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The nurse's guide to superior patient care

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Depression: Making the Diagnosis in Primary Care

By Sally Beattie, MS, RN, CS, GNP

Summary—The prevalence of depression in the general population surpasses that of hypertension, which makes it one of the most frequently treated diseases in the primary care milieu. Unfortunately, up to 50% of cases go undetected, partially because primary care providers lack the time and knowledge to apply established diagnostic criteria to screen and assess for depression.¹ Researchers identified two screening questions from the Primary Care Evaluation of Mental Disorders Procedure (PRIME-MD)² and four core subset symptom criteria from the Diagnostic and Statistical Manual of Mental Disorders (DSM) that quickly and effectively pointed to a diagnosis of depression in 1000 subjects.³ Findings were validated with a patient questionnaire that included three depression assessment tools. Results were favorable when compared with the complex DSM IV questionnaire. Also, the core subset of depressive symptoms appeared to differentiate between subjects with milder levels of impairment and those with moderate to severe depression. Clinicians are encouraged to use the two-item PRIME-MD and the SALSA (sleep disturbance, anhedonia, low self-esteem, appetite change) core subset symptom criteria mentioned in this article to facilitate identification of clinical depression in primary care practice.²

EXPERTS ESTIMATE 5-9% OF ADULT OUTPATIENTS SEEN BY PRIMARY care providers suffer from a major depressive disorder, and even more report milder but still clinically significant levels of depression. Such high rates of depression in the general population make it one of the most common disorders found in medical practice, with its prevalence surpassing that of hypertension. Studies show that 35-50% of cases go undetected.^{1,2}

The DSM is generally recognized as the ultimate authority for diagnosing psychopathologic conditions; however, it appears few primary care providers use its lengthy, complex criteria to guide diagnosis or treatment.² Obstacles to recognition of depression by primary care providers include inadequate knowledge of the diagnostic criteria, uncertainty about the most appropriate questions to determine if criteria are met, and inherent time limitations in the primary care setting.⁴ Researchers wondered if reducing the number of symptoms

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required to make the diagnosis would make it easier for primary care providers to remember and evaluate them. They set out to answer three questions:

1. What symptoms best predict functional status and well-being?
2. How many symptoms must be present to indicate a diagnosis of depression?
3. How do patients diagnosed by these criteria compare using DSM criteria?

Investigators conducted an analysis to determine if a core subset of symptoms could be used to efficiently and effectively diagnose depression after administering a two-item questionnaire extracted from a recognized screening tool known as PRIME-MD.²

The PRIME-MD was designed for flexible use by busy clinicians to facilitate rapid and accurate diagnosis of common mental disorders seen in primary care. Two of its 26 questions were designed specifically to screen for depression by asking: "In the past month, have you often been bothered by 1) little interest or pleasure in doing things and/or 2) feeling down, depressed, or hopeless?"⁴ A positive response to either of these triggers an evaluation for major depression.

Identifying a Subset of Depressive Symptoms

One thousand patients seen by 31 primary care physicians in four sites completed the questionnaire. The mean age was 55; 60% were women; 58% were white; and 28% were college graduates. All 1000 completed a validation questionnaire including three assessment tools:

1. Medical Outcomes Study Short Form General Health Survey (SF-20) to measure pain; functioning in physical, role, social, and mental areas; and general health perceptions.⁵
2. Somatic Symptom Inventory to determine how much a patient was bothered by common symptoms over the past six months.⁶
3. Zung Depression Scale to measure severity of depression.⁷

Researchers also assessed disability days and health care utilization by subjects.

Multiple regression analysis was used to identify a core subset of symptoms revealed by the validation questionnaire as most predictive of functional status and well-being. Researchers chose to develop criteria for depression that were maximally predictive of these two outcomes as they represent the primary goals of health care.

Investigators found sleep disturbance, anhedonia, low self-esteem, and change in appetite consistently explained almost all the variance in functional status and well-being attributable to the nine DMS IV symptoms of depression. Researchers found that forcing in the five remaining symptoms did not increase the explained percentage of variance. Of 1000 patients, 325 screened positive for depression. Two of the four symptoms were experienced by 8.3% of study subjects. Another 8.2% experienced three or four symptoms, which gave a depression prevalence rate of 16.5% (165 patients) with a cut-off of just two symptoms. The prevalence rate using DSM-IV criteria was 11.5%. Further analysis indicated that patients who experienced two of the symptoms demonstrated a milder form of depression than those with three or four. This indication was validated by scores obtained from the validation questionnaire tools.²

Comparison with DSM-IV Criteria

From 115 patients with major depression according to the DSM-IV, all but three had at least two of the core subset of depressive symptoms. Based on the validation questionnaire outcomes, these three patients were only moderately impaired. Additional analysis of the 325 patients who screened positive with the PRIME-MD depression screening questions revealed that the identified core subset of depressive symptoms were as effective as the DSM-IV criteria in identifying patients with suicidal thoughts.²

The authors concluded that evaluation of the core subset of four symptoms after screening with the two-item PRIME-MD tool effectively identifies patients needing clinical attention for depression.² Also, the data indicated the core subset of symptoms identifies and distinguishes between patients with a milder form of depression (2

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Questions & Comments

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symptoms) and those with more severe impairment, including suicidal ideation (3-4 symptoms). The analysis indicated the latter group was equally impaired in functional status and well-being as those evaluated using the full set of DSM-IV criteria. A previous analysis comparing six commonly used case-finding instruments with PRIME-MD validated the current findings.⁸

Authors of the present study presented several caveats regarding interpretation of their results:

- collection of this type of information via clinical interview without PRIME-MD might yield slightly different outcomes;
- recent bereavement, drug and alcohol abuse, and known medical problems were not considered in this data set;
- and although suicidal ideation is not one of the four core depressive symptoms, it must be considered in any patient believed to have a mood disorder.

Implications for Practice

Depression causes tremendous personal suffering, disability, and lost work time at an estimated cost of \$43.7 billion in 1990 alone.^{8,9} Patients suffering clinical depression as a primary or a concomitant condition often present with somatic rather than psychological complaints. Studies show the diagnosis is frequently overlooked by time-pressured practitioners. To facilitate diagnosis and lower the percentage of cases missed in the primary care milieu, develop an index of suspicion and include depression in the differential diagnosis when the cause of a patient's symptoms are unclear or not fully explained by other medical disease processes. Routinely ask the two-item PRIME-MD depression screening questions during the patient assessment. If positive, ask about the core subset criteria for depression that are easily remembered by using the mnemonic SALSA: sleep disturbance, anhedonia, low self-esteem, and appetite change.

A positive diagnosis usually can be made based on an adequate medical interview, observation of the patient, and the help of user-friendly case-finding tools.^{3,4,9,10} In light of depression's high prevalence and tremendous disease burden, it is imperative that all providers in the primary care setting become proficient at recognizing and treating depression. ❖

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Drug Warning: Beware of Troglitazone (Rezulin)

By Patricia McGinley, RNP, MSN

Summary—Although more than 800,000 patients in the United States and in Japan have received troglitazone for control of type 2 diabetes, reports of severe hepatic dysfunction resulting in hepatic failure in several patients causes concern.¹ New drugs are now advertised in consumer magazines as well as professional journals, and patients come into the office requesting them to control their diseases. Clinicians must be knowledgeable about adverse effects of medications, especially those newly approved, and exercise caution when initiating therapy. Troglitazone underwent clinical trials at several medical centers and reported only a 2% incidence of adverse liver function. It was deemed safe by the U.S. Food and Drug Administration (FDA) after the six-month trial period. Since the release of troglitazone (Rezulin, Parke-Davis, Morris Plains, NJ), the drug manufacturer, the FDA, a major newspaper, and medical journal letters and editorials have expressed concern about serious

adverse affects following its use.^{2,3,4,5} Clinicians are well-advised to abide by recommended liver function monitoring and patient education parameters.

RECENTLY, THE SUNDAY *LOS ANGELES TIMES* RAN A front-page article holding troglitazone, (Rezulin), responsible for the deaths of 33 diabetic patients due to acute liver failure. Some of the 33 deaths occurred within the first month of taking this drug.¹ This is alarming news for patients and for practitioners prescribing the new drug who need reliable data from controlled research studies to respond to clients' questions.

Troglitazone came on the market in March 1997. It is a member of a new class of drugs called the thiazolidinediones, which improve the function of insulin through activation of the peroxisome-activated insulin receptors found in muscle, adipose tissue, and the large intestine. These receptors regulate insulin action, lipid homeostasis, and adipocyte differentiation. Troglitazone improves insulin action within the muscle and reduces basal glucose production in the liver.^{6,7} Initially, the FDA approved troglitazone for patients with type 2 diabetics in poor control and/or those on two injections of insulin daily. Later in 1997, the FDA approved troglitazone for use as monotherapy or in combination with oral sulfonylureas.

Study Methodology

A 26-week multicenter double-blind, placebo-controlled study with open-label extension recruited 222 subjects who had failed prior oral antidiabetic medication and took 30-150 U of insulin daily.⁸ The study was designed to determine the maximum reductions in insulin dose achievable with troglitazone without causing an increase in the mean fasting blood glucose (FBG). Subjects were randomly assigned to one of three treatment groups:

1. 200 mg of troglitazone;
2. 400 mg of troglitazone;
3. or matching placebo.

Subjects completing the double-blind phase entered the open-label extension trial using 200 mg troglitazone with an option of titrating to 400 mg. Eligibility criteria for the trial included the following:

- type 2 diabetes;
- HbA1c > 7%;
- C-peptide \geq 0.5 nmol/l;
- FBG > 7.8mmol/l at the end of a 2-4 week placebo baseline phase, which preceded the study;
- mean daily insulin dose 30-150 U;
- and failure on oral medication before initiating insulin.

Exclusion criteria included:

- subjects with hepatic enzymes elevated \geq two times normal;
- serum creatinine elevations \geq 177 mmol/l;
- history of ketoacidosis;
- symptomatic angina pectoris;
- cardiac insufficiency;
- uncontrolled hypertension;
- and active cancer within five years of screening.

Women of child-bearing potential were required to use contraception (barrier or hormonal) provided they were not pregnant or lactating. Antidiabetic medications other than the study medications and insulin were not permitted.

Study Results

Of 222 enrolled subjects, 194 (87%) completed the double-blind phase. Of these, 70% using 400 mg of troglitazone and 51% of those treated with 200 mg troglitazone reduced the amount of insulin required to control FBS up to 50%. The placebo group had only a 19% reduction. Reductions in daily insulin dose were as follows:

- placebo — 18%;
- troglitazone 200 mg — 41%;
- and troglitazone 400 mg — 57%.

Sixteen patients were able to discontinue insulin completely. The 400 mg troglitazone subjects had a 0.4% decrease in HbA1c compared with 0.1% for placebo group subjects. Reductions also were noted in the FBG and FSG (fasting serum glucose). No notable trends or differences with regard to adverse events were found among troglitazone-treated patients and placebo subjects. Twenty-eight patients did report serious adverse events; however, none were believed to be associated with the study medication. The incidence of hypoglycemia was 17% higher in troglitazone patients when compared with placebo patients; however, there was no severe hypoglycemia. Modest increases were found in high-density lipoprotein (HDL), low-density lipoprotein, and total cholesterol (TC) without changes in TC/HDL ratio.

Less than 2% of patients were found to have abnormalities of liver function, and all abnormalities reversed upon discontinuation of the drug.⁸

In another study, researchers reported a 52-week clinical study of 552 poorly controlled diabetics on oral sulfonylureas randomized into three groups:

- micronized glyburide only;
- troglitazone monotherapy;
- and combined troglitazone and glyburide.

Seven patients were withdrawn from the study at the investigator's discretion due to an elevation of liver

enzymes. All enzyme levels returned to baseline or normal levels after withdrawal of troglitazone.⁸

Another author notes that 48 out of 2510 patients who received troglitazone (1.9%) experienced hepatic dysfunction with serum aminotransferase concentrations more than three times the upper limit of normal as compared with three of 475 placebo patients (0.6%).⁹

Practice Implications

Although numerous trials have demonstrated that troglitazone increases insulin action, improves dyslipidemia, and enhances oral glucose utilization for type 2 diabetes, practitioners must remain wary and alert for indicators of possible adverse effects upon the liver.

In a series of warnings,^{1,2,3,4,5} Parke Davis and the FDA published recommendations for clinicians, including the following:

- Check serum transaminase levels for the first two months and then every two months during the first year of troglitazone therapy.
- Any patient with symptoms suggesting liver dysfunction should receive liver function tests.
- Patients with a 1.5 or > elevation in ALT (serum alanine aminotransferase) levels should not begin troglitazone.
- ALT levels should be measured at the initiation of troglitazone, monthly for eight months, every two months for the remainder of the first year, and periodically thereafter.
- Patients with ALT levels > 1.5-2 times normal during troglitazone therapy need to be retested within one week then weekly until back to normal.
- If ALT levels rise above three times normal, discontinue the drug.

In December 1998, the FDA strongly recommended liver function testing for patients on troglitazone at the start of therapy, at monthly intervals for the first six months, every other month for the next six months, and periodically thereafter.^{7,8,9,10}

It is vitally important for the clinician to be knowledgeable about contraindications for using the drug. Practitioners must carefully educate each patient who is prescribed troglitazone about signs and symptoms such as jaundice, nausea, vomiting, loss of appetite, fatigue, or dark urine that may indicate liver dysfunction. ❖

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Smoking Increases Among College Students

By Barbara A Biedrzycki, RN, MSN, AOCN, CRNP

Summary—Educational level is one of the strongest correlates of nonsmoking status, but the latest research provides shocking data. The prevalence of smoking among college students increased by 27.8% ($P < .001$) over four years, according to national surveys done in 1993 and 1997. Half of college students are trying to quit, with 18% having tried more than five times in the previous year. The highest absolute increase in the number of cigarettes smoked occurred in those who smoked fewer than nine cigarettes a day.¹ Interventions by advanced practice nurses are needed to decrease smoking among college students and to prevent occasional smokers from becoming nicotine-dependent.

THE CENTERS FOR DISEASE CONTROL AND PREVENTION in Atlanta reports, "If trends continue, approximately 5 million persons ages <18 years will die eventually from a smoking-attributable disease."² This tenacious personal and public health dilemma is largely due to the addictive effects of nicotine, a neuroendocrine stimulant, as well as a depressant. (See Table 1, p. 22.) In 1996, U.S. statistics show, 1,226,000 young people under 18

Table 1
Drug Addition Criteria and Nicotine Effects
<p>Criteria for defining a drug addiction:</p> <ul style="list-style-type: none"> • Compulsive use • Psychoactive effects • Drug-reinforced behavior • Tolerance and physical dependence <p>Nicotine effects:</p> <ul style="list-style-type: none"> • Produces a compelling urge to smoke • Provides pleasurable alterations in mood • Motivates chronic tobacco-seeking and using behavior • Abstinence induces withdrawal syndrome <p><i>Source:</i> Holbrook JH. Nicotine addiction. In: Fauci AS, Braunwald E, Isselbacher KJ, et al., eds. <i>Harrison's Principles of Internal Medicine</i>. New York: McGraw-Hill;1998:2516.</p>

years of age became daily smokers, an increase of 50% over eight years. This occurred even though tobacco use is known to be the No. 1 preventable cause of Americans' deaths. Furthermore, the earlier in life someone begins smoking, the greater the risk of smoking-attributable diseases.

Nicotine causes many compounded effects through catecholamine release and increases serum concentrations of glucose, cortisol, vasopressin, free fatty acids, and b-endorphin. An analysis of cigarette smoke identified more than 4,000 substances, including some that are pharmacologically active, antigenic, cytotoxic, mutagenic, and carcinogenic.³

The increased incidence of children smoking is a highly publicized, serious problem being addressed nationally as a public health concern, but little is known about the smoking trends of college students. Studies show a higher education level correlates with nonsmoking status. One might assume college students would have greater access to educational materials on hazards of smoking as well as assistance with smoking cessation and therefore do not need additional attention. The featured research provides startling results that may affect your practice.

Study Methodology

More than 29,000 randomly selected students in 140 four-year colleges nationwide participated in research to explore smoking trends among college students. In 1993, data on cigarette use was obtained as part of the College Alcohol Study.⁴ A second survey conducted in 1997, which also focused mainly on alcohol use, sought identical information on demographic and background

characteristics, smoking, and other high-risk behaviors. Two additional questions asked how old subjects were when they first smoked a cigarette and the age when they started smoking regularly. Researchers felt confident that the self-report questionnaires did not need a biological measure because past national surveys validated the positive correlation of self-reported smoking status with biological measurements.¹

Of the original participating colleges, 130 (93%) chose to be part of the 1997 study. The great response rates (70% in 1993, 60% in 1997) were prompted by sending three mailings within three weeks that included the questionnaire, a postcard reminder, and a repeat questionnaire; ensuring that the survey was anonymous and voluntary; and providing a cash award (monetary amount not disclosed).¹

Study Results

Data analysis revealed dismaying facts. Cigarette smoking had increased in 85% of 116 colleges in the study. Only one college reported smoking prevalence significantly decreased. The proportion of students who reported smoking in the previous month increased 28% in the four years between the two studies. The proportion of students who smoked in the previous 12 months increased by 25%. The number of cigarettes smoked daily also increased 6-14%, the larger increase among smokers who consumed fewer than nine cigarettes per day. The proportion of students who quit smoking in the past year decreased by 6%.

The study did provide some encouraging news. Data revealed a decrease in severely nicotine-dependent college students who smoked 20 or more cigarettes a day, and more than 40% of college students in both surveys reported smoking less than one cigarette a day. No association was found between increased smoking prevalence and binge drinking or marijuana use. Interesting data were collected in the 1997 survey on smoking initiation and attempts to quit. (See Table 2, p. 23.)

Implications for Practice

Recent stop-smoking efforts focused on educating children and counseling older adults. This study points clinicians in a new direction, toward a generation of college students establishing their independence and life-long habits. The challenge is not only how to decrease the number of students who start smoking, but how to prevent the sporadic smoker from becoming nicotine-dependent and promote greater quit rates among college students.

Included in the pharmacological arsenal against nicotine addiction are:

Table 2	
1997 Smoking Initiation and Quit Data	
Event	(N = 2014)
First cigarette at ≥ 19 years of age	11%
Began regular smoking at ≥ 19 years of age	28%
Quit for ≥ 24 hours in the past year	50%
Made ≥ 5 attempts to quit in the past year	18%
<i>(Editor's note: These questions were not asked in 1993.)</i>	
<i>Source: Wechsler H, Rigotti NA, Gledhill-Hoyt J, et al. Increased levels of cigarette use among college students. JAMA 1998;280:1677.</i>	

- nicotine gum and patch approved for over-the-counter use since 1995 and 1996, respectively;
- nicotine nasal spray, which provides rapid delivery of nicotine;
- nicotine inhaler, a prescription drug available since 1998 that is not really an inhaler because it delivers nicotine buccally;
- and bupropion, an atypical antidepressant with dopaminergic and adrenergic actions approved in 1998 in slow-release preparation for smoking cessation.⁵

The physical addiction to nicotine is not the only problem. Cigarette use is a complex, learned behavior promoted by strong conditioned cues such as physical activities (after dining or sex), stress (many smokers say smoking “calms their nerves”), and habits (sitting in a favorite chair with an ashtray nearby). When research data show half of college students are trying to quit and 18% tried more than five times in one year, it is obvious that college students desperately need interventions.

Researchers say interventions to prevent the transition from occasional to nicotine-dependent smoking can be strengthened through environmental and policy changes to discourage tobacco use and strong messages that smoking is not the norm.¹ Concentrated efforts by advanced practice nurses nationwide could reduce the likelihood a student will start smoking, encourage college students to quit, slow the transition to nicotine dependence, and change health outcomes for the new millennium. ❖

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Clinical Briefs

Does Contraception Lead to Diabetes in Latina Women?

By Sharon Myoji Schnare, RN, FNP, CNM, MSN

RESEARCH SUGGESTS POSTPARTUM USE OF PROGESTIN-only oral contraception may increase the risk of developing type 2 diabetes mellitus in Latina women who had gestational diabetes. A retrospective cohort of 904 Latina women with gestational diabetes mellitus (GDM) who gave birth between 1987 and 1994 was tested at 4-16 weeks postpartum and found to have no diabetes. The women were divided into three groups. Group one (443 women) chose no hormonal contraception at their initial postpartum visit. Group two (383) received low-dose combination (estrogen and a progestin) oral contraceptives (OCs). Group three (78) were breast-feeding and chose a progestin-only oral contraceptive. Because estrogen inhibits lactation, the drug manufacturers of combination OCs state it is not recommended for nursing women. These women were followed for up to 7.5 years with periodic glucose tolerance tests.

Researchers found the annual incidence rates for developing diabetes mellitus (DM) were 8.7% for Latina women using no hormones, 10.4% for women using low-dose combination OCs, and 26.5% for the women who used progestin-only oral contraceptives. Patients who used progestin-only OCs developed DM more rapidly within the first two years. The research showed the use of progestin-only OCs almost tripled the risk of type 2 DM compared with equivalent use of low-dose OCs. The risk increased with duration of uninterrupted use. The authors conclude that progestin-only OCs were associated with an increased risk of diabetes in breast-feeding Latina women with recent GDM and “should be prescribed with caution, if at all.” Long-term use of low-dose OCs did not increase the risk of type 2 diabetes compared with use of nonhormonal contraception; “thus, combination OCs do not appear to increase the risk of diabetes in nonbreast-feeding

women with recent GDM.” (See *patient handouts enclosed in this issue: “Diabetes in Hispanic Americans” and “Diabetes in African Americans.”*) ❖

Source

Kjos S. Contraception and the risk of type 2 diabetes mellitus in Latina women with prior gestational diabetes mellitus. *JAMA* 1998;280.

Cognitive Therapy May Benefit Depressed Diabetics

By Joan Unger RN, MS, ARNP-C

RESEARCHERS FOUND THAT USING A COMBINATION OF cognitive behavior therapy (CBT) techniques with diabetes education was effective in treating major depression among patients with type 2 diabetes. A bonus was improved glycemic control as well.

Researchers recruited 42 type 2 diabetics suffering major depression for a 10-week study using biweekly diabetes education. Twenty of the subjects also had individual weekly CBT sessions with a psychologist. Researchers used the Beck Depression Inventory to assess depression and glycosylated hemoglobin (HbA1c) to evaluate diabetic control. After 10 weeks, 85% of patients in the CBT group achieved remission of depression, compared with only 27.3% in the control group. At the six-month follow-up, 70% in the CBT group were in remission, compared with 33% of control patients.

The study found no difference in HbA1c levels after 10 weeks, but there was a significant improvement in mean HbA1c levels in the CBT group on six-month follow-up. Researchers noted that improvement in depression may have a positive effect on sleep, dietary practices, physical activity, or physiologic paths involved in glucose regulation. Other experts suggest CBT may help diabetics without depression because it teaches valuable coping skills. It might improve education results for patients feeling overwhelmed by demanding diabetic care, they say. ❖

Source

Lustman P. Cognitive therapy may improve glycemic control in diabetics with depression. *Ann Intern Med* 1998;129:605-621.

CE Objectives

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After reading each issue of *RN Advanced Practice Alert*, the reader will be able to do the following:

- Identify current scientific research and thinking regarding prevention, diagnosis, and treatment of specific diseases and health care concerns. (See *Depression: Making the Diagnosis in Primary Care*, p. 17.)
- Identify research-based indications and opportunities to implement appropriate changes in day-to-day advanced nursing practice. (See *Drug Warning: Beware of Troglitazone [Rezulin]*, p. 19.)
- Identify strategies and opportunities to educate patients about diagnoses and current medical treatment options to assist them in making informed choices about health care. (See *Smoking Increases Among College Students*, p. 21.)

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In the March issue of *RN* magazine

- ❖ Getting UTI patients back on track
- ❖ The patient with Crohn's disease
- ❖ When MRSA reaches into long-term care

Three articles devoted to management needs of patients that nurse practitioners see every day!

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❖ Life care planning

Examining a new tool to ensure chronically ill or disabled patients have the means—clinical and financial—to live the best possible quality of life.

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Anticonvulsant drug relieves post-herpetic neuralgia

How effective is today's hypertension therapy?

Dietary fiber/risk of colorectal cancer and adenoma in women