

PCPs MAY PLAY GREATER ROLE IN COLONOSCOPY, PAGE 28 Family Practice News

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IN NEWS AND MEETING



Software that simulates a discharge nurse who provides patient-specific guidance is being tested, says Dr. Brian Jack.

Discharge Protocol **Cuts Readmissions**

BY HEIDI SPLETE Senior Writer

RIO GRANDE, P.R. — A comprehensive discharge program aimed at educating patients about their diagnoses and their medications, and nailing down appointments for followup tests and primary care physician visits, reduced hospital readmission rates and emergency department visits together by 30%, according to the results of a randomized trial of more than 700 adult patients.

"This isn't rocket science," said family physician Brian Jack of Boston Medical Center. Dr. Jack designed the protocol dubbed the reengineered discharge (RED) intervention.

As hospital lengths of stay shrink, patients are being sent home earlier and in more serious condition. "We have a responsibility to prepare them to go home and do the things necessary to take care of themselves until they can see their family physicians," he said in an interview. The protocol's 11 steps are aimed at helping them do that.

Research has shown that existing discharge practices are often fragmented, and few patients understand their diagnoses and medications when they are discharged, said Dr. Chris Manasseh, director of hospital medicine at Boston Medical Center.

To determine the impact of an improved discharge program, Dr. Jack and his colleagues compared hospital use among 370 patients who received the RED protocol with 368 who received the standard discharge protocol. The average age of the patients in both groups was 50 years; 50% were men and 52% were black. The majority (80%) had primary care providers, and 48% had insurance or Medicaid coverage.

Dr. Manasseh presented the study at the annual meeting of the North American Primary Care Research Group.

The key components of the RED intervention were devel-See Discharge Protocol page 32



Pharma Funding Dr. Steven Miles and Jeff Stier debate whether industry-sponsored research is necessarily biased.

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All for Naught?

intensive glucose control may be overrated.



Exercise **Options**

Pediatric obesity clinics are emerging as an expensive strategy for weight loss.

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Fibro News

Diagnostic criteria are tweaked; milnacipran is approved.

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Persistent STD **Rates Are a 'Major** Area of Concern'

Chlamydia poses opportunity for impact.

BY JEFF EVANS Senior Writer

he rates of three major sexually transmitted diseases continued to follow a nearly decade-long climb that has disproportionately affected minorities and women, according to a report issued by the Centers for Disease Control and Prevention.

These national trends in infection rates of chlamydia, gonorrhea, and syphilis are "not new, but the fact that they are continuing at such a dramatic level is really the major area of concern," said Dr. John M. Douglas Jr., director of the di-

vision of STD prevention at the CDC. All three STDs have longstanding federally funded control programs.

The report is compiled from 2007 surveillance data obtained from case reports from state and local STD programs and national surveys implemented by federal and private organizations.

Chlamvdia

Since 1994, Chlamydia trachomatis infections have comprised the greatest percentage of all STDs reported to the CDC. This trend continued in 2007, with more than 1.1 million sexually transmitted cases of chlamydia re-See STD page 2

Out-of-Network Care Costs To Patients to Be Rectified

BY MARY ELLEN SCHNEIDER New York Bureau

s part of an agreement with A New York Attorney General Andrew Cuomo, United-Health Group has agreed to shut down a national billing database used by health plans to determine reimbursements to members who use out-of-network physician services.

The billing database, which is operated by the UnitedHealth Group (UHG) subsidiary Ingenix Inc., will be replaced with a new, independent database run by a qualified nonprofit organization. Under the terms of the agreement, UHG will pay \$50 million to help establish the new database. In addition, the nonprofit organization will develop a public Web site where consumers can research-before seeking services-how much they may be reimbursed for common out-of-network medical services in their area.

Aetna, the nation's third largest insurer, also has entered into an agreement with the New York attorney general to abandon its use of the Ingenix data-See Out-of-Network page 4



The heart benefits of PAGE 10

Far Fewer Rehospitalizations

Discharge Protocol page 1

oped by applying several scientific methodologies to hospital discharge to determine which processes truly benefit patient outcomes, Dr. Jack said. (See box.)

According to the RED plan, the discharge advocate (a nurse) worked with the patient's care team, reviewed medications and follow-up appointment schedules with the patient, and provided a personalized booklet of information. A clinical pharmacist called the patient

> **BRIEF SUMMARY - Consult full** prescribing information before use. TussiCaps®

(Hydrocodone Polistirex and Chlorpheniramine Polistirex) Extended-Release Capsules

Rx only

CONTRAINDICATIONS TussiCaps[®] extended-release capsules are contraindicat-ed in patients with a known allergy or sensitivity to hydrocodone or chlorpheniramine.

The use of TussiCaps[®] extended-release capsules are contraindicated in children less than 6 years of age due to the risk of fatal respiratory depression.

WARNINGS

WARNINGS Respiratory Depression – As with all narcotics, TussiCaps[®] extended-release capsules produce dose-related respira-tory depression by directly acting on brain stem respirato-ry centers. Hydrocodone affects the center that controls respiratory rhythm, and may produce irregular and period-ic breathing. Caution should be exercised when TussiCaps[®] extended-release capsules are used postop-eratively and in patients with pulmonary disease, or when-ever ventilatory function is depressed. If respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride and other supportive measures naloxone hydrochloride and other s when indicated (see **OVERDOSAGE**). supportive measures

When inducated (see OVENDSAGE).
Head Injury and Increased Intracranial Pressure – The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions, or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions, which may obscure the clinical course of patients with head injuries. iniuries

Acute Abdominal Conditions – The administration of nar-cotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

Obstructive Bowel Disease – Chronic use of narcotics may result in obstructive bowel disease especially in patients with underlying intestinal motility disorder.

Pediatric Use – The use of TussiCaps[®] extended-release capsules are contraindicated in children less than 6 years of age (see CONTRAINDICATIONS).

age (see CONTRAINDICATIONS). In pediatric patients, as well as adults, the respiratory center is sensitive to the depressant action of narcotic cough suppressants in a dose-dependent manner. Caution should be exercised when administering TussiCaps[®] extended-release capsules to pediatric patients 6 years of age and older. Overdose or concomi-tant administration of TussiCaps[®] extended-release cap-sules with other respiratory depression in pediatric patients. Benefit to risk ratio should be carefully considered, especially in pediatric patients with respiratory embar-rassment (e.g., croup) (see **PRECAUTIONS**).

PRECAUTIONS

General

Caution is advised when prescribing this drug to patients with narrow-angle glaucoma, asthma, or prostatic hyper-

Special Risk Patients - As with any narcotic agent Special risk ratients – As with any harcolic agent, TussiCaps[®] extended-release capsules should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy, or urethral stricture. The usual precautions should be observed and the possibility of respiratory depression abuild be torat in price or urethral stricture. T observed and the pos should be kept in mind.

Information for Patients

Information for Patients As with all narcotics, TussiCaps[®] extended-release cap-sules may produce marked drowsiness and impair the mental and/or physical abilities required for the perform-ance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly. TussiCaps[®] extended-release capsules must not be diluted with fluids or mixed with other drugs as this may alter the resin-binding and change the absorption rate, possibly increasing the toxicity.

Keep out of the reach of children.

Cough Reflex – Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when TussiCaps[®] extended release capsules are used postoperatively, and in patients with pulmonary disease. Drug Interactions

Patients receiving narcotics, antihistamines, antipsy-chotics, antianxiety agents, or other CNS depressants

within 2-4 days to review medications and reinforce the follow-up care plan.

Overall, during the first 30 days after discharge the rate of rehospitalization among patients in the RED group was significantly lower compared with the usual-care group (21% vs. 15%). The RED group also had significantly fewer emergency department visits compared with controls (24% vs. 16%).

Patients in the RED group were more

(including alcohol) concomitantly with TussiCaps® extend-ed-release capsules may exhibit an additive CNS depres-sion. When combined therapy is contemplated, the dose of one or both agents should be reduced.

The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone.

The concurrent use of other anticholinergics with hydrocodone may produce paralytic ileus. Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity and reproductive studies have not been conducted with TussiCaps® extended rologi se capsules

Pregnancy

Teratogenic Effects. Pregnancy Category C – Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no ade-quate and well-controlled studies in pregnant women. TussiCaps[®] extended-release capsules should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects – Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irri-tability and excessive crying, tremors, hyperactive reflex-es, increased respiratory rate, increased stools, sneezing, yawning, vomiting, and fever. The intensity of the syn-drome does not always correlate with the duration of maternal opioid use or dose.

Labor and Delivery

As with all narcotics, administration of TussiCaps[®] extend-ed-release capsules to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from TussiCaps[®] extended-release cap-sules, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

The use of TussiCaps[®] extended-release capsules are contraindicated in children less than 6 years of age (see CONTRAINDICATIONS and ADVERSE REACTIONS, Respiratory, Thoracic and Mediastinal Disorders).

TussiCaps[®] extended-release capsules should be used with caution in pediatric patients 6 years of age and older (see WARNINGS, Pediatric Use).

Geriatric Use

Geriatric Use Clinical studies of hydrocodone polistirex and chlorpheni-ramine polistirex extended-release did not include suffi-cient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differ-ences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of con-comitant disease or other drug therapy. This drug is known to be substantially excreted by the kid-

This drug is known to be substantially excreted by the kid-ney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS Gastrointestinal Disorders

Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of TussiCaps[®] extended-release capsules may produce constipation.

may produce co General Disorders and Administration Site Conditions

Death

Nervous System Disorders

Sedation, drowsiness, mental clouding, lethargy, impair-ment of mental and physical performance, anxiety, fear, dysphoria, euphoria, dizziness, psychic dependence, mood changes.

Renal and Urinary Disorders Ureteral spasm, spasm of vesical sphincters, and urinary retention have been reported with opiates.

Respiratory, Thoracic and Mediastinal Disorders

Dryness of the pharynx, occasional tightness of the chest, and respiratory depression (see **CONTRAINDICATIONS**). TussiCaps® extended-release capsules may produce likely than were those in the usual-care group to be discharged with a primary care provider appointment (94% vs. 35%).

In addition, self-reports at 30 days after hospital discharge from 307 patients in the RED group and 308 patients in the control group showed that significantly more patients in the RED group identified their primary care providers by name (95% vs. 89%), followed up with their primary care providers (62% vs. 44%), and knew their discharge diagnoses (79% vs. 70%).

"Self-reported readiness for discharge was higher" in the intervention group,

dose-related respiratory depression by acting directly on brain stem respiratory centers (see **OVERDOSAGE**). Use of TussiCaps[®] in children less than 6 years of age has been associated with fatal respiratory depression. Overdose with TussiCaps[®] extended-release capsules in children 6 years of age and older, in adolescents, and in adults has been associated with fatal respiratory depres-sion.

Skin and Subcutaneous Tissue Disorders Rash, pruritus.

DRUG ABUSE AND DEPENDENCE

DRUG ABUSE AND DEPENDENCE TussiCaps[®] extended-release capsules are Schedule III narcotics. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of narcotics; therefore, TussiCaps[®] extended-release capsules should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when TussiCaps[®] extended-release capsules are used for a short time for the treatment of cough. Physical dependence, the condition in which continued adminis-tration of the drug is required to prevent the appearance of a withdrawal syndrome, assumes clinically significant proportions only after several weeks of continued oral harcotic use, although some mild degree of physical dependence may develop after a few days of narcotic therapy.

OVERDOSAGE

OVERDOSAGE Signs and Symptoms – Serious overdosage with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence pro-gressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. Although miosis is characteristic of narcotic overdose, mydriasis may occur in terminal narcosis or severe hypoxia. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur. The mani-festations of chlorpheniramine overdosage may vary from central nervous system depression to stimulation. Treatment – Primary attention should be given to the

Treatment – Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone hydrochloride is a specific antidote for respiratory depres-sion which may result from overdosage or unusual sensi-tivity to narcotics including hydrocodone. Therefore, an appropriate dose of naloxone hydrochloride should be administered preferably by the intravenous groute simultaappropriate dose of naloxoné hydrochloride should be administered, preferably by the intravenous route, simulta-neously with efforts at respiratory resuscitation. Since the duration of action of hydrocodone in this formulation may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration. For further information, see full pre-scribing information for naloxone hydrochloride. An antag-onist should not be administered in the absence of clinical-by significant respiratory depression. Oxygen. Intravenous bills sindual not be administered in the absence of climical-by significant respiratory depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated. Gastric emptying may be useful in removing unabsorbed drug.

A Schedule CIII Narcotic

For Medical Information Contact: Product Monitoring Department Phone: 800-778-7898

Manufactured by: Mallinckrodt Inc. Hazelwood, Missouri 63042 U.S.A.

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compared with the control group, when patients were interviewed 30 days after discharge, Dr. Manasseh added. Patients in the RED group were more likely than controls to understand their diagnoses, drugs, and appointments, and to have had their questions answered.

The results were limited by the use of patient self-reports, but the findings suggest that the plan should be used for all patients, Dr. Manasseh noted.

In terms of workload, the discharge plan required approximately 90 minutes per patient, including 14 minutes with a pharmacist. But the hospital saved approximately \$400 in outcome costs per patient, Dr. Manasseh said.

Dr. Jack added that a computerized version of the RED protocol has been well received by patients in separate preliminary tests. Software developed by Timothy Bickmore, Ph.D., of the College of Computer and Information Science at Northeastern University, Boston, allows patients to interact with a simulated discharge nurse named Louise. The software operates on a touch-screen kiosk and reviews patient-specific information regarding the individual's after-hospital care plan. Louise can also test competency, "which is something none of us take the time to do now," Dr. Jack said.

If a nurse were to spend 30 minutes going over a patient's discharge plan, there would never be enough time to repeat it when the patient's son or daughter arrived at the hospital later. The beauty is that "Louise isn't in a rush. ... She can do it all over again," he added.

The research was funded by a grant from the Agency for Healthcare Research and Quality.

For more information about the protocol, visit www.bu.edu/fammed/projectred.

RED's 11 Steps

1. Educate patient about relevant diagnoses throughout hospital stay. **2.** Make appointments for clinician follow-up and postdischarge testing. 3. Discuss with patient any in-hospital tests or studies completed and who will follow up with results. 4. Organize postdischarge services. 5. Confirm medication plan; explain what to take and why. 6. Reconcile discharge plan with national guidelines and critical pathways.

7. Review appropriate steps for what to do if a problem arises. 8. Transmit discharge summary to physicians and services accepting responsibility of patient's care. 9. Assess degree of understanding by asking patient to explain in his or her own words the details of the plan.

10. Give the patient a written discharge plan at the time of discharge.

11. Pharmacist telephones patient to reinforce discharge plan, review medications, and problem solve.

Source: Dr. Jack