demonstration—Teaching a Skill

While knowledge and analytic thinking processes can be taught either in the examination room or separately in a precepting encounter, hands-on skills involving physical examination or procedural interventions require the preceptors' presence in the patient room, demonstration, supervision, and feedback. "Activated demonstration" has been described as one way for a preceptor to maximize the educational value of a demonstration and provide the learner with more than just a passive experience (Table 4). Activated demonstration begins with determination of the learner's relevant knowledge and the learning objectives for the demonstration. The preceptor then provides clear guidance as to what the learner should do during the skill demonstration, including discussions with and examination of the patient. After the skill demonstration, the preceptor discusses learning points with the learner and sets an agenda for future learning opportunities. An evaluation of preceptor training in this approach, conducted with 128 preceptors over 8 different sessions, found that preceptors improved in their ability to select learner-focused teaching strategies.[17]

CONCLUSION

All 4 teaching models have the potential to help improve the effectiveness of office-based teaching. OMP has been evaluated most extensively, and has been shown to improve preceptor diagnosis of patients' medical problems as well as emphasis on disease-specific teaching. OMP also improves preceptors' performance on the specific teaching skills of getting a diagnostic commitment from the learner, motivating the learner to independent learning, and providing feedback. Students working with preceptors using OMP show improved history-taking and physical-examination abilities, case presentations, clinical reasoning skills, and knowledge base. SNAPPS has been evaluated less extensively, but it also shows promise for improving student case presentations, clinical reasoning, and independent learning. Studies have demonstrated that pattern recognition can play a role in teaching and testing clinical reasoning by students, and the "Aunt Minnie" approach to precepting is an intriguing application of pattern recognition to clinical teaching, but so far no formal evaluation of this teaching model has been published. Activated demonstration shows promise for improving the ability of preceptors to select learner-focused teaching strategies and is another teaching model that would

benefit from further evaluation and characterization as to its optimal use and benefits.

While the impact of teaching on office efficiency and physician productivity has been documented as a concern for clinical teachers, thus far only OMP and SNAPPS have been assessed for their impact on office efficiency, and neither OMP or SNAPPS has been found to shorten teaching encounters.[9,11]

Both OMP and SNAPPS demonstrate promise for improving learner's clinical skills, clinical reasoning, and motivation for independent learning. OMP also has been shown to improve precepting skills and has been proposed as a model that can be learned by new clinical teachers 1 micro-skill at a time. SNAPPS has the theoretical advantage of placing more emphasis on self-directed learning, but no comparison between SNAPPS and OMP in terms of their impact on self-directed learning has been done to date. Future research on clinical teaching could add to the body of knowledge in this area by focusing on several questions: Does either OMP or SNAPPS do more to encourage learner self-direction? What strategies can help improve the efficiency of office-based teaching? How can pattern-recognition and activated demonstration be used most helpfully in clinical teaching?

Funding/Support: None declared.

Financial Disclosure: None declared.

Planners/Reviewers: The planners and reviewers for this journal CME activity have no relevant financial relationships to disclose.

Appendix. Additional Resources

Irby DM, Wilkerson L. Teaching when time is limited. *BMJ.* 2008;336(7640):384-387. Review. PubMed PMID: 18276715. (http://www.bmj.com/cgi/content/full/336/7640/384). Accessed June 30, 2011.

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Escherichia coli Pyomyositis in an Immunocompromised Host

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ABSTRACT

Background: Pyomyositis due to *Escherichia coli (E. coli)* is rarely reported in immunocompromised patients with hematological malignancy.

Case Report: We present a case report of a 34-year-old man who developed *E. coli* pyomyositis as a complication of acute myelogenous leukemia (AML). Magnetic resonance imaging (MRI) of the right hip suggested myofascial infection of the gluteal muscles, and a needle muscle aspiration grew *E. coli* phylogenetic group B2. The patient responded to intravenous piperacillin/tazobactam followed by prolonged oral levofloxacin.

Conclusion: Pyomyositis should be suspected in all immunocompromised patients complaining of muscle pain and may exhibit signs of localized muscle infection. Appropriate antibiotic therapy targeting fluoroquinolone-resistant *E. coli* should be considered for initial empiric therapy of pyomyositis in immunocompromised patients.

CASE REPORT

A 34-year-old man was transferred from a rural, community hospital following 4 days of severe right back pain radiating to his buttocks and right thigh. While his occupation required some light lifting, he did not recall any trauma. He denied rigors, feverishness, hemoptysis, dyspnea, polyuria, dysuria, or diarrhea. His muscle pain was severe, and he was unable to walk despite the use of ibuprofen. He denied any chronic medical problems or pertinent family history and did not use any illicit drugs. The patient was from Oxaca, Mexico, but had not traveled there within the last 9 months. He recently had a tooth extraction treated with amoxicillin and ibuprofen for a possible dental abscess.

Because of persistent muscular pain and the finding of pancytopenia, he was transferred to Mayo Clinic Health System.

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Subjective findings included severe right thigh pain worsened with minimal motion. Examination revealed extremely tender right paraspinous, gluteal, and thigh muscles without crepitus, fluctuance, or crackles on auscultation. The patient was unable to move his right leg due to severe pain, and passive motion localized the pain primarily to the right trochanteric area and anterior thigh. The skin above that area had small, superficial, broken bullae without skin inflammation due to his prior overzealous use of heating pads. There were no adenopathy or gross neurologic deficits.

Laboratory testing revealed hemoglobin of 8.6 gm/dl, platelet count of 178,000 cells/mm^3, and a white blood cell count of 1800 cells/mm^3, with 12% neutrophils, 2% bands, and 78% lymphocytes. Electrolytes were normal with creatinine of 0.9 mg/dl, aspartate transaminase of 27 units/L, alanine transaminase of 38 units/L, creatine phosphokinase of 75 units/L, and erythrocyte sedimentation rate >120 mm/hour. Urinalysis was negative for leucocyte esterase, nitrates, white cells, blood, and bacteria.

Additional laboratory tests included urine and blood cultures, quantiFERON-TB test for *Mycobacterium tuberculosis,* and antibody tests for HIV and *Brucella,* all of which were negative. Anemia evaluation revealed normal iron, iron binding capacity, vitamin B12, and folate levels, but an elevated ferritin of 1447 ng/ml. A bone marrow aspirate revealed >80% blasts compatible with acute myelogenous leukemia (AML), later found to be *M1* type.

On the second day of hospitalization, his temperature rose to 39.3°C. After cultures of blood, urine, and sputum were obtained, the patient was started on cefepime; however, because of persistence of fever, severe pain, and immobility despite narcotic medication, he was switched to piperacillin/tazobactam. Magnetic resonance imaging (MRI) of the hip revealed increased T2 signal along the fascial planes in the

vicinity of the right hip and within the anterior thigh muscles—the adductor group, gluteus minimus, and tensor fascia lata (Figure 1). There was no evidence of abscess or gas. He was switched to intravenous piperacillin/tazobactam. Aspiration of the adductor muscle in the right upper thigh grew *E. coli* that was susceptible to levofloxacin, cephalosporins, and piperacillin/tazobactam but resistant to amoxicillin. He was switched to levofloxacin and had gradual but progressive improvement in pain and mobility. He received a total of 6 weeks of oral levofloxacin and also was started on cytarabine and idarubicin induction chemotherapy.

Characterization of the Myositis *E. Coli* Isolate

The *E. coli* isolate was positive for β-lactamase using an acidometric screening and was nonhemolytic when grown on a sheep blood agar plate. It was negative for 0157:H7 by serologic testing. Phylogenetic grouping of the isolate was done according to Clermont et al.[1] The strain was shown to be part of the B2 phylogenetic group. A virulence factor gene analysis then was performed targeting several virulence factor genes common among extraintestinal *E. coli* strains.[2] The myositis *E. coli* isolate was positive for the *aer, fimH, fyuA,* and *usp* genes, but was negative for the *cnfI, papGI, papGII, papGIII, hlyC,* and *hra* genes.

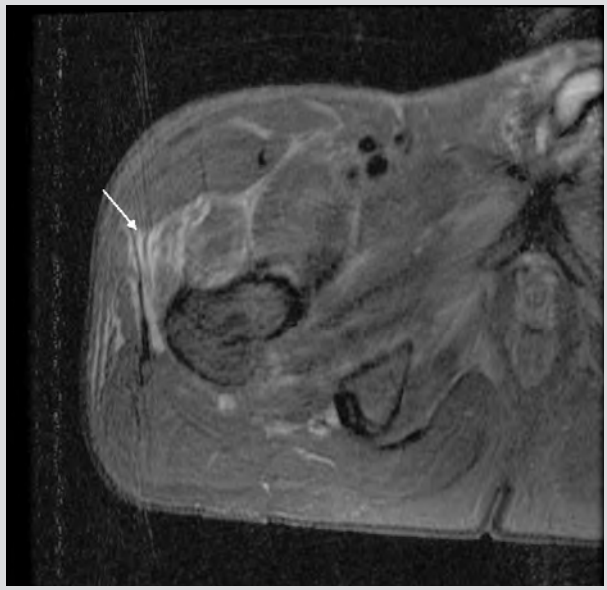

Figure 1. MRI of hip revealing increased T2 signal intensity along the fascial planes in the vicinity of right hip, involving anterior upper thigh, the adductor group, gluteus minimus, and the tensor fascia lata (white arrow) suggesting myositis with no evidence of abscess, soft tissue gas, or septic hip or osteomyelitis.

DISCUSSION

Escherichia coli is the most common cause of urinary tract infections and gram-negative bacteremia in the United States.[3-5] *E. coli* sepsis causes approximately 40,000 deaths per year in the United States and substantial morbidity and health care costs.[5] Extraintestinal infection with community-acquired *E. coli* is associated typically with multiple virulence factors.[6] Pyomyositis is a rare extraintestinal manifestation of deep tissue *E. coli* infection.

While infectious pyomyositis can be caused by a variety of pathogens, including viral and parasitic, it usually is caused by gram-positive bacteria, especially *Staphylococcus aureus* and, less frequently, *Streptococcus pyogenes.*[7] In tropical countries, pyomyositis may occur due to synergistic co-infections with tissue parasites.[2] In these regions, bacterial pyomyositis occurs most frequently in the upper back paraspinous muscles or the anterior thighs. In contrast, in non-tropical countries, the thigh and trunk muscles, as found in our case, are most commonly involved.

Review of current literature reveals our case is very unusual. Pyomyositis due to enteric, gram-negative rods is quite rare, and even fewer reports of its occurrence in hematologic malignancies are noted in the literature (Table 1).[8-14]

This is the first case of *E. coli* pyomyositis at our 345-bed secondary referral center, and, in a period of 30 years, only 1 other case of bacterial pyomyositis, also a gram-negative rod *(Salmonella enterica),* was diagnosed. Interestingly, in the latter case, which occurred in a gastrocnemius muscle, the patient also was suffering from AML (observation by third author). Since this was a case report, IRB approval was not obtained.

In the present report, several host factors allowed the initial infection to ensue. First, the patient had recently received amoxicillin to which the isolate was resistant, predisposing him to selective colonization; second, he was immunocompromised (neutropenic) due to AML.

The *E. coli* isolate collected from the patient phylogenetically typed as a B2 group that is common among extraintestinal *E. coli* isolates, but displayed few virulence factor genes, which is unusual for these *E. coli* isolates.[6] When compared to uropathogenic *E. coli* isolates, the myositis isolate mapped closely with 1 broad group of uropathogenic *E. coli* identified through optical mapping.[15] What is interesting about this broad group of extraintestinal *E. coli* strains is that they are missing many key virulence factors normally associated with extraintestinal *E. coli.* The loss of several virulence factors may have allowed this isolate to initiate and sustain myositis because of the absence of toxins that would trigger an immune response and the lack of adherence structures that could have targeted the *E. coli* cells for elimination by his diminished number of white blood cells. We believe the source of infection could be transmigration of *E. coli* from the gut, and earlier exposure to amoxicillin may have contributed to its resistance to amoxicillin.

Table 1. A Literature Review of Cases of *E. Coli* Pyomyositis in Immunocompromised Hosts

Reported by	Number of Cases	Age (years)	Sex	Site	Underlying Condition	*E. Coli* Susceptibility	Treatment
Hall[7] (1990)	1	62	Female	Gluteus maximus	Trauma/unknown	Unknown	Unknown
Lortholary[9] (1994)	1	42	Male	Psoas	HIV-AIDS	B-lactamase +	Ceftazidime, amikacin, fosfomycin x 16 days
Vilades[10] (1994)	1	28	Male	Gluteus	HIV-AIDS	Sensitive	Ciprofloxacin x 6 weeks
Cone[11] (1997)	1	68	Male	Anterior tibial compartment	Metastatic prostate cancer	Fluoroquinolone -resistant	Ampicillin and gentamicin (unknown duration)
Jou[12] (1998)	3	Unknown	Unknown	Intra/extra pelvic	Unknown	Unknown	Unknown
Johnson[13] (2003)	1	56	Male	Psoas, erector spinae	Diabetes mellitus	Sensitive	Piperacillin/tazobactam x 6 weeks
Chiu[14] (2008)	1	48	Female	Calf	Neutropenia due to chemotherapy for acute myelogenous leukemia	B-lactamase +	Meropenem x 3 weeks
Vigil[8] (2010)	6	38-67 years	Male (4), Female (2)	Calf (5) Thigh (2)	Leukemia (5), Lymphoma (1)	Fluoroquinolone-resistant	Carbapenum and amikacin

Pyomyositis has been classified into 3 stages: Stage I, initial muscle inflammation that is not associated with abscess; Stage II, associated with early abscess, usually occurring approximately 2 to 3 weeks into illness; and Stage III, with signs of toxicity and systemic infection.[8] We believe that our patient, presenting 2 to 4 days after onset of symptoms, did not mount a full inflammatory response due to severe neutropenia. Hence, abscess formation, as often noted in tissue infections of patients with severe neutropenia, did not occur.

Based on a report from MD Anderson Cancer Center at the University of Texas, the clinical course of *E. coli* myositis can be severe. Fifty percent of its patients required Intensive Care Unit management due to sepsis, and 33% died.[8] All of these isolates were fluoroquinolone resistant. Fortunately, our patient's strain was fluoroquinolone-susceptible, and, with prompt diagnosis and therapy of 6 total weeks, the infection responded despite his underlying acute leukemia.

Acknowledgments: We wish to thank the clinical microbiology laboratory for identifying the bacterial isolate. The phylogenetic grouping and virulence factor gene detection was supported by NIH grant AI065432-01A2 to W. R. S.

Funding/Support: None declared.

Financial Disclosures: None declared.

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Large Cervicothoracic Thymic Cyst Causing Prominent Airway Deviation in a 3-Day-Old Neonate

Benson S. Hsu, MD; Diane G. Heatley, MD; Michael Wilhelm, MD

ABSTRACT

Cervicothoracic mass in the pediatric population is uncommon and has a broad differential diagnosis. Frequently, masses in the cervical region present with airway compromise, particularly in younger patients. We present a case of an extremely large cervicothoracic mass causing airway obstruction in a 3-day-old, otherwise healthy male infant. Following awake intubation for airway protection, a 4.5 cm x 2.5 cm x 1.5 cm thymic cyst was removed. This case illustrates the wide differential diagnosis of cervicothoracic masses and shows the difficulty of preoperative diagnosis, especially in the case of thymic cysts with extension into the cervical space.

CASE

Our patient was a 3-day-old male infant born to a 17-year-old G1P1 (Gravida 1, Para 1) female. Pregnancy was uncomplicated with routine prenatal care. Prenatal labs were notable for negative Group B streptococcus, hepatitis B, rubella, and a nonreactive VDRL (Venereal Disease Research Laboratory). The patient was born by vaginal delivery at 39 and 5/7 weeks gestation and had APGARS of 9 and 9 at 1 and 5 minutes, respectively. Initial course in the newborn nursery was unremarkable, with no signs of respiratory distress or feeding difficulty. Patient appeared well, without any outward signs of neck mass. He was discharged to home after 2 days.

Over the following 24 hours, the patient developed difficulty feeding with increasing lethargy and intermittent apnea at home and was brought to the local emergency department for evaluation. On exam, he was found to have a large, soft neck mass with biphasic stridor. A computed tomography (CT) scan, performed without sedation, noted a cystic lesion extending posteriorly from the anterior mediastinum to the prevertebral space and superiorly into the hypopharyngeal region, causing prominent rightward and posterior laryngeal and tracheal deviation. The mass was noted to contain an air-fluid level with homogenous fluid on CT imaging (Figure 1). Given this finding, he was transported to the University of Wisconsin Hospital & Clinics for evaluation by pediatric otolaryngology.

On arrival, he was on nasal cannula oxygen but continued to have significant respiratory distress and intermittent desaturations, which were more prominent with agitation. Following evaluation by pediatric otolaryngology, he was taken to the operating room for mass resection. Airway control was obtained through awake intubation using rigid bronchoscopy after failed direct laryngoscopy.

During resection, the lesion was noted to arise from the hypopharynx in the area of the left pyriform sinus and contained foul smelling, purulent fluid (Figure 2). Tissue pathology revealed a thymic cyst with components of thyroid and parathyroid tissue. The fluid grew multiple organisms, including *S viridans*, *H parainfluenzae,* and *S anginosus,* consistent with oral flora. Given this finding, we hypothesized that the mass, which may have had a connection to the oral cavity, enlarged secondary to the introduction of food. Post-operatively, the patient developed hypocalcaemia, but was responsive to vitamin D and calcium supplementation. The hypocalcaemia was determined to be secondary to parathyroid tissue removal and the stress of surgery in a newborn. Specifically, evaluation for 22q.11 deletion by fluorescent in situ hybridization (FISH) was negative. The patient recovered from his surgery without complications and was discharged from the hospital at 13 days old.

DISCUSSION

Differential diagnosis of cervicothoracic masses can be classi-

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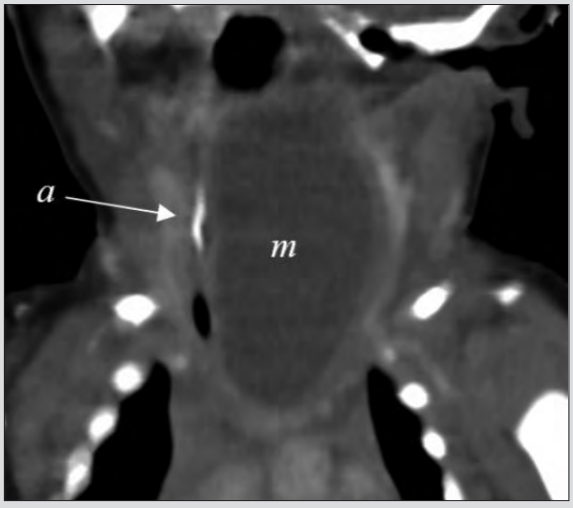
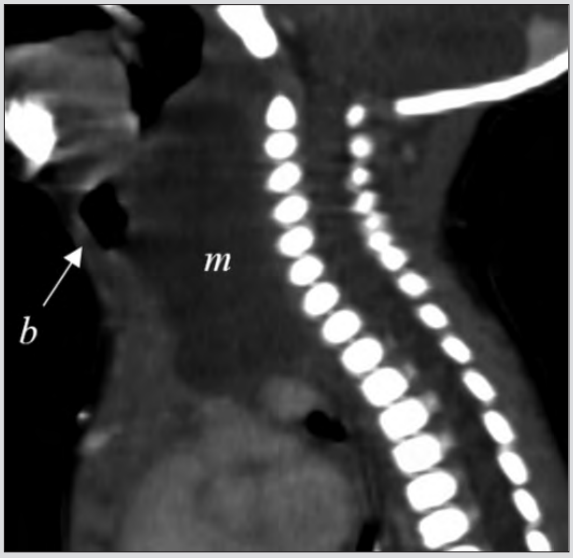




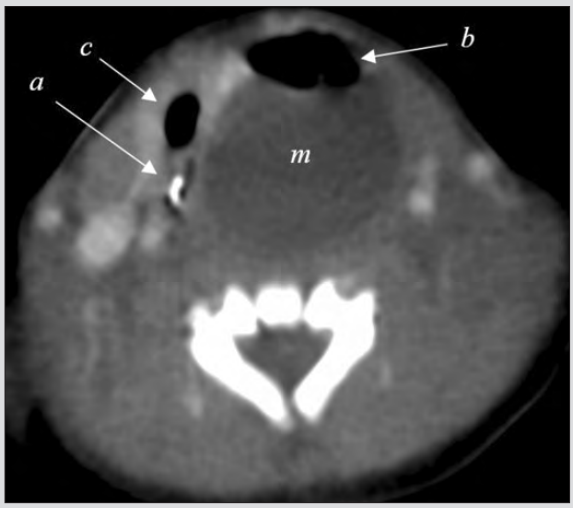
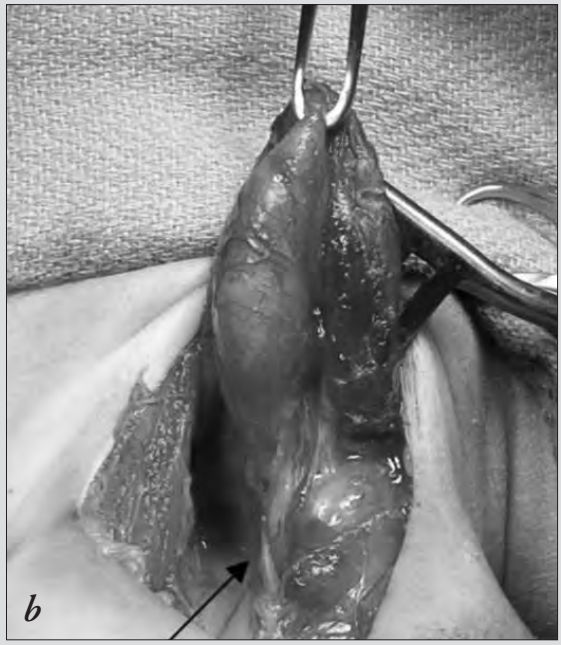


Figure 1. CT images showing a cystic lesion (*m*) extending posteriorly from the anterior mediastinum to the prevertebral space and superiorly into the hypopharyngeal region with a homogenous fluid layer and air pocket (*b*) causing prominent esophageal (*a*) and tracheal (*c*) deviation.



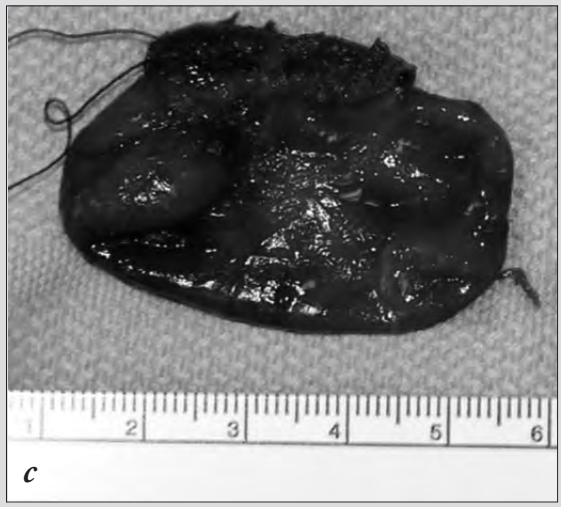


Figure 2. Imaging demonstrating the position of the lesion at dissection (*a*), decompression of cyst with yellow fluid noted (*b*, arrow), and size of mass after resection (*c*).

fied into 4 broad categories: congenital lesions, inflammatory lesions, tumors – benign or malignant, and traumatic lesions. Congenital lesions include lymphatic malformations, hemangioma, thymic cysts, and vascular abnormalities. Inflammatory lesions include inflammatory adenopathy reactive to tuberculosis, mononucleosis, tularemia, cat-scratch fever, or other upper respiratory illness. In addition, inflammatory lesions may include abscess formations from tuberculosis or other causes. Benign tumors include lipoma, lipoblastoma, aggressive fibromatosis, and nerve sheath lesions. Malignant tumors may include lymphoma, thyroid carcinoma, neuroblastoma, and chest wall tumors such as rhabdomyosarcoma and Ewing sarcoma. Traumatic lesions may include esophageal foreign body, granuloma, and cervicothoracic hematoma. Within the pediatric population, congenital lesions are most frequent, with lymphatic malformations being most common.[1]

The differential for thymic enlargement, in contrast, is associated with 4 causes: cysts, hyperplasia, hemorrhage, or neoplasm.[2] The differential diagnosis when presented with a fluid-filled cyst in the cervical region includes thymic cysts, brachial cleft cysts, thyroglossal duct cysts, dermoid cysts, thymic tumors, cystic hygromas, teratomas, and abscesses.[1,3]

Congenital thymic cysts compose <1% of pediatric cervicothoracic masses and are essentially benign, with 80%-90% presenting as asymptomatic, slow growing masses.[2,4,5] Presentation with symptoms often occurs between 5 and 7 years of age,[5] with 6% to 10% having airway complaints, vocal cord paralysis, or pain. Thymic cysts develop from the persistence of thymic tissue during the degeneration of the thymopharyngeal duct in the third and fourth pharyngeal pouch.[3,5] Consequently, the cyst will occasionally connect to the pyriform sinus by an internal sinus, which provides access for bacterial organisms, as happened with our patient. Most lesions are soft, nontender, and lie on the anterior border of the sternomastoid muscle opposite the thyroid and found on the left side of the neck. Approximately 39% to 50% of cervical thymic cysts will extend into the thoracic space.[3,5]

On CT imaging, these cysts are well marginated, with attenuation close to that of water. In comparison, on MRI, the T1-weighted lesions are of low signal intensity, and T2-weighted lesions are of intermediate or high signal intensity.[1] Histologically, the thymic cysts are commonly lined by a flattened cuboidal epithelium and Hassall's corpuscles.[2] Management of thymic cysts is surgical, with excision of the lesion.[5]

There have been 4 reported cases of cervicothoracic thymic cysts within the pediatric literature.[2-4,6] Two of the 4 cases presented with airway complications (1 patient was 6 years of age and the other 20 months). The 6-year-old patient presented with difficulty breathing but not frank respiratory failure, most likely due to a larger cervical space. In comparison, the 20-month-old with a smaller airway presented with both apnea and respiratory failure. Both patients were intubated prior to resection of the mass, although the airway control strategy was not commented on within the case reports. In our patient, who clinically was in impending respiratory failure, an awake intubation strategy was used to allow for spontaneous respiration during intubation. This strategy lessened the impact of mass effect on the airway during intubation. Had anesthetics been used, the airway may have been compromised due to decrease in muscle tone and sedation.

Even though the final diagnosis in our patient was determined by pathology, he had features suggestive of a thymic cyst in the homogenous appearance of the fluid with an air fluid level. Imaging may be beneficial, and either CT or MRI modalities are recommended, following initial evaluation by plain neck film.[1,5] However, despite imaging, preoperative diagnosis is quite difficult and lesions almost always require histological analysis for confirmation.[5]

CONCLUSION

The differential diagnosis for cervicothoracic lesions is broad. In addition to diagnosis, clinicians must carefully regard the airway impact of such masses. Clinical features and radiographic findings are helpful, but pathology is ultimately required for diagnosis.

Funding/Support: None declared.

Financial Disclosures: None declared.

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Proceedings from the 2010 Annual Meeting of the American College of Physicians, Wisconsin Chapter

The Wisconsin Chapter of the American College of Physicians held its annual meeting in Wisconsin Dells, September 10-12, 2010. Internal medicine residents from each of Wisconsin's 5 residency programs presented their research and/or unusual clinical experiences via posters and vignettes.

PRESENTED POSTERS

Phlegmasia Cerulea Dolens Involving the Left Extremity

Sudhir Duvuru, MD, Janakiram Reddy Manne, MD, Rajitha Dasari, MD, Mark Hennick, MD, FACP; Marshfield Clinic, Marshfield, Wis

Introduction: Deep Vein Thrombosis (DVT), postphlebitic syndrome and recurrent venothromboemboloism is a major health concern leading to considerable morbidity and mortality. Identifying acquired or inherited thrombophilic and structural factors leading to thrombosis is important in order to provide appropriate treatment and prevent complications.

Case: A 49-year old woman presented with a 10-day history of left buttock and thigh pain and a 2-day history of marked swelling and bluish discoloration of the left leg. Ten days prior to presentation, she underwent a vaginal hysterectomy for menorrhagia and dysmenorrhea. Doppler ultrasound of the left leg at the time of presentation was negative for DVT. Computed tomography (CT) of the abdomen and pelvis showed extensive thrombus within the left common iliac, internal iliac, and external iliac venous system and compression of the left iliac vein by the right iliac artery consistent with May-Thurner syndrome. Patient underwent a left lower extremity venogram confirming iliac vein compression, Trellis phannacomechanicallysis/thrombectomy, and angioplasty and stent placement in left common iliac vein. She also received warfarin to maintain international normalized ratio (INR) 2-3 for 3 months. Follow-up Doppler ultrasound examination of left lower extremity and iliac veins showed no evidence for thrombosis.

Discussion: DVT is the most common cause of unilateral leg swelling. Phlegmasia cerulean dolens is a severe form of DVT caused by proximal venous outflow obstruction estimated to occur in 2% to 5% of patients who undergo evaluation of lower extremity venous disorder. Location and extent of the thrombus as seen in our patient should raise suspicion of congenital structural abnormalities such as May-Thurner syndrome or iliac compression syndrome. This condition occurs predominantly in middle-age women and is caused by the compression of left common iliac vein by the right common iliac artery. Because the artery has greater pressure than the vein, it compresses the vein against the pelvic rim, causing venous stasis, which predisposes to thrombus formation. Diagnosis is made by Doppler ultrasound, CT, or venogram. Anticoagulation therapy without correction of the structural abnormality will not prevent thrombotic complications. The approach to treatment should include prevention of thrombosis propagation, pulmonary embolism, and restoration of venous outflow in the lower extremity.

Conclusion: May-Thurner syndrome should be considered with patient presentation of left lower extremity swelling and iliac vein thrombus. Treatment involves thrombolysis and stent placement followed by anticoagulation therapy. Prompt therapy is important in order to prevent venous gangrene.

Metastatic Pancreatic Small Cell Carcinoma Presenting as Acute Pancreatitis

Christina Fitzmaurice, MD, Patrick Pfau, MD; Department of Medicine, University of Wisconsin Hospital and Clinics, Madison, Wis

Case: A 77-year-old woman was found to have pancreatitis based on abdominal pain and an elevated amylase and lipase level. An abdominal CT scan revealed an ill-defined 2.2-cm mass in the pancreatic head and bilateral 4-cm adrenal masses. An endoscopic ultrasound redemonstrated the pancreatic and adrenal mass lesions; fine needle aspirations of both were performed, revealing small cell carcinoma by cytological examination. Immunohistochemistry was performed, and thyroid transcription factor-1 (TTF-1), synaptophysin, and chromogranin were positive, confirming the diagnosis. The patient did not have any respiratory complaints but was a long-time smoker. A chest CT demonstrated enlarged axillary, mediastinal, and hilar lymph nodes as well as a solitary 8-mm sclerotic lesion in the midthoracic spine but was notably negative for pulmonary nodules or masses. A brain CT showed brain metastases. The patient declined chemotherapy and succumbed to her disease within 2 months after the initial diagnosis.

Background: Small cell carcinoma of the pancreas is a very rare and aggressive tumor with a high metastasis rate. Approximately 1% of all primary pancreatic neoplasm are small cell carcinomas; 4% of all small cell carcinomas have an extra-pulmonary origin. In a review of all published cases of small cell carcinoma of the pancreas, 91% of cases were in a metastatic stage at time of the initial diagnosis. Bilateral adrenal metastases from a primary small cell carcinoma of the pancreas as described in this case is exceedingly rare and has only been described on 1 other occa-

sion. The main treatment option in small cell carcinoma of the pancreas is chemotherapy. However, no consensus exists due to the limited number of cases. Survival seems to be worse than in small cell carcinoma of the lung, with a median survival of 1 month with symptomatic treatment alone, 2 months with chemotherapy alone, and 4 months with chemotherapy and local treatment.

An Uncommon Presentation to a Common Diagnosis

Jeff Gehl, MD, Ritika Patel, MD; Medical College of Wisconsin, Milwaukee, Wis

Case: A 63-year-old white man with a history of psoriasis was admitted from an outside hospital with hypercalcemia. He was followed by nephrology for a urethral stricture with routine labs and told to go to the emergency department (ED) because of a calcium level of 13.5. The patient had not seen a doctor for many years until 1 month prior. He complained of a mild "smoker's cough" and generalized malaise. His exam revealed psoriatic lesions throughout his body but was otherwise unremarkable. Parathyroid hormone was appropriately low, and an extensive malignancy workup was negative. Chest CT showed no pulmonary nodules, a thickened interstitium, and peribronchial thickening. After finding an elevated angiotensin converting enzyme level, sarcoidosis was considered. Dermatology was consulted to biopsy a lesion on his thigh that did not appear consistent with psoriasis; it showed noncaseating granulomas, confirming the diagnosis of sarcoidosis.

Discussion: Sarcoidosis is a multisystem inflammatory disease characterized by noncaseating granulomas commonly affecting the lungs, liver, skin, and eyes. In the United States, we commonly think of young, healthy African American women presenting with respiratory symptoms and hilar adenopathy, but worldwide, Scandinavians have the highest prevalence rates, are often asymptomatic, and have a second peak in incidence in those over age 50. By remembering that sarcoid affects all ages, ethnicities, and has a variable a presentation, we may be able to diagnose patients sooner and affect patient outcomes.

The clinical picture of sarcoidosis often depends on ethnicity, duration of the disease, organs involved, and the activity of the granulomatous process. Ninety percent of patients will have lung involvement, while the diagnosis can be difficult without obvious pulmonary involvement. Hypercalcemia, due to increased conversion of Vitamin D 25-OH to 1,25-OH by the granulomatous marcrophages leading to increased intestinal absorption of calcium, may only occur in 2% to 10% of patients with sarcoid. Hypercalciuria and an elevated angiotensin-converting enzyme (ACE) level are other biochemical markers of disease, but not specific to sarcoidosis. Therefore, it is imperative to obtain tissue for a definitive diagnosis. Skin, superficial lymph node, salivary gland, or renal biopsies are an option when lung pathology is not present. Thus, it is important to consider sarcoid in nonparathyroid homorone-related hypercalcemia with a negative malignancy workup, because it is a disease that affects all individuals of different ages and commonly presents in an uncommon manner.

Holy Macro: Hypopituitarism Due to Mass Effect

Sherrill Gutierrez, MD; Medical College of Wisconsin Affiliated Hospitals, Milwaukee, Wis

Introduction: Recognizing hypopituitarism can be difficult due to the nonspecific presenting symptoms, which can be as unimpressive as a simple headache or fatigue, if there are any presenting symptoms at all. However, identifying hypopituitarism early is essential as many of the causes may be catastrophic including primary or metastatic tumors, and outcomes are dependent upon timely initiation of treatment.

Case: A 78-year-old man with past history significant for prostate and colon cancer, diabetes mellitus, and coronary artery disease, presented to the ED with a 2-week history of progressive headache, weakness, and vision changes. During his initial presentation at the onset of symptoms, a head CT was performed. No acute processes were identified to explain his symptoms. He was discharged home with plans for supportive care, but his symptoms progressed to include anorexia, nausea, and vomiting. Upon re-evaluation, magnetic resonance imaging (MRI) revealed a posterior pituitary macroadenoma with extension into the right cavernous sinus. Further workup noted hypocortisolism, hypothyroidism, and decreased testosterone levels. Treatment with steroids and radiation therapy were initiated, and his fatigue, weakness, and vision improved significantly. Given his prior oncologic history, a more aggressive evaluation was pursued, and he was found to have concurrent mantle cell lymphoma and diffuse large cell lymphoma in mediastinal lymph nodes. The patient was discharged home but had increasing difficulty caring for himself and subsequently required readmission to the hospital. Shortly thereafter, prior to beginning treatment for his lymphoma, he passed away.

Discussion: Hypopituitarism consists of the deficiency of many or all (panhypopituitarism) of the pituitary hormones. Clinical manifestations of hypopituitarism are dependent upon which hormone is deficient and to what degree. Therefore, presenting symptoms are fairly nonspecific and may include fatigue, headache, weight changes, dry skin, cold intolerance, loss of sex drive, loss of pubic or body hair, decreased appetite, and hypotension. Headaches and vision disturbances may accompany any of the above symptoms if a mass lesion is present. In addition to masses, which are the most common cause of hypopituitarism and can be primary or metastatic (rare), other etiologies of hypopituitarism include surgery, radiation, infection, pituitary infarcts, and genetic diseases. Treatment of hypopituitarism is dependent upon the cause and range from hormone replacement to chemoradiation and surgery.

Long-Term Outcomes in Patients with *Borrelia burgdorferi* Reinfection

Tyler Jares, MD, Todd Kowalski MD; Gundersen Lutheran, La Crosse, Wis

Background: Reinfection with *Borrelia burgdorferi* is recognized increasingly, but long-term outcomes are described incompletely.

Methods: We conducted a retrospective outcome study of patients with Lyme

reinfection, characterized by recurrent erythema migrans (EM) lesions, and matched controls with a single episode of early Lyme disease. Long-term outcomes were assessed by chart review, a survey consisting of a 36-item short form health survey (SF-36), and a standardized 10-item symptom questionnaire.

Results: From a population of 404 patients diagnosed with definite Lyme disease during 2000-2004, reinfection was identified in 24 patients (6%). Sixteen patients had complete long-term follow-up data available and were matched to 48 controls. One patient had 2 documented episodes of reinfection. Patients with reinfection were treated with oral doxycycline for a median duration of 14 days (range 5-28). SF-36 scores of patients with reinfection were similar to matched controls. There were no significant differences between patients with reinfection vs controls with regards to pain (78.9 vs 77.1, $P=0.747$), role limitations due to physical health (84.4 vs 73.6, $P=0.248$), general health (72.0 vs 65.5, $P=0.230$), social functioning (93.8 vs 89.1, $P=0.403$), vitality (60.6 vs 56.4, $P=0.515$), role limitations due to emotional problems (83.3 vs 85.1, $P=0.829$), emotional well-being (79.3 vs 81.0, $P=0.650$), or physical functioning (84.4 vs 74.5, $P=0.177$). Additionally, there were no significant differences between the 2 groups on the 10-item symptom-based questionnaire.

Conclusion: Lyme reinfection is relatively common in patients from endemic areas. Long-term outcomes were similar to outcomes of patients with a single episode of early Lyme disease. The clinical features and long-term outcomes of patients with recurrent EM lesions are consistent with reinfection etiology and not persistent *B. burgdorferi* infection.

An Unusual Case of Pancreatitis Caused by *Ascaris*

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Case: A 62-year-old Filipino woman visiting the United States presented with a 2-day history of severe abdominal pain, nausea, vomiting, and chills. She denied any history of alcohol consumption or cholelithiasis. Initial vital signs showed blood pressure (BP) 147/103, heart rate 120, temperature 99.3°F, and SaO_2 of 94%. Physical exam revealed distended abdomen with epigastric tenderness; otherwise unremarkable. Chemistry panel showed amylase 2521, lipase 9058, white blood cell (WBC) of 18.8, normal liver function tests (LFTs) and bone morphogenetic protein (BMP). Gallbladder ultrasound showed prominent thickening of the gallbladder wall and pericholecystic fluid. Abdominal CT scan showed pancreatitis and linear filling defects within the small bowel consistent with intestinal parasites. Stool was positive for *Ascaris lumbricoides.* Subsequent endoscopic retrograde cholangiopancreatography (ERCP) directly visualized the worm. Patient was kept NPO, hydrated, and started on albendazole. Clinical course became complicated with hemodynamic instability, respiratory failure, and acute renal failure (ARF). She was intubated and put on pressors and Meropenem. Patient recovered and was extubated successfully. Upon discharge, patient was stable; her symptoms resolved; amylase, lipase, and kidney functions were normal. Repeated stool microscopy was negative.

Discussion: Most cases of acute pancreatitis in the United States are attributed to alcohol consumption and gallstones, but in 10% of patients miscellaneous causes such as parasitic infections, viruses, and bacteria are responsible. While *Ascaris* is a well-recognized cause in underdeveloped countries, its exact incidence in the United States is unknown. Several cases were reported in recent immigrants or travelers to endemic areas. Abdominal ultrasound and CT have high diagnostic accuracy (80%). However, the diagnostic method of choice is ERCP, which shows not only the exact site but the number of parasites, and also is considered the treatment of choice for extracting parasites. The diagnosis of parasitic pancreatitis is difficult in disease-endemic areas, and even more so in nonendemic areas. This case illustrates that pancreatic ascariasis should be considered even in nonendemic countries, and it may resolve with anthelminthic treatment.

Level of Scientific Evidence Underlying Recommendations Arising from National Comprehensive Cancer Network Clinic Practice Guidelines

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Purpose: The level of scientific evidence on which the National Comprehensive Cancer Network (NCCN) guidelines are based has not been investigated systematically. We describe the distribution of categories of evidence and consensus (EC) among the 10 most common cancers with regard to recommendations for staging, initial and salvage therapy, and surveillance.

Methods: We obtained the latest versions (as of July 6, 2010) of relevant guidelines. The NCCN definitions for EC were Category I (high level evidence with uniform consensus), Category IIA (lower level of evidence with uniform consensus), Category IIB (lower level of evidence without a uniform consensus but with no major disagreement), and Category III (any level of evidence but with major disagreement).

Results: Of the 1023 recommendations found in the 10 guidelines, the proportions of Category I, IIA, IIB, and III EC were 6%, 83%, 10%, and 1%, respectively. Recommendations with Category I EC were found in kidney (20%), breast (19%), lung (6%), pancreatic (6%), non-Hodgkin lymphoma (6%), melanoma (6%), prostate (4%), and colorectal (1%) guidelines. Urinary bladder and uterine guidelines did not have any Category I recommendation. Eight percent of all therapeutic recommendations were Category I. Guidelines with the highest proportions of Category I therapeutic recommendations were breast and kidney cancers (30% and 28%, respectively). No Category I recommendation was found on screening or surveillance.

Conclusions: Recommendations issued in the NCCN guidelines are developed largely from lower levels of evidence but with uniform expert opinion. This underscores the urgent need and available opportunities to expand evidence base in oncology.

Recurrent Rib Fractures

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Case: A 57-year-old white man was evaluated in April 20l0 for recurrent rib fractures and lumbar and proximal femur bone mineral density (BMD) T-score of -5.2 and -3.4 respectively. Past medical history was notable for chronic obstructive pulmonary disease (COPD), coronary artery disease, dyslipidemia, and HIV since 1989. Medications include lamivudine-zidovudine and lopinavir ritonavir since 2006; aspirin, clopidogrel, omeprazole, pravastatin, and niacin. Fluticasone/salmeterol 250/50 mcg bid was introduced in September 2007 for severe COPD. Physical examination showed centripetal adiposity, pronounced pink abdominal and inguinal striae, multiple echymoses and rib tenderness. Complete blood cell count (CBC), renal and hepatic function, electrolytes, calcium, phosphate, intact parathyroid hormone, 25-OH-VitD, prolactin, serum and urine protein electrophoresis, and serum free light chains were normal. Random morning cortisol was 0.5mcg/d (4-24 mcg/dl), 24 hours urine-free cortisol <7.2 mcg, late-night salivary cortisol <10 ng/dl (< 100 ng/dl) and DHEA <30 mcg/dl (40-310 mcg/dl) all were very low. One hour post-corticotropin (ACTH) serum cortisol was 7.1mcg/dl (expected >20 mcg/dl). Serum ACTH was 32 pg/ml (0-46 pg/ml). Pituitary MRI was normal. Biochemical markers did not reveal accelerated bone turnover. Chest radiographs confirmed numerous rib fractures. This patient has iatrogenic Cushing's syndrome and adrenal suppression secondary to the potentiated systemic glucocorticoid effect of inhaled fluticasone by ritonavir. Patient's ritonavir was discontinued and he was placed on raltegravir. He was started on physiological and tapering doses of hydrocortisone and teriparatide. His cushingoid features have since receded and he has no further fractures.

Discussion: Ritonavir is a potent inhibitor of the cytochrome P450 3A (CYP3A4) enzyme activity. Fluticasone is potent inhaled corticosteroid with a long elimination half-life and prolonged glucocorticoid receptor occupancy and is also a substrate for CYP3A4 pathway. Fluticasone is most suppressive of HPA axis and has higher propensity for systemic accumulation when used with agents that inhibit CYP3A4 like ritonavir.

Reactive Hemophagocytosis: Is This Condition Underdiagnosed?

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Case: A 79-year-old woman, HIV negative on long-term steroids, presented with T (CD4) cell lymphopenia and cytomegalovirus (CMV) viremia associated with CMV, *Pneumocystis jiroveci* pneumonia (PCP), and *Aspergillus* pneumonia. She was receiving steroids for a diagnosis of cold agglutinin hemolytic anemia. The patient fulfilled 5 out of 8 criteria required for diagnosis of hemophagocytic syndrome: (1) fever for more than 7 days, (2) bicytopenia with low platelet count of 90 and hemoglobin of 8 without any bone marrow hypoplasia, (3) hypertriglyceridemia with tryglycerides of 400 mg/dl, (4) hyperferritinemia >500 at 9000, (5) natural killer (NK) cell activity low with count at 7. She did not fulfill the following hemophagocytic syndrome criteria: splenomegaly; increased soluble CD 25 levels, which were not checked; and bone marrow biopsy, which essentially was normal and did not show hemophagocytosis.

We considered the patient's syndrome to be associated with the CMV infection; there appeared to be little consensus for a diagnosis of hemophagocytic syndrome among the experts. The patient received 4 doses of intravenous immunoglobulin, which has been used previously for CMV-associated hemophagocytic syndrome. This treatment was chosen because it is relatively safer compared to etoposide. The patient also received the following for her infections: ganciclovir for CMV, TMP/SULFA for PCP and possible nocardia, and voriconazole for *Aspergillus.* She was continued on steroids both because she had been on them chronically and to prevent inflammatory changes with PCP treatment.

Hematology initially saw the patient, and did not see clear evidence of hemolysis. The measured amplitude of the cold-reactive antibody was low (1+), although Coombs C3 was positive, Direct Coombs positive. Current anemia was thought related more to inflammation/infection, thrombocytopenia consumptive, related to acute illness. However, the patient developed full-blown acute respiratory distress syndrome and remained ventilator dependent. In keeping with her advanced directive, her goals of care were transitioned to comfort, and life support was discontinued.

Not a Textbook Case of Headache

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Introduction: Giant cell (temporal) arteritis (GCA) is a chronic vasculitis involving both large and medium vessels. It is characteristically a systemic illness with widespread vascular involvement, but the cranial braches of the aortic arch are affected most often.

Case: An 82-year-old woman with a past medical history of atrial fibrillation, hypertension, and hyperthyroidism presented with a 3-month history of occipital headache radiating around her head and to her neck. A head CT was negative for acute intracranial abnormality except left sphenoid sinusitis. She was treated with antibiotics for sinusitis, but later returned with complaints of a global, unrelenting headache, followed by abrupt onset of jaw claudication with right-sided scalp tenderness. During these symptoms, the patient's physical exam was normal, including 2+ bilateral temporal pulses. Her basic laboratory studies were unchanged from previous values, including a white blood count of 13,000/uL, erythrocyte sedimentation rate (ESR) of 79 mm/hour and C-reactive protein 5.4 mg/dl. She was treated empirically with oral prednisone while arranging temporal artery biopsy. After just 1 day of treatment, the patient had almost complete resolution of her symptoms. Her bilateral temporal artery biopsies subsequently were found to be consistent with giant cell arteritis.

Discussion: GCA is seen rarely in patients <50 years old; the mean age of diagnosis is 72 years. Clinical manifestations are variable and include fever, fatigue, weight loss, new headache, jaw claudication, visual symptoms, and polymyalgia rheumatica. The classic GCA headache occurs in the temporal regions, but it may occur in the occipital or frontal areas and also may be generalized. The American College of Rheumatology diagnostic criteria include the following: age > 50 years; localized, new-onset headache; tenderness or decreased pulse of temporal artery; ESR >50 mm/h; and biopsy revealing necrotizing arteritis with a predominance of mononuclear cells or granulomatous process with multinucleated giant cells. The presence of 3 of 5 criteria is associated with 94% sensitivity and 91% specificity for the diagnosis of GCA. Temporal artery biopsy is the gold standard for GCA diagnosis, and the treatment of choice is oral glucocorticoids. Resolution of the inflammatory infiltrate in GCA occurs slowly after the start of treatment, thus it is possible to make an accurate diagnosis several weeks after the start of prednisone therapy. Thus, scheduling biopsy should not interfere with the start of treatment.

Hemophagocytic Lymphohistiocytosis (HLH)

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Case: A 64-year-old white man was transferred from an outside hospital with presumable diagnosis of pancreatitis and septic shock. He initially presented several months earlier with abdominal pain misdiagnosed with cholecystitis and underwent laparoscopic cholecystectomy. He had continuous decline with progressive weight loss (50 lbs/4 mo), nausea, vomiting, continued abdominal pain, pancytopenia, elevated liver enzymes, and high creatinine. Initial CT showed diffusely enlarged retroperitoneal and peripancreatic lymph nodes, enlarged, "inflamed" pancreatic head. He continued to deteriorate and was admitted and treated for sepsis and pancreatitis. Initial bone marrow finding of mild histiocytosis and hemophagocytosis was considered to be secondary to sepsis. He continued to deteriorate in spite of treatment, required ventilator and pressor support, and was transferred to Aurora St. Luke's for further management. At this point, he developed progressive multiorgan failure including respiratory failure, pancytopenia, elevated liver enzymes with jaundice (total bilirubin >25), renal failure requiring dialysis, coagulopathy with multiple factor deficiencies, hypoglobulinemia, hypertriglyceridemia hyperferritinemia, and elevated factor VIII. Imaging studies showed mild pleural and pericardial effusion, spleenomegaly, ill-defined hepatic mass, enlarged pancreatic head, mild lymph node enlargement, and DVT. Liver biopsy showed nonspecific inflammation. A second bone marrow biopsy revealed extensive lymphohistiocytosis and erythrophagocytosis suggestive of hemophagocytic lymphohistiocytosis (HLH). Although he received intensive care support including mechanical ventilation, pressors, continuous veno-venous filtration (CVVH), intravenous immunoglobulin (IVIG), steroid treatment, and multiple broad-spectrum antibiotics, progressive multi-organ failure eventually led to the patient's demise.

Discussion: HLH is a rare but fatal disorder that results from infiltration of various organs and tissues with lymphocytes, natural killer cells, and hemophagocytic histiocytes, and reflects a highly stimulated yet ineffective immune response triggered by various stimuli. This case shows complexity of HLH diagnosis due to septic shock-like manifestations. Early diagnosis is essential to start appropriate treatment achieving a better outcome. However, this is often very difficult due to varied and nonspecific presentation.

DISPLAYED POSTERS

Common Presentations of an Uncommon Disease: Clinical Aspects of Cardiac Sarcoidosis

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Case: A 51-year-old African American man with history of ventricular arrhythmias, atrial fibrillation on anticoagulation and hypertrophic cardiomyopathy (based on prior ECG) presented to the ED with 2-day history of intermittent chest pain, dyspnea, palpitations, and lightheadedness. On examination he was tachycardic with no jugular venous distention, cardiac murmurs, or edema. Laboratory studies revealed therapeutic INR and troponin of 0.16 but otherwise were within normal limits. Electrocardiogram (ECG) showed supraventricular tachycardia with rate of 172 beats per minute. His tachycardia did not respond to metoprolol, diltiazem, and adenosine. Elective cardioversion was performed, during which the patient went into asystole and was revived with 2 to 3 seconds of cardiopulmonary rescuscitation (CPR). Diffuse patchy enhancement on cardiac MRI suggested an infiltrative process, most likely sarcoidosis. ACE levels and serum protein electrophoresis were within normal limits. Chest CT scan did not show any lymphadenopathy but showed bilateral lung nodules.

Discussion: Most common in Japanese and Scandinavian populations, cardiac sarcoidosis (CS) is clinically apparent in only 5% of the patients but is detected at autopsy in at least 25% of the patients with sarcoidosis. It accounts for 13% to 25% of death from the disease. Presentations include arteriovenous (AV) or bundle branch block, atrial and ventricular tachycardias, congestive heart failure, left ventricular aneurysm and sudden death (SD). SD is responsible for 24% to 65% of all deaths related to CS in the United States. Though endomyocardial biopsy remains the gold standard for diagnosis, it is a high risk procedure with a very low sensitivity. With early and late gadolinium enhancement images, sensitivity and specificity of MRI for CS is reported to be 75% and 77% respectively. Steroids are the mainstay of treatment. Implantable cardioverter-defibrillator (ICD) placement is recommended in patients with sustained ventricular tachyarrhythmias and syncope, ECG abnormalities, or wall motion abnormalities attributed to CS. Cardiac transplantation is the definitive treatment in patients with intractable arrhythmias or

end-stage heart failure. The patient presented, subsequently had an ICD implantation, and was started on steroids.

The Tick Made Him Nervously Sick

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Introduction: Myasthenia gravis is the most common neuromuscular transmission disorder. A myasthenia gravis crisis can be triggered by infections, exertion, excitement, or numerous other stressors. We report a case of myasthenia gravis crisis due to ehrlichiosis.

Case: An 86-year-old white man with history of well-controlled myasthenia gravis presented to the ED with weakness and dyspnea that had been worsening progressively over the past several days. Due to impeding respiratory failure, the patient required intubation within minutes of presentation. Thus, initial history was limited. Exam revealed a weak, septic patient with a maculopapular rash on the bilateral forearms. Lab work was remarkable for thrombocytopenia and transaminitis. Peripheral blood smear revealed morulae inside several neutrophils. The patient was diagnosed with myasthenia gravis crisis due to sepsis from ehrlichiosis. He was treated with doxycycline, plasmapheresis, and IVIG. Later, the patient was extubated and reported a history of tick exposure. After 1 week, the patient recovered well enough to be discharged from the hospital.

Discussion: Many stressors have been associated with causing myasthenia gravis crises but to date there are no other cases of ehrlichiosis-induced myasthenia gravis crisis reported in the literature. This case demonstrates that patients who present with myasthenia gravis crisis can be critically ill, but can quickly recover if their inciting event is identified and treated.

An Illusive Presentation of Upper Extremity DVT

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Case: The patient is 29-year-old white woman with no significant past medical history who presented with 1 week left arm and shoulder pain. Pain started first at the back of the shoulder and progressed to the arm with restriction of range of movement and noticeable superficial vein dilatation on upper extremity. Patient denied fever, recent weight loss, chest pain, shortness of breath or dyspnea on exertion. There was no trauma to upper extremity and no personal or family history of DVT. Physical examination included the following: blood pressure 127/86, pulse rate 94, respiratory rate 16 and temperature 96.4°F. Lungs were clear to auscultation. Left shoulder was tender to palpation, and dilated veins were noted on surface of left arm. Labs showed normal basic metabolic panel and CBC; WBC 8.1, hemoglobin 11.6, hematocrit 34.8 and platelet count 330, prothombin time (PT) 10.4, partial thromboplastin time (PTT) 31 and INR 1. Doppler ultrasound of left extremity showed thrombosis in left axillary and subclavian veins. CT chest with contrast showed a 4.5 homogeneous soft tissue mass in the anterior mediastinum. Pathology report of excisional biopsy done by CT surgery confirmed primary mediastinal diffuse B cell lymphoma. Patient was treated with 4 cycles of R-CHOP followed by radiation therapy. She was anticoagulated with LMH and coumadin as an outpatient and continued to do well without development of complications such as SVC syndrome, pulmonary embolism (PE), or chronic venous insufficiency.

Discussion: Upper extremity DVT accounts for 2% to 3% of all venous thrombosis of which approximately one-third is primary idiopathic. Secondary causes are related to central venous catheters, cancers, and hormone replacement therapy (HRT). Primary mediastinal lymphomas are associated with SVC syndrome. There is little data describing upper extremity DVT in patients with B cell lymphomas.

An Uncommon Cause of Dancing ECG

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Case: A 54-year-old woman with a history of chronic lymphocytic leukemia with progression to prolymphocytic leukemia in remission was admitted with chest pain, exertional shortness of breath, and low back pain. Her vitals were stable and physical examination was unremarkable. An ECG showed electrical alternans and a chest x-ray demonstrated enlargement of the cardiac silhouette with clear lung fields. A transthoracic echocardiogram (TTE) revealed a large infiltrating mass involving the right ventricle, right atrium and atrial-ventricular groove. The tumor involved the root of the aorta and main pulmonary artery. The patient was noted to have a large circumferential pericardial effusion without evidence of tamponade. Pathology from endomyocardial biopsy of right ventricle was consistent with a low-grade B-cell lymphoma positive for CD20 and negative for CD3. CT scan showed disease involving the heart, mediastinal and paraspinal regions, bilateral kidneys, distal superior mesenteric artery, mesentery and pericardium. She was initiated on fludarabine, cytoxan, and rituxan (FCR) chemotherapy to which she initially responded well. However, she was readmitted 2 weeks later with recurrence of the effusion and was subsequently initiated on etoposide, doxorubicin, vincristine, cyclophosphamide and prednisone chemotherapy with rituximab (EPOCH-R). A repeat TTE showed that the effusion as well as the right ventricular outflow area of tumor burden had decreased in size with symptomatic improvement. She is now being followed closely in hematology clinic.

Discussion: This is a very rare and unusual presentation of an aggressive non-Hodgkin lymphoma arising out of prior B-cell prolymphocytic leukemia involving the heart. We initially treated the patient on FCR chemotherapy as her B prolymphocytic leukemia had responded to FCR and was in remission. But she did not respond to FCR chemotherapy. She was later switched over to EPOCH regimen as there is some evidence that EPOCH may produce more cell kill than CHOP-based regimens in untreated B–cell lymphomas (*Blood.* 2002; 99:2685-2693). The prognosis and optimal treatment is uncertain as it has not been reported previously in the literature.

Lymphocytic Esophagitis Presenting as Chronic Dysphagia

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Objective: Recognize lymphocytic esophagitis as a cause of chronic esophageal dysphagia

Case: A 60-year-old diabetic woman with stage IV chronic kidney disease and a lichen planus history presented with chronic intermittent dysphagia to solids for 7 years, which had worsened during the last 1 year. She had associated abdominal discomfort but denied any other gastrointestinal symptom. She had been treated with lansoprazole and famotidine with minimal improvement. The examination was unremarkable. Significant laboratory findings included blood urea nitrogen 58mg/dl, serum creatinine 5.7 mg/dl (baseline), total calcium 8.9 mg/dL, phosphates 4.9 mg/dL, estimated glomerular filtration rate (GFR) 8.2 mL/min, thyroid stimulating hormone 2.56 uIU/mL and hemoglobin ll.l g/dL. Chest radiography was normal and barium swallow showed normal swallowing with non-specific ringing. A follow-up esophagogastroduodenoscopy (EGD) revealed diffuse full-length esophageal ringing and furrowing with no other anomalies. Multiple biopsies were taken and lower esophageal sphincter dilatation done. Histology revealed multifocal peripapillary intraepitheliallymphocytic infiltrates involving the esophageal mucosa consistent with lymphocytic esophagitis. No eosinophilic component was observed. In absence of a standard treatment, a trial of fluticasone was initiated to be followed with sequential EGD. She also continued taking famotidine.

Discussion: Lymphocytic esophagitis is characterized by infiltration of the epithelium by inflammatory T lymphocytes. It is thought that chronic mucosal insult causes infiltration of T-lymphocytes thereby propagating an inflammatory process, leading to esophageal dysmotility, hence dysphagia. No data on prevalence, gender or age distribution exists, but 43 % of lymphocytic esophagitis patients present with dysphagia (*Am J Clin Path.* 2008;130[4]:508-513). Patients can be asymptomatic or have an underlying reflux esophagitis (most common), esophageal infections, radiation, allergy, and autoimmune disease like Crohn's disease or lichen planus. Histology shows extensive infiltration by intraepitheliallymphocytes around peripapillary fields, with CD3, CD4, and CD8 stains dominant. Biopsy findings in absence of structural or neurological causes make this the likely etiology. A proven treatment is unknown but a trial of topical steroids and anti-acid therapy can be given. This is extrapolated from eosinophilic esophagitis data; a familiar but different entity.

Bulging Eye: A Severe Complication of Acute Sinusitis

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Case: An 81-year-old white man was admitted with severe, acute right facial pain; bulging and redness of the right eye for the past day. He developed fulminant symptoms while on therapy with oral doxycycline for presumed acute sinusitis – sinus congestion and pain 2 days prior to presentation in the ED. Physical examination of the right eye showed ptosis and edema of the periorbital area. Right proptosis was present and ocular motility was limited in all 4 directions to about 80% normal. Vision in both eyes was 20/50 and pupils were symmetrical and pinpointed. The right cornea was clear, intraocular pressure was 22. He had leukocytosis of 22,000; CT scan of the orbits and sinuses revealed thrombosis of the superior ophthalmic vein and right-sided paranasal sinus disease with obstruction of osteomeatal units. MRI on the same day confirmed the superior ophthalmic vein thrombosis but no extension to cavernous sinuses.

Patient initially was treated with piperacillin/tazobactam, vancomycin and heparin drip. After 2 days of therapy with no clinical improvement, repeated MRI showed progression to bilateral superior ophthalmic vein thrombosis and cavernous vein thrombosis with persistent paranasal sinuses obstruction. Patient underwent endoscopic sphenoidotomy and maxillary antrostomy, which resulted in rapid clinical improvement. Cultures obtained intraoperatively grew *Streptococcus alpha hemolytic;* blood cultures grew *Streptococcus intermedius.* Antibiotics were adjusted to ceftriaxone, metronidazole. The patient subsequently was discharged on these antibiotics and warfarin therapy after almost total resolution of his symptoms.

Discussion: This case shows importance of evaluation of patient suffering from sinusitis for any ocular symptoms. It may indicate rare but serious complication of thrombosis in cavernous sinuses that carries high risk of mortality and warrants aggressive IV antibiotic treatment and surgical sinus drainage.

Fevers in an HIV Patient

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Introduction: The incidence of infective endocarditis (IE) is estimated to be 4 cases per 100,000 person-years. Of these, an estimated 3% is the result of a HACEK bacteria. While an uncommon diagnosis, HACEK endocarditis should be recognized as part of the differential in individuals presenting with fevers of unknown origin.

Case: A 43-year-old HIV-positive man with a history of drug abuse presented with fevers for 3 weeks. The patient was in the ED 3 weeks prior also for fevers. At that time, chest x-ray was negative. He was swabbed for H1N1 and discharged home with tamiflu. Since then, the patient reported continued temperatures. Physical exam was unremarkable. Initial laboratory studies were notable for leukocytosis of 11.6, a positive urine drug screen for cocaine and opiates, and an unremarkable LP. A head CT showed subtle areas suspicious for acute infarcts. A source of infection was sought with blood cultures, HIV RNA load, CD4 count, and a multitude of urine and respiratory studies. Temperatures consistently were elevated but responded to acetaminophen. Infectious disease was consulted and IV vancomycin and piperacillin-tazobactam were started. On hospital day 2, preliminary blood cultures showed gram negative bacilli. A transesophageal echocardiography revealed mitral valve vegetations. By day 3, the organism was identified as *Haemophilus parainfluen*zae, sensi-

tive to ceftriaxone. A peripherally inserted central catheter (PICC) was placed, and the patient was discharged home to complete 6 weeks of IV ceftriaxone.

Discussion: Although IE is associated typically with a history of cardiac lesions or injection drug use, it is important to recognize the diagnosis as part of the fever differential even without such histories. The HACEK group is a rare cause for IE but is not an uncommon cause of native-valve endocarditis in individuals without injection drug use. The recognition and identification of endocarditis is important to be prepared for its numerous complications, such as heart failure, which affect a significant portion of patients.

Severe Bleeding from an Uncommon Disorder

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Introduction: Acquired factor inhibitors present with severe spontaneous bleeding in adults. Here we describe a case of acquired factor V (FV) inhibitor with pelvic and soft tissue bleeding in a renal transplant patient, likely related to an occult infection.

Case: A 44-year-old man presented with an extensive right pelvic, gluteal, and thigh hematoma and hemoglobin 7.7 g/dL. His medical history was significant for renal failure secondary to Alport syndrome requiring renal transplantation in 1994. He required transplant nephrectomy of the rejected allograft in 2006, and later received a second renal transplant in 2009.

CT imaging demonstrated a 16 x 9-cm hematoma. Coagulation studies were obtained: prolonged partial thromboplastin time (PTT) 65.1 sec (nL 26-34 sec) and INR 2.0 (nL ≤1.1); thrombin time, fibrinogen, and platelet function assay were normal. Liver function tests and platelets (311 K/µL) were normal; a mixing study was negative. Factor X and VIII activities were normal, and FV activity was decreased at 19% (nL 70-135). A FV inhibitor assay was negative (0.2 Bethseda Units). A lupus anticoagulant panel detected a prolonged dilute Russell venom viper time, indicating the presence of a weak FV inhibitor.

As FV-specific concentrates are not available, fresh frozen plasma (FFP) and platelets (which contain ~20% of circulating FV) were given to replete FV. Steroids were given to suppress inhibitor production, and later rituximab was initiated as an immunodulatory agent. The patient had an appropriate response with FV activity >50% and stabilization of bleeding. Two weeks following hospital discharge, he was found deceased at his home. An autopsy showed a 4 x 3 x 3-cm abscess involving the right psoas muscle. Within the abscess cavity were sutures and staples from within the transplant nephrectomy site. No acute hematoma or occult bleeding were found at autopsy.

Discussion: FV activity levels have poor correlation with bleeding risk. Hemophilia patients experience spontaneous bleeds with factor activity levels <5%, but patients with FV activities of ≤20% may experience bleeding. An acquired FV inhibitor should be suspected in the setting of prolonged PTT and INR and clinical bleeding. Empiric therapy with factor replacement (FFP and platelets) and high-dose steroids should be considered while the diagnosis is being confirmed.

Itching for a Diagnosis

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Introduction: Cutaneous T-cell lymphomas (CTCLs) should be considered in any patient with chronic dermatitis that does not respond to conventional treatments. The most common CTCLs are mycosis fungoides (MF) and Sezary syndrome (SS) with initial presentation with skin manifestations and pruritis.

Case: A 66-year-old African American woman with a history of eczema was admitted for increasing pruritis. She was diagnosed with eczema 6 years ago. It initially began as nummular lesions on her extremities relieved with over-the-counter (OTC) medications. Over the years, the lesions became eczematous with pink pigmentation. The past few months it became generalized to her entire body with increasing pruritis. She tried OTC vaseline and various topical medications with no relief. Past biopsies taken 4 times were unremarkable. She denied any fevers, chills, weight loss, recent travels, changes in medications, or allergies. The patient was admitted for triamcinolone wraps and further evaluation. On admission, vitals were stable and physical exam was unremarkable except for diffuse hyperkeratotic skin lesions with patchy hyperpigmented areas and eczematous changes, thickened hyperkeratosis on palms and soles, and small, pink, firm nodules predominantly on her back. Skin biopsy showed hyperplastic epidermis with Pautrier's micro-abscesses consistent with MF. Flow cytometry of the peripheral blood showed peripheral T cell clone consistent with SS. Chest/abdomen/pelvis CT showed axilla and inguinal lymphadenopathy. Biopsy of cervical node showed benign thyroid tissue. Based on these findings, a diagnosis of CTCL Stage IV A1 with SS was made. The patient was started on photophoresis and IFA.

Discussion: Cutaneous T-cell lymphomas (CTCLs) should be considered in any patient with chronic dermatitis that does not respond to conventional treatments. CTCLs are uncommon and represent 2.2% of all lymphomas. They increase with age and are 2 times more common in men and in African Americans. The etiology is unclear. MF generally presents with skin patches/plaques, eczematous-like lesions, or erythroderma with pruritis. Sezary syndrome is a more aggressive variant with peripheral blood involvement by malignant T cells. Often, multiple skin biopsies are required for diagnosis.

Metastatic Pulmonary Calcification Secondary to Primary Hyperthyroidism

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Objectives: Metastatic pulmonary calcification (MPC) has been described in a variety of benign and malignant diseases. Differentiation of primary hyperparathyroidism (PHP) from other causes of hyper-

calcemia (HCa) in the setting of MPC and subacute renal failure is important in order to expedite appropriate management.

Case: A 67-year-old man with a past history of hypothyroidism treated with levothyroxine (LT) 300 mcg daily, and cryptogenic cirrhosis presented with 1-week history of bilateral leg pain self-treated with aspirin 325 mg 6-7 tablets daily. He reported taking 2 tablets of β-carotene (βC) daily. Both medications were discontinued 1 week prior to presentation. He denied vitamin D or herbal supplementations, long periods of inactivity, weight loss, chills, or night sweats. Chemistry evaluation was significant for total calcium level (TLC) 14.7 mg/dl (8.5-10.3), PTH (parathyroid hormone) intact 47 pg/mL (N=11-67), ionized calcium (iCa) 7.6 mg/dl, phosphate 5.2 mg/dl (2.2-4.5), BUN 105, Cr 6.8, TSH 0.01 uIU/mL (0.40-5.70), free T4 2.9 ng/dl (0.6-1.2), thyroglobulin (0.6 ng/ml <3.0), free retinol 423 uglL (325-780), 1,25-hydroxyvitamin D 48 pmol/L (39-193), angiotensin converting enzyme 26 U/L (30-80), normal serum protein electrophoresis and skeletal survey. Fungal panel was negative for histoplasmosis, blastomycosis, coccidiomycosis, quantiFERON-TB. Urinalysis was normal without Bence Jones protein. He received vigorous hydration and diuretics with resolution of HCa and normalization of iCa. Repeat chemistry found PTH 231 pg/mL. Chest radiograph showed small nodular densities in the upper lobes. Chest CT showed multiple small calcified nodules. Neck ultrasound showed a hypoechoic parathyroid nodule posterior to the left thyroid gland. Parathyroid SPECT/CT revealed parathyroid adenoma. He underwent successful radioguided parathyroidectomy with PTH control.

Discussion: Metastatic calcification refers to the deposition of calcium salts in normal tissue due to conditions causing HCa, hyperphosphatemia, and local alkaline environment. MPC in the setting of PHP is an uncommon medical condition. It has been described in such diverse conditions as chronic renal failure on hemodialysis, hyperparathyroidism, bone osteolytic bone tumors and granulomatous diseases. PHP and malignancy are the most common causes of HCa. Other contributing factors leading to HCa in our patient include exogenous hyperthyroidism and βC consumption. As found in our patient, parathyroid adenomas are not completely autonomous, and PTH secretion may be partially suppressed by elevated Ca levels.

The Use of Plasmaphoresis in the Treatment of Wegener's Granulomatosis: A Case Report

Yuan Zhou, MD; St. Joseph Hospital Department of Medicine, Marshfield, Wis

Background: Wegener's granulomatosis is a form of vasculitis that causes rare cases of renal-pulmonary symptoms. While predominantly treated with corticosteroids, the use of plasmapheresis may be beneficial in severe cases involving pulmonary hemorrhage.

Case: A 72-year-old man with a past medical history significant for hypertension and gout presented with a 2-week history of progressive shortness of breath. He initially was diagnosed with acute otitis media in an outpatient setting and prescribed a 10-day course of amoxicillin. During his antibiotic course, the patient's shortness of breath worsened and he developed diarrhea and oliguria. Patient first went to an outside hospital where he was noted to have significant abnormal kidney functioning with creatinine of 10.2 and serum urea nitrogen (BUN) of 100. Hemoglobin was 7.2; ESR was 107; chest x-ray showed pulmonary edema. Patient was admitted for acute renal failure and placed on dialysis. He also was treated with broad-spectrum antibiotics for possible multilobar pneumonia. Autoimmune antibody tests were conducted and C-ANCA was positive. Patient was given a working diagnosis of Wegener's granulomatosis and started on pulse solumedrol and referred to our hospital for confirmatory testing and initiation of plasmapheresis.

On exam, patient was noted be afebrile, nontachycardic, nonhypertensive. He appeared dyspnic with respiratory rate of 16 and oxygen saturation of 92% on 15L oxygen. On pulmonary exam, he had diffuse coarse crackles bilaterally and decreased breath sounds along both lung bases. Cardiac, abdominal, and neurologic exam was within normal limits and noncontributory. Labs on admission showed an elevated WBC of 15.3, low hemoglobin of 8.8, C-reactive protein (CRP) of 13.3, BUN of 133, and creatinine of 9.8. Chest x-ray demonstrated bilateral infiltrates, suggestive of pulmonary hemorrhage. Patient was started on broad-spectrum antiobiotics, hemodialysis, and plasmapheresis. Kidney biopsy was obtained later confirming the diagnosis of Wegener's granulomatosis.

Discussion: This case explores the treatment modalities for a patient with severe ANCA-positive vasculitis. Plasmapheresis is theorized to help remove ANCAs from the bloodstream and, in retrospective studies, has been suggested to be beneficial for patients with severe renal disease and pulmonary hemorrhage. In 2 randomized clinical trials, patients receiving plasma exchange along with immunosuppressants had a greater likelihood of recovering renal function after initially being placed on dialysis vs patients treated with immunosuppressants alone. Plasma exchange has the potential to be a more prominent treatment adjunct in Wegener's granulomatosis and other vasculitis syndromes, but more studies are necessary before such recommendations can be made.

VIGNETTES

Valvular and Nonthrombotic Neurologic Sequelae from Antiphospholipid Antibody Syndrome: A Case Report

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Background: Antiphospholipid antibody syndrome (APS) is a relatively common cause of acquired thrombophilia and recurrent pregnancy-related complications. While less well-known, its non-criteria manifestations can also have clinical significance.

Case: A 43-year-old man with dementia, epilepsy, and suspected APS was referred to the rheumatology clinic for further evaluation. In addition to seizures, he had expe-

rienced progressive cognitive decline and recurrent headaches. Prior labs revealed high titer anticardiolipin antibodies and positive lupus anticoagulant. An earlier electroencephalogram (EEG) demonstrated posterior slowing. Positron emission tomography (PET)/CT had revealed hypometabolism of bilateral mesial temporal lobes. Review of systems was negative for rash, photosensitivity, oral ulcers, arthritis, serositis, venous/arterial thromboses, or stroke. Family history was negative for thrombotic events or recurrent miscarriages.

On exam, his thought process was slightly slowed. Cardiac exam revealed no regurgitant murmur and no evidence of synovitis; skin exam without livedo reticularis or rashes. Cranial nerves were intact. Treatment was begun with baby aspirin, hydroxychloroquine, and rituximab. Repeat EEG demonstrated generalized background slowing in the high-theta band. Neuropsychologic testing showed borderline/mildly impaired results in multiple cognitive domains. Transthoracic echocardiogram (TTE) revealed mild-moderate mitral regurgitation plus mildly thickened leaflet tips. Transesophageal echocardiogram (TEE) later showed a nonmobile mass on the anterior mitral leaflet measuring 1.3 x 0.7 cm, concerning for Libman-Sacks endocarditis.

This case highlights 2 noncriteria manifestations of APS—neuropsychiatric disease and Libman-Sacks endocarditis. The spectrum of neurologic abnormalities is varied, ranging from behavioral changes to seizures. Libman-Sacks endocarditis involves sterile, nonbacterial lesions that most commonly affect the mitral valve. While often clinically silent, they can predispose to complications such as severe valvular regurgitation and thromboembolic events. This case also illustrates the use of hydroxychloroquine and rituximab as novel treatments for APS. Multiple case reports suggest clinical improvement in APS patients treated with these agents. Further validation of their efficacy through randomized controlled trials is necessary before they become standard treatment options.

Ski Trip Results in Paralysis

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Case: A 20-year-old Chinese man presented to the ED with progressive paralysis. He was skiing earlier that day, and in the evening he developed diffuse muscle cramping and woke up later that night with profound muscle weakness, mainly in lower extremities. The symptoms progressed over a couple hours to the point when he was "unable to move." Patient denied trauma during skiing and had no difficulty breathing or swallowing. Past medical history was significant for hyperthyroidism diagnosed 10 years prior; patient was taken off the medications for about a year. Review of systems revealed weight loss of 10 pounds in 1 year and occasional palpitations. Exam found a tachycardic (pulse 120) anxious patient, with systolic flow murmur, muscle strength 0/5 in both upper and lower extremities bilaterally, absent patellar, axilles, biceps, and brachioradialis reflexes. Neurological examination revealed intact cranial nerves. Initial laboratory work was only significant for hypokalemia. ECG indicated sinus tachycardia and first-degree atrioventricular block. Further testing was significant for elevated T3 and T4 as well as low thyroid-stimulating hormone. Initial diagnosis of thyrotoxic periodic paralysis was made. Treatment was initiated with potassium chloride supplementation and nonselective beta-blockers. Symptoms of quadriplegia completely resolved within 48 hours. The patient was started on antithyroid treatment for the diagnosis of Grave's disease.

Discussion: Thyrotoxic periodic paralysis is a rare and dramatic complication of hyperthyroidism. It is more common in Asian population, predominantly men. Precipitating factors like strenuous exercise and large carbohydrate load are frequently identified. Signs of hyperthyroidism are commonly subtle. Hypokalemia and muscle weakness result from intracellular shift of potassium. Early diagnosis and treatment with potassium supplementation prevent possible complications of cardiac arrhythmias and respiratory failure. Nonselective beta-blockers can help ameliorate the symptoms and prevent future attacks. Definite treatment of hyperthyroidism abolishes thyrotoxic periodic paralysis.

Not Your Typical Chest Pain

Rachel R. Johnson, MD, R. Frank Cornell, MD, Heather Toth, MD; Medical College of Wisconsin, Milwaukee, Wis

Introduction: Pernicious anemia is the most common cause of Vitamin B12 deficiency, secondary to autoantibodies against parietal cells and intrinsic factor. Indentifying pernicious anemia is important to prevent neurologic complications, correct underlying hematologic abnormalities, and identify associated autoimmune conditions.

Case: A 47-year-old African American man with a history of throat cancer, now in remission, presented with a chief complaint of substernal chest pain and shortness of breath over 2 weeks. In addition, he reported weight loss, fatigue, and weakness. On initial exam, he had pallor of his lips, conjunctiva, and palms, and the rest of his exam was normal. In the ED, ECG demonstrated normal sinus rhythm without ischemic changes. Initial cardiac enzymes were normal but CBC demonstrated pancytopenia with platelet count of 144, white count of 3.7, hemoglobin of 7.0 gm/dL, hematocrit of 21 and a mean corpuscular volume (MCV) of 134. Peripheral blood smear was significant for megaloblastic changes with hypersegmented neutrophils and Holly-Jolly bodies. Work-up of his pancytopenia demonstrated a Vitamin B12 of <30, normal folate , thyrotropin (TSH) elevated to 14.45 and Free T4 of 0.61. Anti-parietal cell antibody was negative but intrinsic factor blocking antibody was positive, leading to the diagnosis of pernicious anemia. The patient was discharged on intramuscular (IM) Vitamin B12 injections as well as levothyroxine 100µg.

Discussion: Pernicious anemia is the most common cause of Vitamin B12 deficiency. Autoantibodies against intrinsic factor and parietal cells are useful markers for pernicious anemia, with 73% sensitivity and 100% specificity when used together. Approximately 90% of patients with pernicious anemia have antiparietal cell antibod-

ies and 60% have intrinsic factor blocking antibodies. Vitamin B12 deficiency can result in megaloblastic changes and pancytopenia, as in this patient, as well as subacute combined degeneration of the spinal cord that is often irreversible even after Vitamin B12 supplementation. Neurologic deficits include loss of vibratory sensation, proprioception, dementia, and psychosis. Pernicious anemia also often presents with numerous constitutional symptoms, as in this case. As pernicious anemia is an autoimmune disease, it is often associated with other autoimmune diseases including Grave's disease, autoimmune thyroiditis, vitiligo, and hypoparathyroidism. At the initial diagnosis, it is important to screen for these other autoimmune diseases to also appropriately treat these conditions as supplementation of Vitamin B12 is initiated.

Waiting with Wegener's

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Background: Wegener's granulomatosis is a necrotizing vasculitis involving small- and medium-sized blood vessels that commonly affects the respiratory tract and kidney. The gradual onset of symptoms often results in delayed diagnosis, thus recognition of the systemic effects is important for timely diagnosis and treatment.

Case: A 23-year-old man presented to his primary physician complaining of shortness of breath, hemoptysis, and bilateral foot purpura. He related a 10-month history of intermittent epistaxis and 2-month history of persistent cough, rhinorrhea, and nasal congestion. Chest radiograph showed bilateral pulmonary infiltrates and chest CT showed bilateral infrahilar consolidation and interstitial infiltrates. Bronchoscopy revealed nucleated cells and blood. Urinalysis was positive for red blood cells and protein, and his ESR was elevated. He received a working diagnosis of Goodpasture's syndrome and was referred to multiple specialists for further workup. He subsequently developed sharp earache, left-sided hearing loss, diffuse arthralgias, and lower extremity edema, prompting hospital admission. On exam, his vital signs were stable with oxygen saturation at 94% on room air. His lungs were clear with decreased breath sounds bilaterally, and he had 0.5 cm palpable purpura on his lower extremities. A complete blood cell count (CBC) showed normocytic anemia. Further testing found positive cytoplasmic antineutrophil cytoplasmic antibodies (C-ANCA) and serum proteinase 3 antibodies. Nasal mucosal biopsy showed neutrophilic vasculitis and acute granulation. He was diagnosed with Wegener's granulomatosis and started on high-dose steroids and cyclophosphamide. The patient stabilized and was discharged 2 days after admission.

Discussion: Wegener's granulomatosis is a necrotizing vasculitis involving small- and medium-sized blood vessels predominantly affecting middle-aged men. Common manifestations include sinusitis, mastoiditis, hemoptysis, and hematuria. American College of Rheumatology diagnostic criteria are as follows: nasal or oral inflammation; abnormal chest radiography showing nodules, fixed infiltrates or cavities; abnormal urinary sediment; and arterial or perivascular granulomatous inflammation on biopsy. Two or more of the 4 criteria yields a sensitivity of 88% and a specificity of 92%. C-ANCA, especially anti-proteinase 3 antibodies, are also present in the serum of up to 95% of patients and can support the diagnosis. The average time from symptom onset to diagnosis is 3 to 12 months, with patients seeing an average of 4.4 physicians before diagnosis. The delay typically is due to the gradual onset of symptoms over time. It is important to recognize the clinical manifestations of Wegener's granulomatosis so as to not delay diagnosis and treatment. Untreated, the course is malignant and 80% of patients die within 1 year. Standard treatment is a combination of high-dose corticosteroid and cyclophosphamide, which induces remission in at least 85% of patients within 6 months.

Hip Pain in a Patient with Systemic Lupus Erythematosis and Tuberculosis

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Case: A 48-year-old woman who recently emigrated from Mexico presented to urgent care with a chief complaint of right hip pain. The pain had been constant for 8 months and was described in the trochanteric bursa and groin region. Physical exam revealed intact range of motion with some limitation on internal rotation. She had a past medical history significant for systemic lupus erythematosis treated with high doses of prednisone for 3 years. A hip x-ray showed osteoarthritis with blood tests revealing anemia and leukocytosis. A quantiferon gold test for tuberculosis (TB) was positive. MRI showed evidence of either synovitis or a complex joint effusion. Therefore, a hip athrocentesis was performed to more clearly delineate the etiology of the pain. The results were bacterial and fungal culture negative and acid-fast baccilus (AFB) smear and culture negative. Suspicion for septic arthritis with TB remained high. Three months later, the patient underwent a second hip arthrocentesis. Pathology from the synovium revealed granulomatous inflammation, and AFB culture positive. At that time she also complained of 2 weeks of cough. A chest x-ray revealed multinodular disease in the lungs suspicious for military TB. She was admitted to the hospital and started on isoniazid, rifampin, pyrazinamide, ethambutol, and moxifloxacin. Her pulmonary nodules resolved on x-ray but her hip pain had not resolved.

Discussion: This case illustrates the potential risk of unregulated use of immunosuppressive drugs in a patient with an already impaired immune system who is also in a high-risk area for TB exposure. It raises the discussion of whether the benefits of immunosuppressive therapy outweigh the potential side effects in this type of scenario.

Dietary Polyherbacy and the Problem of a Didn't Ask, Don't Tell Attitude

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Introduction: Recent national surveys reveal that at least 1 in 3 patients use a dietary supplement, and the average patient uses 3

to 5 dietary supplements, usually containing multiple active ingredients—a practice termed polyherbacy akin to polypharmacy.

Case/Discussion: A 79-year-old man with COPD reported increasing weakness for a month to the point of collapsing prior to admission. He was alert and oriented, in no acute distress, registering elevated systolic blood pressures of 170 -180 mmHg, a heart rate of 65 bpm, a respiratory rate of 18/min and an O_2 saturation of 97% on room air. Examination was unremarkable except for features of mild COPD. He did not have any muscle tenderness nor was he cushingoid. He was noted to be profoundly hypokalemic, 2.1 mmol/L (normal 3.4-5.1 mmol/L), had a bicarbonate of 37 mmol/L (normal 22-28 mmol/L) and a creatinine of 0.9 mg/dL. Dietary history confirmed adequate potassium intake. The transtubular potassium gradient of 14 (normal < 10) with urinary potassium-creatinine ratio of 8 in the face of severe hypokalemia (normal < 3mEq/mg creatinine) confirmed renal potassium wasting raising a differential diagnosis of primary hyperaldosteronism or adrenal tumor. Abdominal CT was unremarkable and AM cortisol was 28 ng/dl. Unexpectedly, the plasma aldosterone was very low, < 2.5ng/dL (normal 3-34), plasma renin was low normal, 0.24ng/mL/h, which led to the diagnosis of an Apparent Mineralocorticoid Excess state.

Following repeated inquiry, the patient's wife brought in a respiratory herbal supplement—"Second Wind," which he had been taking for 6 weeks. Content review revealed among other things, licorice root extract, 250 mg per serving size of vegetable capsule. He recovered 2 weeks after discontinuation of the supplement, with aggressive potassium replacement.

Conclusion: Despite growing knowledge of the widespread use of dietary supplements, many patient-physician encounters are "didn't ask, don't tell" when it relates to use of dietary supplements. This clinical vignette, in addition to showcasing a Syndrome of Apparent Mineralocorticoid Excess, highlights the unintended consequences of polyherbacy, the urgent need to deconstruct the myth that herbal and dietary supplements are "all natural, all pure, and therefore free of harm." It stimulates us to consider a concerted effort for a public health policy and clinical practice guideline to address a burgeoning problem.

ANCA + Vasculitis Presenting as Diabetes Insipidus

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Introduction: Wegener's granulomatosis is a necrotizing granulomatous vasculitis associated with antineutrophil cytoplasmic antibodies that typically involves the upper and lower respiratory tracts and the kidneys. It can affect any organ system and many patients will have neurologic involvement at some point in the course of their disease. However, central diabetes insipidus (DI) as the first symptom of Wegener's is extraordinarily rare.

Case: A 66-year-old man presented with a 2- to 3-week history of polyuria and thirst. The symptoms developed gradually with progression to hourly urinary frequency. The patient denied hesitancy, urgency, dysuria, or hematuria. He noted migrating myalgias and arthralgias occurring over the preceding 2.5 years. He also reported a dry cough. Physical exam was unremarkable. Serum osmolality was mildly elevated at 309 with urine osmolality low-normal at 106. A water deprivation test was conducted with findings consistent with partial central diabetes insipidus. The patient was started on nasal DDAVP with appropriate decrease in urine output and increase in urine osmolality. MRI of the brain and sella turcica demonstrated absence of the "normal pituitary bright signal," which was thought to suggest an infiltrative process in the posterior pituitary gland. A chest CT demonstrated multiple pulmonary nodules bilaterally with necrotic centers. Biopsies of these nodules revealed inflammatory changes with giant cells, microabscesses, and some granulomatous features, with patchy surrounding interstitial fibrosis with centrilobular predilection, favoring a diagnosis of Wegener's granulomatosis. P-ANCA was positive but c-ANCA and myeloperoxidase (MPO) were negative. Renal function was normal. PCR for TB was negative.

Approximately 5% of patients with Wegener's granulomatosis will be p-ANCA positive, though the majority are c-ANCA positive. As with this patient who had no renal impairment, approximately one-fourth of cases of Wegener's granulomatosis will occur as a "limited" form with clinical findings isolated to the upper respiratory tract or lungs. Other organ systems that may be involved include the joint, skin, eyes, and nervous system. Central DI associated with Wegener's granulomatosis is rare, with only approximately 22 cases reported in the literature. Fewer cases exist of central diabetes insipidus as the presenting symptom of Wegener's granulomatosis.

Not a Drop of Blood: Managing a Jehovah's Witness with Cardiac Disease and Gastrointestinal Blood Loss

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Case: A 62-year-old woman with a past medical history significant for persistent coronary artery disease despite bypass, breast cancer, and diverticulosis presented to Aurora Sinai Medical Center because of bright red blood per rectum. Initial hemoglobin was 10.3 g/dL. The patient was a Jehovah's Witness and clearly stated she would accept no blood product because of her beliefs.

Six hours after admission, the patient became acutely symptomatic from her blood loss with dizziness and chest pain. Repeat hemoglobin was 7.0 g/dL. The patient was transferred to the intensive care unit where she was started on fluid resuscitation and erythropoetin. A nuclear medicine study was performed, which confirmed ongoing bleeding. The patient was embolized by interventional radiology. The next day, her hemoglobin continued to drop, to 4.0 g/dL. She developed altered mental status and severe chest pain. An ECG demonstrated evidence of ischemia. The patient was transferred to Aurora St. Luke's Medical Center for possible hyperbaric oxygen therapy.

After transfer, the patient was reevaluated and had improved mental status. Hemoglobin was 2.9 g/dL. Because of

improving symptoms, hyperbaric treatment was deferred and patient was managed supportively. Two weeks later, the patient was clinically improved and discharged with hemoglobin of 4.0. On follow-up a month after the inciting event, her hemoglobin was 11.9 and she was completely asymptomatic.

Discussion: This case highlights some of the difficulties in treating patients without blood products, and some of the strategies used to provide adequate tissue oxygenation in this setting. This case also represents 1 of the lowest survived hemoglobin ever recorded in a patient without blood transfusion, and the lowest reported in a patient with coronary disease.

Monoclonal Antibody Therapy for Recurrent Abdominal Pain?

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Background: Recurrent abdominal pain can be a challenging diagnosis for clinicians, especially in elderly patients with chronic pain who have previously had extensive evaluations. Abdominal pain associated with cytopenias deserves thorough evaluation, as a potentially treatable underlying diagnosis can be uncovered. To demonstrate this, we present a case of previously unidentified paroxysmal nocturnal hemoglobinuria (PNH) causing repeated admission for abdominal pain that was successfully treated with eculizumab.

Case: An 86-year-old woman with history of chronic back pain, abdominal surgeries, and pancytopenia attributed to a myelodysplastic syndrome (MDS) was admitted to the hospital for abdominal pain and emesis. She had 4 hospital admissions within the preceding 8 months for abdominal pain attributed to opioid-induced ileus and partial small bowel obstructions (SBO). A previous enteroscopy had shown only small bowel inflammation, and workup of her anemia several years earlier showed a relatively small fraction of her blood cells with an immunophenotype consistent with PNH; however, she had no prior evidence of active hemolysis. She had been receiving intermittent transfusions for anemia and thrombocytopenia. Her presentation on admission was consistent with recurrent SBO and subsequent CT scan revealed multiple focal segmental areas of small bowel wall thickening as well as dilatation of proximal jejunal small bowel loops. Laboratory evaluation on admission showed hemoglobin of 9.6, platelets of 71, white blood cell count of 8.5, and total bilirubin of 0.9, all stable from previous testing. Enteroscopy with biopsy showed severe jejunal ulceration and venous thrombus formation consistent with ischemic jejunitis. Magnetic resonance angiography (MRA) was negative for mesenteric venous thrombus, and thrombophilia workup was also negative but reevaluation of the patient's anemia revealed a positive urine hemosiderine, low haptoglobin, and elevated lactate dehydrogenase (LDH) consistent with hemolysis. Immunophenotype testing showed loss of GPI-anchored proteins on both granulocytic (58% of total granulocytes) and erythroid (8% of total erythrocytes) cells consistent with PNH. Treatment with eculizumab was initiated, and at 3 months she had not required a single transfusion or had recurrence of her abdominal pain.

Discussion: PNH is a treatable disorder occurring in the setting of MDS in 5% to 9% of cases that should be considered in all patients with recurrent abdominal pain. As demonstrated by this case, proper diagnosis and treatment can result in decreased hospital admissions and improved quality of life.

Metastatic Angiosarcoma Presenting as Diffuse Pulmonary Hemorrhage

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Introduction: The syndrome of diffuse pulmonary hemorrhage (DPH), which includes hemoptysis, anemia, and bilateral pulmonary infiltrates, has a broad differential diagnosis. Establishing the specific cause of DPH can be challenging. Hemoptysis can be a feature of metastatic angiosarcoma, but these patients often have an established diagnosis of angiosarcoma from their primary tumor. We report a case of metastatic angiosarcoma presenting as diffuse pulmonary hemorrhage, a rare presentation for this uncommon disease.

Case: A 32-year-old white man with no significant past medical history presented with hemoptysis for 6 weeks. He reported dyspnea and palpitations for 3 weeks. He had a 10-pack/year history of tobacco abuse and also reported binge alcohol use and smoking marijuana. He denied intravenous drug use. His physical exam was normal except for pallor. Laboratory studies revealed hemoglobin of 6g/dL. His ESR and C-reactive protein were elevated. Tests for HIV, fungal infection, autoimmune disease, and TB were negative. Chest radiograph revealed diffuse ground glass appearance. Chest CT revealed innumerable clusters of micronodules in the peripheral distribution in upper and lower lobes bilaterally. Nodular lesions also were noted in the liver and spleen. Percutaneous liver biopsy showed malignant cells with extensive necrosis, but a definitive diagnosis could not be made. Bronchoscopy with lavage and fine needle aspirate of the lymph node was negative for malignant cells. Video-assisted thoracoscopic surgery (VATS) with wedge biopsy of lung was performed, and the specimen showed extensive intravascular involvement of malignant cells consistent with metastatic angiosarcoma. The patient received paclitaxel with resolution of the hemoptysis and lung lesions and was doing well 6 months after initial presentation.

Discussion: Metastatic angiosarcoma should be included in the differential diagnosis of DPH. Bronchoscopy may not be a reliable method for diagnosing angiosarcoma presenting as DPH as the pathological findings can be obscured by hemorrhage. A more definitive diagnostic procedure such as VATS-guided lung biopsy needs to be considered.

AML with Blast-Negative CNS Involvement

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Introduction: Central nervous system (CNS) involvement in acute myelogenous leukemia (AML) is less common than in acute lymphoblastic leukemia (ALL). CNS leukemia can present as headache, nausea, vomiting, cranial nerve palsies, or seizures. However, CNS leukemia cannot be confirmed reliably by detection of blasts in the cerebrospinal fluid (CSF). CNS deficits in a previously diagnosed AML patient should be considered recurrence of disease unless proven otherwise.

Case: A 28-year-old man with a diagnosis of AML achieved complete remission with 7+3 induction chemotherapy with cytarabine and daunorubicin. Months later, he presented with right facial droop, left ptosis, and diplopia. Physical exam was remarkable for right facial nerve palsy and left third cranial nerve palsy. Laboratory studies revealed a white cell count of 1.0, absolute neutrophil count of 0, hemoglobin 8.8 g/dL, platelets 452. The CSF had 2 white blood cells (WBC), glucose 120, protein 26. CSF bacterial and fungal cultures, viral serologies, and Lyme titers were negative. Six separate CSF collections were negative for blasts. MRI of the brain was unremarkable. Bone marrow aspirate revealed 88% blasts. The patient was diagnosed with recurrent AML with CNS involvement despite blast-negative CSF.

Discussion: CNS involvement is less common in AML than ALL and also is less common in adults than children. Since high-dose cytarabine—which penetrates the CNS—has been incorporated into AML treatment, the incidence of CNS leukemia has decreased. However, CNS AML does occur in 3% to 5% of patients and it cannot always be confirmed by blasts in the CSF. Despite clinical CNS involvement, the CSF may be blast-negative on serial collections. Expert consensus dictates that if clinical evidence of CNS involvement is present, the patient should be treated for CNS leukemia, which typically includes systemic and intrathecal chemotherapy.

Palatal Eschar in Sinusitis: Scan Them Early, Treat Them Swiftly

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Introduction: Sinusitis is a common and relatively benign diagnosis in office practice and zygomycetes are an extremely unusual cause of sinusitis in immunocompetent individuals. However, these ubiquitous fungi can quite literally transform into a bone-erosive, life-threatening species, particularly in the context of diabetes with ketoacidosis or other immunocompromised states.

Case: We report a 38-year-old obese white woman, with diabetes, who presented with 1 week history of severe right-sided facial pain, a several month history of sinusitis that had failed to respond to augmentin and fluroquinolones. Earlier that morning in urgent care, she was recommended to start moxifloxacin and prednisone for sinusitis. Later that night in the ED, she was tachycardic (heart rate 146 bpm), tachypneic (respiratory rate 26/min) had a BP of 150/105 mmHg. Her exam was remarkable for severe right facial tenderness, periorbital ecchymosis, and a painful black eschar on the palate. Her chemistries revealed blood glucose of 592 mg/dl, sodium of 120 mEq/dL, bicarbonate of 6 mEq/dL, anion gap of 32, and an arterial blood pH of 7.08. Urinalysis was remarkable for dipstick ketones, albuminuria, and glucosuria. CT of the head and paranasal sinuses revealed large, localized, complete opacification of the right maxillary antrum, and mucosal thickening in the right and left ethmoid sinuses without any intracranial abnormality. She was initiated on aggressive hydration, IV insulin therapy, with amphotericin B. Intraoperatively at emergency surgery she was noted to have necrotic tissue with the eschar extending from the lateral edge of the alveolar rim to the midline of the hard palate and involving the right incisor all the way to the last molar. Partial right maxillectomy along with excision of floor of right nasal cavity and debridement of necrotic tissue was performed. Cultures from that necrotic tissue grew *Rhizopus* species. She subsequently required further debridement, micafungin, and posaconazole therapy with recovery over 4 months.

Discussion: Rhinocerebral mucormycosis typically manifests with sequential involvement of the nasal cavity, sinuses, eyes, internal carotids, brain, and often is complicated by seizures and hemiplegia. The mortality rate (50% to 85%) is very high. Nasal ulcerations occur in half the patients, and a painful black eschar on the palate or nasal mucosa is a classic but nonspecific sign. Awareness of the disease, a high index of suspicion, early imaging and diagnosis, emergent surgical resection, and aggressive medical management are cornerstones in preventing a fatal outcome.

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1. To describe 4 strategies for clinical teaching of students and residents in the office setting.
2. To describe the evidence for improvements in educational outcomes associated with each teaching strategy.
3. To compare and contrast the roles of teacher and learner in the One-Minute Preceptor (OMP) and SNAPPS strategies.

PUBLICATION DATE: August 15, 2011

EXPIRATION DATE: August 15, 2012

QUESTIONS

1. Strategies for teaching clinical medicine described in this article include:
   A. "OMP" or "one-minute precepting"
   B. "SNAPPS" or learner-led education
   C. Clinical lectures
   D. "Aunt Minnie" or pattern recognition
   E. Small group discussions led by a preceptor
   F. Activated demonstration or teaching a skill

Answer:

- ❑ A, B, C, and F
- ❑ A, C, D, and E
- ❑ A, B, D, and F
- ❑ B, C, D, and E
- ❑ A, C, D, and F

2. Which teaching strategies have been shown in studies to improve educational processes and outcomes?
   A. "OMP" or "one-minute precepting"
   B. "SNAPPS" or learner-led education
   C. Clinical lectures
   D. "Aunt Minnie" or pattern recognition
   E. Small group discussions led by a preceptor
   F. Activated demonstration or teaching a skill

Answer:

- ❑ A, B, C, and F
- ❑ A and B
- ❑ A, C, and E
- ❑ A, B, and C
- ❑ All of the above

3. Some of the elements of "one-minute precepting" include getting a commitment from the student, which is designed to encourage the learner's processing and synthesis of information obtained from the patient, and then to ask for supporting evidence to help the preceptor understand the learner's fund of knowledge, analytic processes, and areas for further learning.
   - ❑ True
   - ❑ False

4. The SNAPPS strategy relies more on a preceptor-directed learning process in which the student is asked probing questions after their initial summary of the pertinent history and physical. It is designed to direct the student's analysis to the most important features of the case.
   - ❑ True
   - ❑ False

5. The "Aunt Minnie" pattern-recognition approach has been advocated as representing the typical approach applied by most physicians for common ambulatory problems.
   - ❑ True
   - ❑ False

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The ABCs of ACOs

Lora L. Zimmer, JD

You've probably been hearing a lot about Accountable Care Organizations (ACOs) lately. But, like many other health care professionals, you may not have the time or inclination to research the latest developments in clinical integration. So, here, in just a few pages, is your primer on what ACOs are, what the latest news on ACOs has been about, and what the critics and proponents of ACOs have been saying.

What is an ACO?

The Centers for Medicare & Medicaid Services (CMS) has defined an ACO as "a recognized legal entity under State law … comprised of a group of ACO participants (providers of services and suppliers) that have established a mechanism for shared governance and work together to coordinate care for Medicare fee-for-service beneficiaries."[1]

The concept of ACOs is relatively new. ACOs gained attention in 2010 when they were included in the Patient Protection and Affordable Care Act (PPACA). PPACA requires CMS to create a Shared Savings Program that incorporates ACOs. This program is intended to improve beneficiary outcomes.

Eligible providers, hospitals, and suppliers can choose to participate in the Shared Savings Program by creating or joining an ACO. ACOs would enter into a 3-year agreement with CMS to be accountable for the quality and cost of care of at least 5000 beneficiaries of Medicare Parts A and B. Medicare would continue to pay individual providers and suppliers participating in ACOs for the specific items and services it does currently under the fee-for-service payment systems. However, ACOs would also be eligible to receive additional payments from Medicare in the form of shared savings.

Under the program, CMS would compare Medicare payments made to an ACO for beneficiaries assigned to that ACO to estimates of what the total Medicare expenditures for those beneficiaries otherwise would have been in the absence of the ACO. If the ACO achieves cost savings compared to this benchmark, while achieving specific quality performance standards, it will be eligible to receive up to 60% of those savings back from Medicare in addition to the fee-for-service payments.

How are beneficiaries assigned to an ACO?

Under the ACO model, Medicare beneficiaries may seek services from any provider they prefer, regardless of whether the provider is part of the ACO. Beneficiaries will be "assigned" retrospectively to an ACO by Medicare after the end of each year based on a determination of whether the ACO has provided the bulk of the patients' primary care during that year. Due to this retrospective assignment, Medicare beneficiaries generally would not be aware of whether they are "assigned" to an ACO.

What types of providers can be part of an ACO?

An ACO may include the following types of groups of providers and suppliers of Medicare-covered services:

- Physicians, physician assistants, nurse practitioners, and clinical nurse specialists (collectively known as "ACO professionals") in group practice arrangements
- Networks of individual practices of ACO professionals
- Partnerships or joint venture arrangements between hospitals and ACO professionals
- Hospitals employing ACO professionals
- Other Medicare providers and suppliers as determined by the US Department of Health and Human Services

In order to participate in the Shared Savings Program, providers would need to form or join an ACO and apply to CMS.

What's the latest news on ACOs?

On March 31, 2011, CMS issued proposed regulations for ACOs, as required under PPACA.[2] These long-awaited regulations provide important guidance but also raise significant questions for those considering establishing an ACO.

The proposed regulations cover a number of topics, including measures to assess the quality of care furnished by an ACO, quality performance standards, and reporting requirements. An example of the regulations' level of detail can be seen when reviewing CMS's proposed method of calculating ACO quality performance standards. CMS has

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proposed 65 measures for this calculation. To qualify for shared savings, an ACO would need to report data accurately on an annual basis on all of these measures.

The high level of complexity provided by the proposed regulations has supplied those interested in the formation of ACOs with a great deal of information to evaluate and has given detractors fodder for criticism, resulting in ACOs being a hot topic in recent health care news.

What's the controversy all about?

Proponents of the Shared Savings Program believe the ACO model will improve health care quality and lower health care costs by encouraging greater coordination of care between providers and by giving providers incentives to improve patient outcomes. Some patient advocates are also pleased with the program, which allows patients freedom to choose their providers while focusing on improving care delivered to the elderly.

However, critics of the program argue that the proposed regulations are so complex that they are unworkable, and that the benchmarks for achieving shared savings are too difficult to meet. Critics also argue that the retrospective assignment of beneficiaries to an ACO does not allow providers to track benchmarks and quality standards throughout the year.

So what's next?

The comment period for the proposed regulations closed in June 2011. Currently, CMS is considering the comments it received and plans to issue final rules at some point in 2011. Once these final rules are published, providers can determine whether they wish to participate in the Shared Savings Program, which is slated to begin on January 1, 2012.

It remains to be seen whether ACOs will become popular among Medicare providers as a means of increasing their Medicare revenues while more efficiently providing care to their patients. It also remains to be seen whether the Shared Savings Program will result in increased quality of care or reduced health care costs. However, regardless of whether the program is a success, there is little doubt you can expect to hear a great deal more about ACOs in the coming months and years.

References

1. Shared Savings Program Overview. Centers for Medicare & Medicaid Services. https://www.cms.gov/sharedsavingsprogram/. May 17, 2011. Accessed July 3, 2011.

2. Medicare Shared Savings Program: Accountable Care Organizations, Proposed Rule. *Federal Register* 76(67):19528-19654. April 7, 2011.

Reflections for the Next Generation of Physicians

Robert N. Golden, MD

The new academic year is starting at the University of Wisconsin School of Medicine and Public Health—in a way. Our most important work—taking care of patients—and the two synergistic academic missions of research and teaching continue year-round on a 24/7 schedule. Still, the recent arrival of our new Class of 2015 and the upcoming White Coat Ceremony, in which we officially welcome our new medical students into the profession, serve as important calendar events celebrating the annual rejuvenation of academic medicine. This is also an opportune time to pause and reflect on the proverbial "big picture."

What thoughts should we share with the newest recruits? First and foremost, we should commend them on their wise decision to become physicians, and congratulate them on their success in gaining admission. The level of competition has become incredibly intense, even as the number of positions has increased at our school and across the country. This year we received nearly 4000 applications for our available positions, and even though we have continued to expand our class size, this year's class of 175 students represents one of the most selective cohorts in the 104-year history of our school.

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Doctor Golden is the Robert Turell Professor in Medical Leadership, Dean of the School of Medicine and Public Health, and Vice Chancellor for Medical Affairs at the University of Wisconsin-Madison.

Our new students bring a remarkably diverse array of talents, experiences, and backgrounds. Individually and collectively, they are the kind of colleagues we need in our field. Even more important, they will become the kind of clinicians we want to have caring for ourselves, our families, and our neighbors.

It is easy for all of us, as we confront on a daily basis the emerging challenges in the health care arena, to lose sight of the fact that the practice of medicine is more exciting than ever. We continue to see amazing translations of basic and clinical science into new and more effective ways of diagnosing and treating disease—and more than ever, into the identification and modification of risk factors as we seek to prevent disease.

It is also extremely encouraging that more institutions have begun to embrace an integrated model in which public health and preventive approaches are melded into the traditional focus on the diagnosis and treatment of disease in individual patients. At the same time, the growing emphasis on quality, safety, and interdisciplinary models of care will have a huge impact on our ability to make a difference in the lives of the people and communities we serve.

At the same time, we should not sugarcoat the very real issues confronting us. We still have health disparities that are inexcusable in any fair-minded society. We must make some tough choices in the allocation of resources, which will continue to be restricted. Those tough choices should be shaped by a sense of equity and social good. Also, we have a long way to go before we can take full advantage of the explosive growth in the science of genetics and epigenetics. Our capacity to translate new knowledge in these and other important areas into meaningful advancements in clinical practice will require further investment by society at a time when economic resources are limited. We must not commit the error highlighted in the old joke about the man who set out to swim across the English Channel. After swimming two thirds of the distance, he decided he couldn't make it and instead turned around and swam back!

All of us have many experiences and perspectives to share with each new generation of physicians. Regardless of whether we spend most of our time in the clinic, hospital, research laboratory, or classroom, we have important insights to offer. We have a shared responsibility to provide mentoring and guidance to our junior colleagues. I encourage all of you to share your wisdom and leadership with the Class of 2015 and beyond.

On a personal note, I want to thank Dr Susan Turney for the wisdom and leadership that she has shared during her many years of dedicated service to the Wisconsin Medical Society. The School of Medicine and Public Health is proud to claim her as a distinguished alumna, but in reality the entire state of Wisconsin should be proud and grateful for all she has given us over the years. We wish her the very best in her future adventures.

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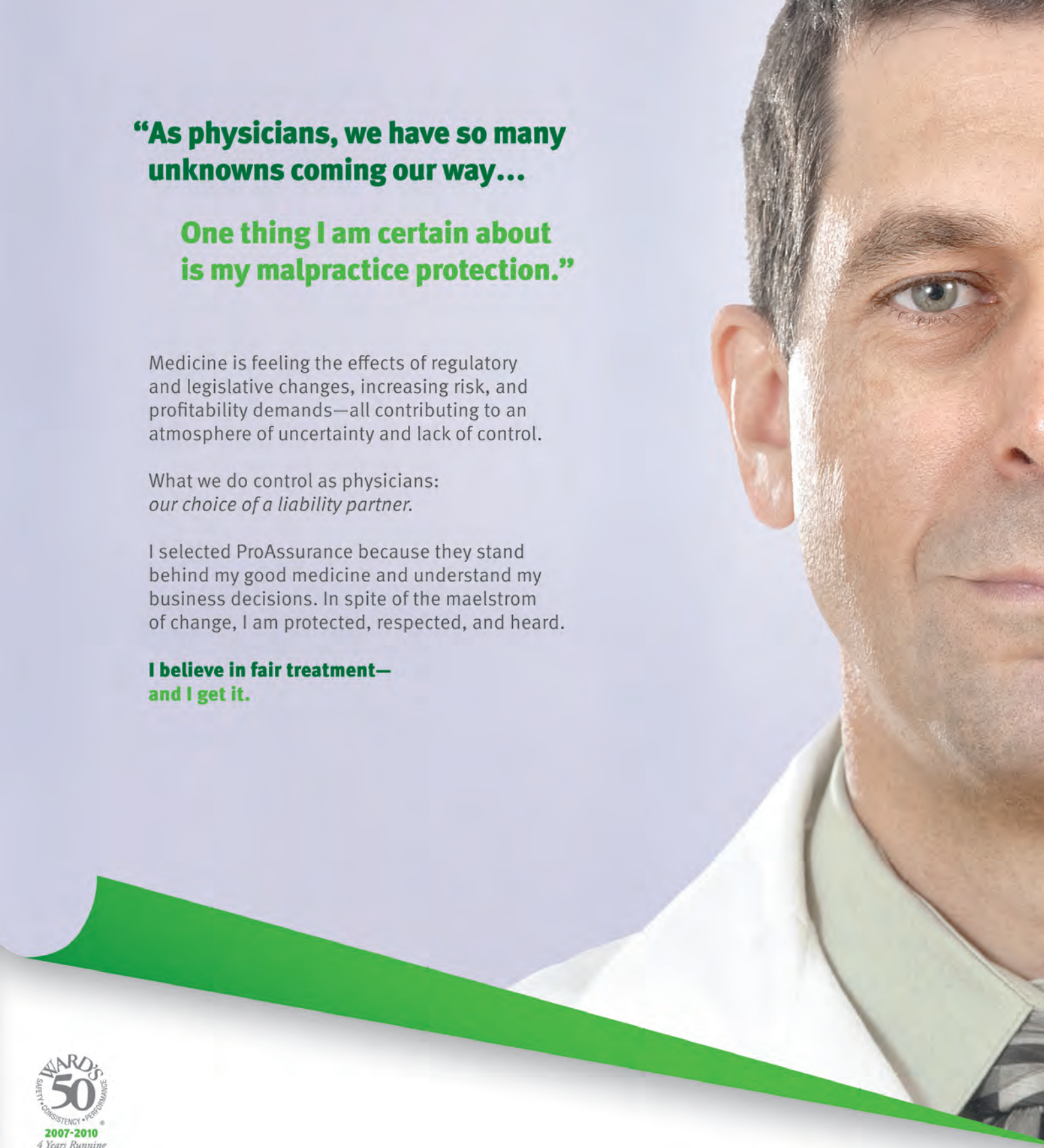

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