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Combination Nicotine Replacement Therapy

Scott Dyer, DO, National Health Service Corps Physician, Winslow Indian Health Center, Winslow, Arizona

Healthcare is a growing industry. The cost of delivering healthcare in the U.S. reaches billions of dollars each year, and with the population aging it is expected that the costs will rise even higher. In order to reduce these projected costs, there need to be more interventions in preventative medicine.

One area that can be focused upon is smoking cessation. It is estimated that smoking related diseases kill 430,000 Americans each year, and that it costs the U.S. $97.2 billion in combined healthcare costs and lost productivity. Among those who are most likely to smoke and to be exposed to the risks of lung disease and cancers are Native Americans. Thirty four percent of Native Americans are smokers. The next highest rates of smoking are among African Americans (26.7%), Caucasians (25.3%), Hispanics (20.4%), and Asians/Pacific Islanders (16.9%). It is also estimated that 22.4% of U.S. teenagers smoke, and nearly 90% of all smokers began before age 21.[1]

Not only does smoking cause most cases of chronic obstructive pulmonary disease (COPD), it is also estimated that smoking causes 25% of all cancers. Smoking is known to be a risk factor in cancers of the oral cavity, respiratory tract, bladder, renal pelvis, and pancreas.[2] In particular, smoking is directly responsible for 87% of all lung cancers. Furthermore, secondhand smoke causes approximately 3000 lung cancer deaths annually in the U.S. Today, lung cancer has taken the lead in female related cancer deaths. In 2000 an estimated 67,600 women died of lung cancer; by comparison there were approximately 40,800 deaths from breast cancer.[1]

Smoking is also directly related to cardiovascular disease. Twenty percent of the 500,000 coronary heart disease (CHD) deaths each year are attributable to smoking. Furthermore, in males, the death rates from CHD are 60-70% higher in smokers than nonsmokers. Also, women who smoke have higher CHD death rates, but in conjunction with oral contraceptives, they have a ten-fold increase. Cigarette smoking also contributes to coronary atherosclerosis, acute ischemia, and thrombotic and arrhythmic coronary events. It is also known to cause fifteen percent of the 150,000 stroke deaths each year. Lastly, it is the strongest risk factor for arteriosclerosis obliterans and thromboangitis obliterans.[3]

In order to combat the use of cigarette smoking, nicotine replacement therapy began in the 1970s in the form of gum.

In this Issue...

Since then, there have been more forms made available, including the patch, pill, inhaler, nasal spray, and film. The success rates have only been fair with a single nicotine replacement therapy. However, there have now been a few randomized, controlled trials that have addressed combination nicotine replacement therapy. This paper will review the best of the available trials on combination replacement therapy and examine whether or not this method has significantly higher success rates for smoking cessation after 12 months, and if so, which patients would best benefit from combination nicotine replacement therapy.

There are only two studies that have compared nicotine gum to the 16 hour patch.[4,5] Kornitzer took 374 volunteers from the workplace from three insurance companies in Brussels, Belgium. They were men and women age 20 - 65, with a mean age of 40. They smoked 10+ cigarettes a day (mean 25), for at least three years (mean, 22 years). They were motivated to quit, and had a mean Fagerstrom Tolerance Score (FTS) of 6. Exclusion criteria were symptomatic cardiovascular disease, pregnancy, breast-feeding, abuse of alcohol or other drugs, dermatological disorders, peptic ulcers, use of smokeless tobacco, or involvement in any other smoking cessation programs.

Patients were enrolled in a double blind, randomized, controlled trial (RCT) into three groups. Group 1 (n=149) used a 15 mg patch and 2 mg nicotine gum. Group 2 (n=150) used a 15 mg patch and placebo gum. Group 3 (n=75) used a placebo patch and placebo gum. The patches were tapered over 24 weeks as follows: weeks 1 - 12, 15mg patch; weeks 12 - 18, 10 mg patch; weeks 18 - 24, 5 mg patch. The gum was a 2 mg nicotine gum, and patients were encouraged to use four pieces a day for six months. Treatment failures were defined at each visit as self reported smoking, measured breath carbon monoxide (CO) levels > 10 ppm, or patients lost to follow up after week one.

Table 1. Abstinence rates (as a percentage) using three nicotine replacement regimens

	wk 12	wk 24	wk 52
Patch + Gum	34.2 (p=0.027)	27.5 (p=0.004)	18.1
Patch	22.7	15.3	12.7
Placebo	17.36	14.7	13.3

As can be seen from Table 1, those subjects using active gum and patch had higher abstinence rates than the patch alone. This was statistically significant up to 24 weeks. This would suggest it is better to give combination therapy to patients earlier in their treatment to help prevent relapse. At 52 weeks there was no statistical significance in abstinence rates, although rates trended higher in the patch plus gum group. Surprisingly, the study showed no statistically significant advantage of the patch over placebo at any point in the study. This most likely is due to random chance, poor design, or inadequate power of the study, considering the evidence in support of the patch in other studies. Lastly, the patients in this trial were all volunteers from the workplace and likely had high rates of motivation to quit.

The second trial by Puska[5] enrolled 300 volunteers recruited from a newspaper advertisement in North Karelia, Finland. Represented were men and women ages 20 – 65 (mean 40), smoking 10+ cigarettes a day (mean 20) for at least three years (mean 20). Patients were motivated to quit and had a mean FTS of 5.6. Exclusion criteria were similar to the former study. Patients were considered treatment failures if they were lost to follow up, reported smoking at week three or later, or had measured CO levels > 10ppm at any clinic visits.

Patients were enrolled in a double-blinded, RCT into two groups. Group 1 (n=150) used a 15 mg patch and 2 mg gum. Group 2 (n=150) used a placebo patch and 2 mg gum. Patients used a 15 mg patch for 12 weeks, then a 10 mg patch for three weeks, and then a 5 mg patch for three weeks. The patients were encouraged to use at least four pieces of gum a day for 12 months.

Table 2. Abstinence rates (as a percentage) using two nicotine replacement regimens

	wk 12	wk 24	wk 52
Gum + Patch	39.3 (p=0.038)	27.3	24
Gum only	28	20.7	17.3

The results show an advantage in favor of combination therapy up to 12 weeks. Afterwards, although abstinence rates were higher in the combination group, this did not reach statistical significance. What was discovered though was that the answer to the question, "Which cigarette do you most of all hate to give up?" had a significant impact on relapse [OR=1.89; 95%CI (1.08-3.32)]: those who most hated to give up their first cigarette in the morning fared the worst. It is possible that giving patients combination therapy early in their treatment helps prevent relapse by suppressing early withdrawal symptoms, and that those who are highly dependent on nicotine would benefit most by early combination therapy up to 12 weeks.

Blondal[6] conducted a double-blinded RCT comparing the patch and nasal spray to the patch alone. 237 smokers from Reykjavik, Iceland were recruited by television and newspaper advertisements. Men and women ages 22 - 66, (mean 42), who smoked at least one cigarette a day, (mean 25) for three or more years were included. Their mean FTS was 5.7. Again the exclusion criteria were similar to those in the other studies. Patients were considered smokers if after stopping smoking they took a single puff of a cigarette, had a measured CO > 10 ppm at any visit, or were lost to follow up. Patients used a 15 mg patch for three months, 10 mg patch the fourth month, then a 5 mg patch the fifth month. A 1 mg nicotine nasal spray was used ad libitum for up to 12 months. Group 1 (n=118) used a 15 mg patch and 1 mg nasal spray. Group 2 (n=119) used a 15 mg patch and placebo nasal spray.

Table 3. Abstinence rates (as a percentage) using three nicotine replacement regimens

	3 mo	6 mo	12 mo	72 mo
Patch + Spray	37.3 (p=0.045)	31.4 (p=0.005)	27.1 (p=0.001)	16.2
Patch	25.2	16	10.9	8.56

The data in Table 3 show that the patch and spray regimen was significantly more effective than the patch alone at nearly all treatment periods. The numbers even approach significance at 72 months (p = 0.08). Plasma cotinine levels were significantly higher in those who used the spray at all periods compared to placebo spray. It may be that the higher nicotine levels, reflected by higher plasma cotinine levels, increase the abstinence rates in those who used the patch and nasal spray. It may also be that those who used the spray had a longer period to work on behavioral changes, up to 12 months, compared with the patch only users who stopped after the fifth month. Also, the nasal spray system delivers nicotine faster than the patch, thus meeting the users' needs immediately.

Bohadana[7] enrolled 400 subjects from a newspaper advertisement in Nancy, France, in a double-blinded RCT comparing the patch and nicotine inhaler to the patch alone. Men and women age 18 – 70 (mean 37), who smoked at least 10 cigarettes a day (mean 24), for three or more years (mean 20) were enrolled. The mean FTS was 6.2. Patients enrolled had to be motivated to quit. The standard exclusion criteria were followed. Abstinence was defined as self-reported after week one and measured CO levels < 10ppm at each visit. Those lost to follow up were considered treatment failures. The inhalers used had 10 mg nicotine cartridges and patients were instructed to use 6 - 12 cartridges a day for three months and then were tapered off over the next three months. The patch used was either a 15 mg patch or placebo patch for six weeks and then a placebo patch for six more weeks. Group 1 (n=200) used the inhaler and 15 mg patch for six weeks, then placebo patch for six weeks. Group 2 (n=200) used the inhaler and a placebo patch for 12 weeks.

Table 4. Abstinence rates (as a percentage) using two nicotine replacement regimens

	wk 12	wk 24	wk 52
Inhaler + Patch	42 (p=0.02)	25	19.5
Inhaler	31	22.5	14

It is clear from Table 4 that starting with combination therapy yields significantly higher levels of abstinence up to 12 weeks. This can probably be explained by the higher levels of nicotine used in the first six weeks of the study. At week six the cotinine levels were significantly higher in group 1, as expected with the use of a patch and inhaler; however by week 12 there were no significant differences in cotinine levels between the two groups, and yet group 1 still had significantly higher abstinence rates. Therefore, higher levels of nicotine exposure cannot be solely responsible for the increase in abstinence. In addition, this study only used six weeks of patch therapy compared to the usual 3 - 5 months in other combination trials, yet it demonstrated equal if not better abstinence rates at 12 months. Therefore, using six weeks of patch therapy, without taper, could replace the longer treatment of 3 - 5 months. Lastly, even at 12 months the abstinence rates are 39% higher in the combination patch and inhaler group (19.5% vs. 14%) although lacking statistical significance (p=0.14).

Tonnesen[8] conducted a double-blinded RCT comparing placebo patch, patch, and patch plus inhaler. Four hundred and forty-six patients were recruited from a lung clinic in Hellerup, Denmark. They were men and women age 20 – 70 (mean 49), smoked at least 10 cigarettes a day (mean 18), and were motivated to quit. The mean FTS was 5.6. The exclusion criteria were similar to the other studies. The study had four arms. Group 1 (n=109) was a placebo group using a 5 mg nicotine patch. Group 2 (n=104) used a 15 mg patch. Group 3 (n=118) used a nicotine inhaler. Group 4 (n=115) used a nicotine inhaler and 15 mg patch. The chosen nicotine replacement therapy was used for three months, with individuals continuing up to nine months if they wished. Patients were encouraged to use 4 - 12 cartridges a day with the inhalers. Since the study was performed in a lung clinic, and probably enrolled smokers with a low motivation to quit, it was assumed the placebo could negatively influence the study. Therefore, a low dose nicotine patch was used as placebo. Abstinence was defined as self reported non-smoking after week two and a measured CO level < 10 ppm on any visit.

Table 5. Abstinence rates (as a percentage) using four nicotine replacement regimens

	wk 12	wk 24	wk 52
Placebo, 5mg Patch	9.2	6.4	1.8
15mg Patch	19.2 (p<0.05)	14.4(p=0.061)	8.7 (p<0.05)
Inhaler	13.6	5.9	5.1
Inhaler+15mg Patch	14.8	8.7	3.5

The results shown in Table 5 do not favor using combination therapy. In fact, only the 15mg patch group had a statistically significant higher abstinence rate compared to placebo. Even early combination therapy up to 12 weeks offered no advantage over single therapy. It was discovered by Cox-regression analysis that male sex, higher age, lower cigarette consumption, lower initial CO level and FTS were all statistically significant pretest predictors of higher success. The study may have had lower abstinence rates due to the participants having an assumed lower motivation to quit, coming from a lung disease clinic. In addition, they may have felt pressured to join the study. Also, the short quit date, within two weeks of the onset of the study, may have been too short for subjects who

were not ready to quit. Lastly, it may have been random chance that the inhaler and inhaler plus patch groups did not work better than placebo.

Discussion

After reviewing the studies, it appears that in the long term, combination nicotine replacement therapy has no significant benefit over single therapy. The evidence shows that in four of the five studies, combination therapy gave significantly higher abstinence rates in the short term, that is, over 12 - 24 weeks. It was suggested by Blondal that higher cotinine levels might have been responsible for this. It also may have been due to a longer time period using nicotine replacement, which allowed the patients time to implement behavioral changes. Bohadana, however, showed significantly higher abstinence rates in the combination group even after cotinine levels were similar in his patch plus inhaler vs. inhaler and placebo groups six weeks after the patch was discontinued. Therefore, the higher levels of nicotine replacement do not appear to be the only reason for a higher abstinence rate in the combination therapy group.

Conclusions

It would seem sensible that in patients who are more addicted to nicotine it is better to use combination therapy for at least 12 weeks to help them avoid early relapse. Although at one year there was never a statistically significant advantage to combination therapy, all the studies reported higher abstinence rates, and Bohadana's study did approach statistical significance. So one could argue that in the long term, combination therapy is best. However, when looking at the staggering costs of cigarette smoking, $97 billion a year in healthcare costs and lost productivity, even a slight advantage with combination therapy is better than none. Also, since 90 percent of smokers begin before age 21 any early interventions with nicotine replacement therapy that could reach teenage smokers would significantly impact the number of future adult smokers.

Physicians need to be aware of the data regarding smoking and nicotine replacement therapy and offer their patients the best options available. The time and cost of initiating nicotine replacement therapy will pay dividends in improved health and cost savings benefits to the patient and society over time.

References

1. American Lung Association Fact Sheet: Smoking [on line]. *http://www.lungusa.org/tobacco/smoking_factsheet99.html*
2. Abeloff MD, Armitage JO, Lichter AS, Niederhuber JE. Clinical Oncology. New York, NY, Churchill Livingstone 2000, p 280-284.
3. Fauci, Braunwald, Isselbacher, et al. Harrison's Principles of Internal Medicine. New York, NY, McGraw-Hill 1998, p 2517.
4. Kornitzer M, Boutsen M, Dramaix M, Thijs J, Gustavsson G. Combined use of nicotine patch and gum in smoking cessation: A placebo-controlled clinical trial. *Prev Med*. 1995; 24:41-47.
5. Puska P, Korhonen HJ, Vartiainen E, Urjanheimo E, Gustavsson G, Westin A. Combined use of nicotine patch and gum compared with gum alone in smoking cessation: A clinical trial in North Krelia. *Tob Contrl*. 1995; 4:231-235.
6. Blondal T, Gudmundsson LJ, Olafsdottir I, Gustavsson G, Westin A. Nicotine nasal spray with nicotine patch for smoking cessation: Randomised trial with six year follow up. *BMJ*. 1999; 318:285-289.
7. Bohadana A, Nilsson F, Rasmussen T, Martinet Y. Nicotine inhaler and nicotine patch as a combination therapy for smoking cessation. *Arch Intern Med*. 2000; 160:3128-3133.
8. Tonnesen P, Mikkelsen KL. Smoking cessation with four nicotine replacement regimes in a lung clinic. *Eur Respir* J. 2000; 16:717-722.

Editor's Note: It is agency policy that any and all forms of pharmacological support for smoking cessation be accompanied by counseling and education activities. The current clinical evidence supports the need for such a multifaceted approach.

Chronic Kidney Disease: Association of GFR Level with Complications

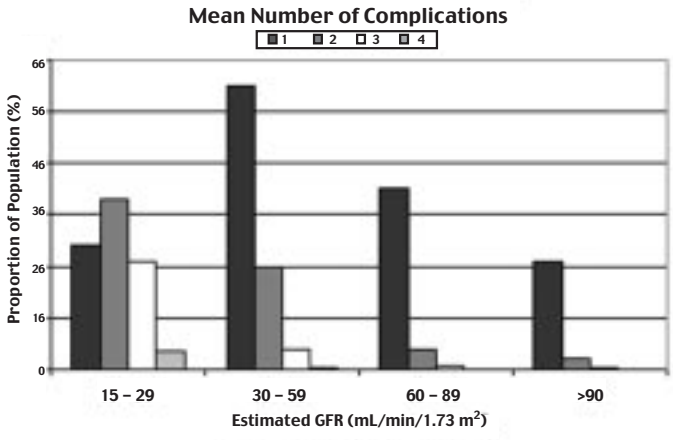
This is the fourth in the series of articles about chronic kidney disease.

Andrew S. Narva, MD; and Theresa A. Kuracina, MS, RD, CDE, both from the Indian Health Service Kidney Disease Program, Albuquerque, New Mexico

As has been described in previous articles in this series appearing in *The Provider*, identification, classification, and stratification of chronic kidney disease (CKD) are important aspect of patient care. The purpose of this article is to review the association of declining glomerular filtration rate (GFR) with complications of CKD in adults.

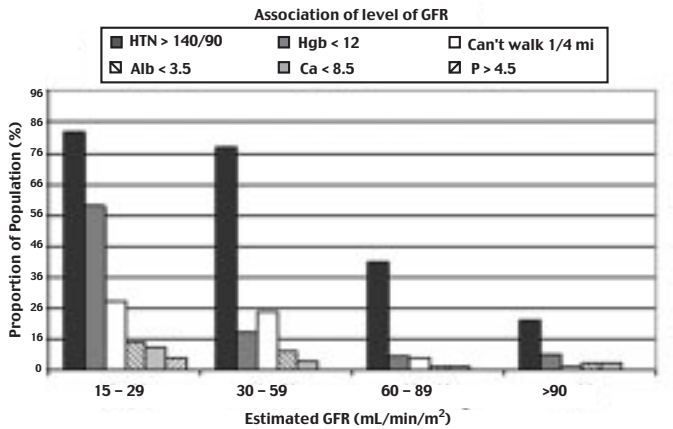
In general, as GFR declines, the number of complications increases. Figure 1 shows the estimated distribution of the number of complications by category of estimated GFR, from the National Health and Nutrition Examination Survey (NHANES III) data.

Figure 1. Comparison of number of complications by estimated level of GFR from NHANES III data (not adjusted for age)



Hypertension, anemia, malnutrition, bone disease and disorders of calcium and phosphorus metabolism, and decreased functioning (defined as an inability to walk 1/4 mile) are more prevalent as GFR declines. Figure 2 illustrates the association of these complications with decreased GFR. These complications are associated with adverse outcomes across the CKD spectrum.

Figure 2. Estimation of prevalence of selected complications by level of GFR from NHANES III data (not age adjusted)



The following provides a brief synopsis for each listed complication. Future articles will describe each in detail.

Hypertension

Hypertension is a cause and complication of CKD. If left untreated, hypertension can lead to more rapid decline in kidney function. All patients with CKD should have their blood pressure monitored routinely and treated aggressively.

Anemia

The anemia seen in CKD is due primarily to erythropoietin deficiency. Patients with a GFR less than 60 mL/min/1.73 m^2 (Stage 3) should be assessed for anemia. Hemoglobin is the preferred measure for assessing anemia since it is not affected greatly by shifts in plasma water. Hemoglobin levels lower than physiologic norms are considered anemic. The work-up for anemia includes a complete blood count, red cell indices, reticulocyte count, iron studies (TIBC, Fe, TSAT), ferritin, and evaluation for gastrointestinal bleeding.

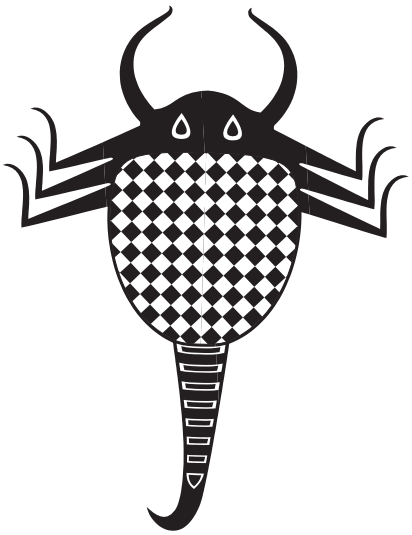
Malnutrition

Both inadequate protein and calorie intake are associated with the malnutrition seen in CKD. Appetite declines with decreased GFR. Metabolic acidosis, chronic inflammation, and altered taste negatively impact nutritional status. Patients with

a GFR less than 60 mL/min/1.73 m^2 should be referred to a registered dietitian for nutritional assessment. For those with GFR less than 20 mL/min/1.73 m^2 the nutritional assessment should include at least one value from each of the following: 1) serum albumin; 2) edema-free actual body weight, percent standard body weight (NHANES II), or subjective global assessment; and 3) normalized protein nitrogen appearance (nPNA) or dietary interviews and diaries.

Bone Disease and Disorders of Calcium and Phosphorus

Bone disease begins early in CKD and is not easily recognized — unless specifically assessed. Problems arise from both high turnover bone disease and low turnover bone disease. Patients with a GFR less than 60 mL/min/1.73 m^2 should be assessed for bone disease and associated disorders of calcium and phosphorus metabolism. Intact PTH, phosphorus, and ionized calcium are the most commonly used markers. Bone biopsies are not routinely recommended.



Functional Status

Functional status appears to decline in relation to declining GFR. Patients with a GFR less than 60 mL/min/1.73 m^2 should undergo regular assessment for functional impairment. Late referrals and inadequate pre-dialysis care; symptoms; effects of illness on physical, psychological, and social functioning; and satisfaction with care are all associated with decreased function. Low income and lower level of education are associated with greater functional impairments.

In summary, when GFR declines below 60 ml/min/m^2 (Stage 3 CKD), patients should be evaluated for anemia, malnutrition, bone disease, and declining functional status. Specific management of these complications will be discussed in future articles.

PALLIATIVE CARE PEARLS ☐

Management of Delirium in Terminal Illness

The following article is the fourth in an ongoing series in support of the development of a unified approach to palliative care services for American Indians and Alaska Natives. Each will present brief, concise facts and information for providers of palliative care.

Judith A. Kitzes, MD, MPH, Soros Foundation, Project on Death In America Faculty Scholar, University of New Mexico Health Science Center, School of Medicine, Albuquerque, New Mexico

- ☐ *Neuroleptics are first line pharmacological agents.*
- ☐ *In elders: start low, titrate slowly.*
- ☐ *Benzodiazepines can cause "paradoxical" worsening.*

Delirium is a common occurrence (up to 70%) in the terminally ill, and can be very disturbing to family, caregivers, and health care providers. Intervention is essential because delirium may be easier to reverse in its earlier stages than in the final days of life. Once it is established, it frequently progresses to severe "terminal agitation." The following are the characteristics of delirium when it presents in terminal illness:

acute onset	often remitting	mental clouding
agitation	diurnal variations	muddled speech
drowsiness	aggressive behavior	anxious or fearful

There are may reversible precipitating and/or exacerbating factors for delirium, including the following:

pain	**fecal impaction**	**urinary retention**
drugs	infection	hypotension
hypoxia	hypoglycemia	alcohol-sedative drug withdrawal
fatigue	hypercalcemia	environmental changes

Intervention Strategies

1. Identify and correct reversible causes.
2. Nondrug interventions: treat patient with respect, never use restraints, avoid bed rails, encourage presence of family member or close friend, use night light, explain every procedure and event in detail.
3. Pharmacological intervention if symptoms are marked, persistent, and cause distress:

   First-line: Haloperidol (Haldol): Starting doses are 0.5 - 1.0 mg PO or IM/IV; titration can occur by 2.0-5.0 mg every hour until daily requirement is established, which is then administered in 2-3 divided doses per day.

   Second-line: Risperidone (Risperidol): 1 - 2 mg PO at night; gradually raised 1 mg every 2 - 3 days until an effective dose (4 - 6 mg PO HS) is reached.

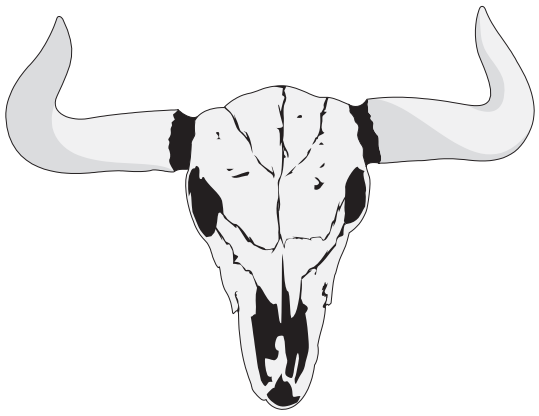
   Olanzapine (Zyprexa): 5 mg PO daily; after one week, dose can be raised to 10 mg/day and titrated up to 20mg/day.

   Quetiapine (Seroquel): Start 25 mg PO BID, then raise as needed 25-50 mg per dose every 2 - 3 days to a target of 300-400 mg/day divided BID or TID.

References

1. Fast Facts and Concepts #60. Pharmacologic Management of Delirium; update on newer agents. Earl Quijada, MD and Andrew Billings, MD. January, 2002. End of Life Physician Education Resource Center. *www.eperc.mcw.edu*.
2. Kinzbrunner B, Weinbreb N, Policzer J. 20 Common Problems in End of Life Care. McGraw Hill, 2002.
3. Twycross R. Introducing Palliative Care. Third Edition. Radcliffe Medical Press Ltd. 1999.

Health care providers should exercise their own independent clinical judgement. Accordingly, official prescribing information should be consulted before any product is used.



New PCC Measurement Tool for Pain

Howard Hays, MD, MSPH, Chairperson, Clinicians Information Management and Technology Advisory Council (CIMTAC)

In recent years there has been considerable attention directed toward the assessment and management of pain. Hospitals and clinics are developing policies requiring that patients be asked if they have pain, and to quantify the severity of that pain if present. National organizations such as the American Pain Society have recommended the evaluation of pain as a "fifth vital sign."

As Indian Health Service, tribal, and urban program (I/T/U) facilities seek to adapt to this trend, some have requested the addition of a means of recording severity of pain in the Patient Care Component (PCC) of the RPMS database. In response to this, ITSC programmers have deployed a PAIN entry into the MEASURE TYPE file, and have asked the Clinicians Information Management and Technology Advisory Council (CIMTAC) to provide guidelines for recording pain data as a measurement.

Pain, as a purely subjective experience, is most properly defined as a symptom, rather than a sign. Unlike other vital signs, it cannot be objectively measured by an observer, but instead must be reported by the patient. Although certain behaviors exhibited by patients experiencing pain may be observed, there is little correlation between the presence and intensity of observed behaviors and the self-reported severity of pain. Moreover, there is no "gold standard" diagnostic test for pain, so validating the accuracy and reproducibility of pain measurements remains problematic.

CIMTAC neither endorses nor rejects the use of a pain scale to record pain reports by patients. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) only requires that pain be assessed, and does not specify a means for doing this when it recommends, "In the initial assessment, the organization identifies patients with pain . . .. This assessment and a measure of pain intensity and quality (for example, pain character, frequency, location, and duration), appropriate to the patient's age, are recorded in a way that facilitates regular reassessment and follow-up according to criteria developed by the organization" (CAMAC standard PE 1.4, 2002). Each organization will need to determine whether their use of numerical or graphical pain scales will be adequate for assessment of pain intensity and quality, or will facilitate reassessment and follow-up as required by JCAHO.

A variety of pain measurement instruments are in use; most are ordinal scales ranging from 0 to 5 or 0 to 10. Some replace numbers with images such as a series of stylized facial expressions evoking the idea of progressive pain, for use with children or others who might have difficulty with a numeric scale. In preparing recommendations for the use of an RPMS measurement for pain, CIMTAC has sought expert information concerning those instruments that have been most extensively validated (to the degree possible, given the vagaries of this measure). We have the following recommendations:

1. The IHS will use a 0-10 scale for documenting patient reports of pain.
2. The PCC Measurement Type for PAIN will accept 11 possible entries, namely the numeric integers 0 through 10. As with other measurements, it is not required that this be completed for every visit.
3. The only instructions to the patient for responding to a pain assessment query should be that "0" represents "no pain" and "10" represents "the worst possible pain." No other instructions concerning intermediate values should be given; these have not been validated as providing any greater accuracy in describing pain, and may in fact detract from the reproducibility of the measure.

4. Some facilities may be using other numeric scales (0-5) or graphic scales (faces) to assess pain. The IHS has permission from the publisher to use the Wong-Baker FACES scale for graphic representation of pain severity (see Figure 1). The owner of this scale recommends assigning the values 0, 2, 4, 6, 8, 10 to the six images, as shown. Users are cautioned that translation of values from one scale to another has not been validated and may result in inaccurate or lost information, so it is recommended that the same scale be used each time a patient is asked about pain.
5. Even though the pain scale uses numbers, users must realize that this is an ordinal scale, not an interval scale. In other words, arithmetic calculations should not be done on these values. For example, the scale does not offer any basis for thinking that a person reporting a pain value of 6 has twice as much pain as someone reporting a 3, or that a change in pain report from 3 to 9 means a person has three times as much pain. Similarly, since every patient's perception of pain is unique, comparing or averaging values among patients has questionable meaning.

Each facility will, of course, determine if and how it will collect and use pain data. Reasonable and appropriate uses for the pain scale might be to follow a single patient's report of pain through the course of an injury or illness, or to retrospectively identify patients with high pain reports to assess the organization's responsiveness. The PCC measurement entry for pain represents current best efforts at quantifying this elusive symptom, and it is available for your use. It is not a required measurement, however. Accrediting agencies are only asking that healthcare facilities develop consistent practices for assessing and addressing pain. The pain scale is one tool for doing the former; the latter is considerably more difficult.

Figure 1. Wong-Baker 0 -10 FACES Pain Rating Scale

NCME VIDEOTAPES AVAILABLE ☐

Health care professionals employed by Indian health programs may borrow videotapes produced by the Network for Continuing Medical Education (NCME) by contacting the IHS Clinical Support Center, Two Renaissance Square, Suite 780, 40 North Central Avenue, Phoenix, Arizona 85004.

These tapes offer Category 1 or Category 2 credit towards the AMA Physician's Recognition Award. These CME credits can be earned by viewing the tape(s) and submitting the appropriate documentation directly to the NCME.

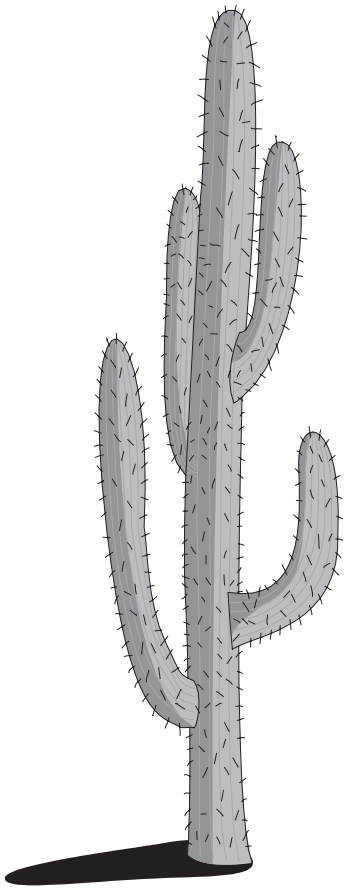
To increase awareness of this service, new tapes are listed in The IHS Provider on a regular basis.

NCME #805

Physical Medicine and Rehabilitation: A Multidisciplinary Commitment over Time *(60 minutes)* Today's widespread recognition of the value of active rehabilitation as a necessary and integral part of the individual's overall management is enabling increasing numbers of patients to experience a return to full active life, or at least to achieve a quality of life they find acceptable given their particular illness or injury. Rehabilitation services are provided throughout the continuum of medical care and in a variety of health care settings – from the intensive care unit to long-term care facilities. Two physicians who specialize in physical medicine and rehabilitation take you through the experience of how they and the nurses, therapists, psychologists, and other allied health professionals work as a team with patients with chronic pain, carpal tunnel syndrome, spinal cord injury, and stroke to achieve the best possible individualized functional outcomes.

NCME #806

Report From Barcelona: Highlights From the 14th International AIDS Conference *(50 minutes)* New HIV infections continue to multiply across the globe, most notably in sub-Saharan Africa and Asia. HIV continues to spread in the United States as well. Prevention efforts, including risk reduction education and intervention strategies, are especially needed in communities of color in rural areas, large and small urban centers, and in communities of young gay men. Ultimately, it is hoped that a vaccine that can offer long-lasting protection against various HIV strains can be developed for use throughout the world. Dr. Berkley provides an update on the progress of HIV vaccine research. In the meantime, scientists and clinicians are trying to maximize the potential of today's antiretroviral therapy by studying various drug combinations in different patient populations and integrating drug resistance testing into therapeutic decision-making. Dr. Grossman summarizes the key clinical trials reported in Barcelona and shares his experience and expertise on various treatment-related issues, including drug-induced side effects and new antiretroviral drugs in development.



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Dept. of Health and Human Services
Indian Health Service
Clinical Support Center
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