

# NONPRESCRIPTION MEDICINES DIGEST



August 2005

Welcome to the August edition of the *NMA Newsletter*. This edition includes an article that indicates patients may be much more willing to pay for pharmacist provided nonprescription medication services than they were 10 years ago. In addition, we present information regarding the additional benefits of using heat wrap therapy in both acute lower back pain and knee osteoarthritis. The third article reminds pharmacists of some current concerns regarding OTC progesterone creams.

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[Patient Valuation of Pharmacist Services for Self-Care with OTC Medications](#)

[Treating Acute Low Back Pain with Continuous Low-Level Heat Wrap Therapy and/or Exercise: A Randomized Controlled Trial](#)

[Safety Concerns with OTC Progesterone Cream](#)



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## Patient Valuation of Pharmacist Services for Self-Care with OTC Medications

**Hong SH, Spadaro D, West D, Tak SH**

Ten years ago, only 20% of sampled patients were willing to pay for pharmacist advice on self-care using OTC products. Researchers at the University of Arkansas for Medical Sciences decided to look at this issue in light of the increasing complexity of the OTC market. Their objectives were to determine the proportion of patients willing to pay for OTC services, how much patients would spend, how much time patients were willing to spend, and whether willingness to pay (WTP) was associated with selected variables such as setting and socioeconomic variables.

Pharmacy students enrolled in an advanced nonprescription drug course were asked to distribute a self-administered checklist questionnaire to consenting, volunteer adults in a community pharmacy. A total of 262 questionnaires were completed and analyzed using descriptive statistics, categorical data and multiple logistic regression analyses. WTP as the dependent variable was used to examine whether patients' willingness to pay was associated with various community settings and socioeconomic variables when all other variables were controlled.

Researchers found over half (51%) of the respondents were willing to pay for OTC services. Of those, 42% were willing to pay \$5 or less for such a service with 9% willing to pay \$10 or more, and 75% preferred to spend no more than 5 minutes receiving the service. Patients who frequented grocery or chain pharmacies were most willing to pay (86%) with mass-market patrons least likely to pay (38%). Independent pharmacies had the next to lowest percentage (53%) of WTP patrons. Although WTP was higher in patrons having drug insurance coverage, there was not a statistically significant difference. In addition, no other variable was significantly associated with WTP.

The authors discussed possible reasons for the increased WTP as related to patients recognizing the value of pharmacist delivered services in an increasingly complex OTC market. The authors also postulated that low WTP associated with independent pharmacies may be due to a high level of service patrons already received from these pharmacies thus patrons see no need for additional expenses. In addition, patrons who frequent mass-market pharmacies (the lowest %WTP) may be primarily concerned with price.

Limitations include not being generalizable beyond the study sample and sampling patient's subjective opinion rather than using actual transaction data.

*J Clin Phar Therap* 2005;30:193-199.

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## Treating Acute Low Back Pain with Continuous Low-Level Heat Wrap Therapy and/or Exercise: A Randomized Controlled Trial

**Mayer JM, Ralph L, Look M, et al.**

Low back pain is a common complaint associated with high costs of treatment and morbidity. Various treatment regimens have been used with mixed results. Maintenance of physical activity along with rehabilitation exercises has been shown to be superior to bed rest. These are also recommended to speed the patient's return to full function and prevent long-term consequences. Often, palliative therapy using heat in combination with such exercises is used, however little is documented about the effects of combining these. Also, previous heat therapies such as a heating pad, limited the use of heat + exercise because it decreased the patient's ability to move around. Therefore, these researchers developed a prospective randomized controlled parallel trial: to evaluate the efficacy of combining continuous low-level heat wrap therapy with directional preference-based exercise on the functional ability of patients with acute low back pain.

Outcome measures included functional ability assessed by the Multidimensional Task Ability Profile (MTAP) questionnaire and pain relief assessed by a 6-point verbal rating scale. One hundred participants were appropriately randomized to one of four groups: heat wrap therapy alone (n=25); therapist supervised exercise alone (n=25); heat + exercise (n=24); or a control group (n=26) that were given an educational booklet only. Inclusion criteria were defined as: ambulatory individuals

between the ages of 18-55 years, having nonspecific, nontraumatic, acute lower back pain (defined as > 2 days and < 3 months duration). Also, included individuals had to be previously pain free for at least 2 months prior to the current episode, and had scored less than 70% functional ability of the MTAP and reported moderate or greater pain. Exclusion criteria were extensive. Over the course of one week, treatment was administered 5 consecutive days, with 4 visits to the study center. All patients were asked to refrain from using other heat/cold modalities or receiving spinal manipulation, however, no restrictions were given for medication use.

Ninety-two subjects completed the study with no adverse events reported. Baseline characteristics were statistically similar. Using exercise + heat showed statistical improvement in both functional ability and pain relief compared to the other three groups at day 4. By day 7 (2 days after the conclusion of treatment), the same exercise + heat group's disability scores were reduced nearly twice the magnitude of heat or exercise alone, and three to four times greater than control. The authors note that 72% of the combined treatment group demonstrated a return to pre-injury function compared with 19-20% in the other three groups.

This study had several limitations such as small sample size and failure to assess long-term outcomes. Also, time spent with participants was approximately twice that in the combined therapy arm compared with either treatment alone. This may have added to the positive results seen.

Another recently presented study showed significant, positive results in pain reduction and increased mobility using heat wrap therapy in osteoarthritis patients. A randomized, single blind, active, placebo-controlled parallel study by W. McCarberg, was presented at the 24th Annual Scientific Meeting of the American Pain Society (APS) in Boston, MA. As concern rises over appropriate drug therapy for acute and chronic non-malignant pain conditions, heat wrap therapy appears to be a safe alternative for some patients.

The Mayer study can be found at: *The Spine Journal* 2005;5:395-403.

The APS abstract can be found at:

<http://www.ampainsoc.org/cgi-bin/abstract2005/search.pl> (type in McCarberg in author box.)

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## Safety Concerns with OTC Progesterone Cream

A small, short-term study recently published in the *Journal of Clinical Pharmacology*<sup>1</sup> raises concerns regarding the safety of progesterone creams that are currently available as non-FDA approved nonprescription products. Researchers studied 12 women who were either given FDA approved progesterone capsules 200 mg once daily or progesterone cream in a dose of 40 mg twice a day. After 12 days (steady state), no significant difference was found in dose-normalized 24-hour progesterone exposure comparing cream to oral capsules.

There have been numerous safety concerns regarding the use of hormonal replacement therapy for menopausal symptom relief and scientific data are lacking

on the efficacy and safety of OTC progesterone cream. Yet these creams are readily available and can potentially be used long-term without medical oversight. For example, a search of the Internet resulted in over 10 pages (with multiple products per page) of listings for OTC progesterone creams. These were listed as beauty creams, or products for relief of hot flashes and even as several products targeted to men. Because of the study results and the concerns with long-term use without oversight, the authors questioned whether progesterone should be available OTC. The North American Menopausal Society also raises concerns regarding content and concentrations of progesterone creams, which can vary widely in these non-FDA approved products and does not recommend their use in their menopausal treatment guidelines.

Without positive safety and efficacy data, it is important for pharmacists to warn their patients of the potential risks associated with using OTC progesterone cream.

<sup>1</sup>For further information refer to: "Over-the-counter progesterone cream produces significant drug exposure compared to a food and drug administration-approved oral progesterone product." *J Clin Pharmacol.* 2005;45(6):614-619.

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