

The Managed Care Pharmacy Perspective

Based on a presentation by Alan H. Heaton, PharmD

Presentation Summary

Despite the important reproductive and non-contraceptive benefits of hormonal therapy, both oral contraceptives (OCs) and hormone replacement therapy (HRT) are underutilized, with only a small portion of eligible women receiving therapy. Increased use of hormonal therapy will result in greater pharmacy costs, a concern in the present era of cost containment that is reflected in the wide variability in coverage of hormonal therapy provided by managed care organizations. However, pharmacoeconomic research demonstrates that relatively small expenditures in pharmacy costs for hormonal therapy result in significantly lower healthcare costs per patient, through the prevention of unintended pregnancy with OCs and the noncontraceptive health benefits of both OCs and HRT.

There are inherent difficulties in conducting pharmacoeconomic and outcomes research while simultaneously presenting and publicizing the results. Alan H. Heaton, PharmD, noted in his presentation that there are 2 models that take into account these conflicting variables. The more formal of these and the one Dr. Heaton has used in his studies, is the ECHO model, which measures Economic, Clinical, and Humanistic Outcomes. The other model, termed BEPA, represents the less formal "back-of-the-envelope" pharmacoeconomic assessment that practitioners make when presented with new drug information to determine the cost/benefit ratio.

Dr. Heaton cited the wide variability in coverage provided by managed care organizations at different stages in a

woman's life to illustrate the need for pharmacoeconomic research that addresses the healthcare needs of women throughout the hormone continuum. Although oral contraceptives (OCs) are generally covered through the early reproductive years (20s and 30s), they are less likely to be covered during the late reproductive (early 40s) and perimenopausal years, when the rate of unintended pregnancy is second only to that of the teenage years.¹ Hormone replacement therapy (HRT) is generally covered after age 45, but is less likely to be covered in patients between 25 and 44 years of age, regardless of ovarian status. However, it is interesting to note that pregnancy tops the list of healthcare expenditures for top diagnostic clusters, at approximately \$43 million within a 435,000-member health maintenance organization (HMO) population. Cancer is in the second position at almost \$35 million, and healthcare expenditures were lower for ischemic heart disease and fractures. Total healthcare expenditures for this particular HMO for the year 2000 were \$339.1 million.²

Data from the National Survey of Family Growth were used to estimate the rate of unintended pregnancy in the United States.¹ Among women 15 to 19 years of age, 78% of pregnancies are unintended, with 45% of these pregnancies aborted; in women 30 to 34 years of age, 33% of pregnancies are unintended, with 56% of these aborted. Women 40 years of age and older are at particular risk for unintended pregnancy; 51% of their pregnancies are unintended, and 65% of these

Table. Total Annual and Cumulative Costs of OC Use and Side Effects Compared with Unintended Pregnancy Costs Over 5 Years

	Year	Cost (\$)			
		Managed Payment Model		Public Payer Model	
		Annual	Cumulative	Annual	Cumulative
OCs	1	422	422	293	293
	2	336	788	263	556
	3	348	1136	251	807
	4	332	1468	239	1046
	5	316	1784	227	1273
No method	1	3225	3225	1428	1428
	2	3072	6297	1360	2787
	3	2926	9223	1295	4082
	4	2786	12,009	1233	5316
	5	2654	14,663	1175	6490

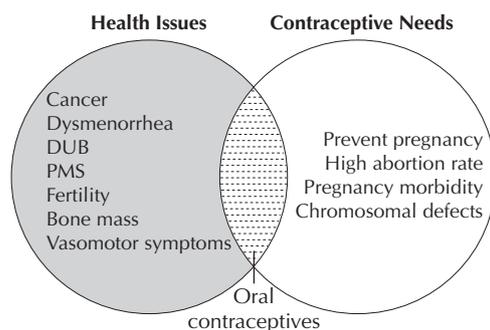
OC = oral contraceptive.

Source: Adapted from Trussell J, Leveque JA, Koenig JD, et al. The economic value of contraception: A comparison of 15 methods. *Am J Public Health* 1995;85:494-503.

end in abortion.¹ However, with perfect use or typical use of OCs, only 0.1% to 5% of women, respectively, experience an unintended pregnancy in the first year.³

OC use is also effective in reducing the rate of ectopic pregnancy.⁴ Although 2.6 ectopic pregnancies occur per 1000 woman years with no contraception, the rate is reduced more than 500-fold, to 0.005 per 1000 woman years with the use of OCs.⁴

Figure 1. Perimenopausal Transition: A Changing Clinical Emphasis



DUB = dysfunctional uterine bleeding; PMS = premenstrual syndrome.

To illustrate how these statistics translate into economic value, Dr. Heaton proposed the following question: Would spending between 20 and 74 cents per patient per month (PP/PM) in pharmacy costs in order to save \$1.54 to \$3.00 in medical costs be reasonable? Dr. Heaton's answer was yes. To support this, he discussed how a minimal expense for OCs can dramatically reduce the much greater medical costs related to pregnancy. According to Dr. Heaton, the direct medical costs for 5 years of OC use are \$1784 under a managed payment model and \$1273 under a public payer model. By comparison, with no contraception, the costs are \$14,663 and \$6490, respectively (Table).⁵ Thus, the use of OCs results in significant dollar savings related to term delivery, induced and spontaneous abortion, and ectopic pregnancy. Investments in contraception provide substantial economic as well as social benefits.

Needs of Perimenopausal Women

Perimenopausal women have unique healthcare needs that are often underappreciated by managed care organizations (MCOs) and clinicians. During this 4- to 5-year transition, endocrine physiology becomes less stable, hormone profiles become highly variable and unpredictable, and cycle length shortens, while the potential for pregnancy remains.⁶⁻⁸ In Dr. Burkman's presentation on this topic (see page S575 in this supplement), it is noted that this is a time in which clinicians and their patients shift their focus from contraception and fertility to other healthcare issues, including cancer risk, dysmenorrhea, dysfunctional uterine bleeding, heart disease, and the prevention of other conditions, such as osteoporosis (Figure 1).

The risk for osteoporosis is of particular concern. Bone mineral density (BMD) peaks around 30 years of age, then declines about 1% each subsequent year. This decline accelerates during perimenopause and menopause, reaching 3% to 5% per year.⁹ At 30% demineralization, the patient is at risk for fractures of the hip, spine, and wrist.

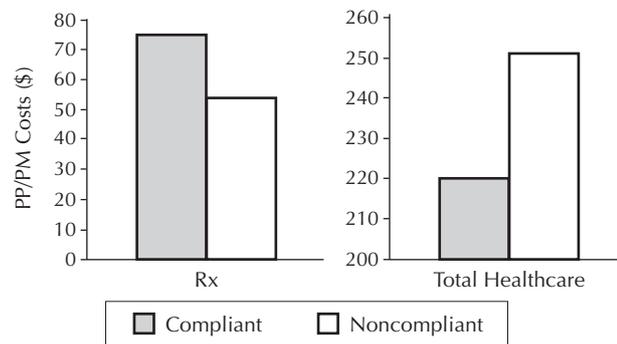
Dr. Heaton pointed out that the use of OCs in these perimenopausal patients is actually better than waiting until menopause and treating with HRT to prevent bone loss. The longer a woman is on OCs, the greater the preservation of BMD.¹⁰⁻¹³ In addition, the protective effect may be greater than that of HRT, at least for the femoral neck bone.¹⁴

HRT and Health and Economic Outcomes

In contrast to hormonal treatments in perimenopausal women, HRT for menopausal women has always been covered by managed care plans. "In terms of an ECHO assessment, the clinical and humanistic benefits of this treatment are well known," Dr. Heaton noted. "HRT reduces vasomotor symptoms, genitourinary symptoms, cardiovascular disease, hip and vertebral fractures, Alzheimer's disease, colorectal cancer, and breast cancer mortality."

Dr. Heaton and his colleagues have recently investigated the impact of compliance with HRT on health and economic outcomes. In a retrospective study utilizing a longitudinal medical event claims database of menopausal women receiving conjugated estrogen, they compared 900 noncompliant patients (defined as having had less than 100 days of therapy or treatment gaps of more than 90 days) with 1112 compliant patients (defined as being 100% compliant, with no treatment gaps).¹⁵ The patients were followed for 3 years, and their rates of depression and cardiovascular disease were recorded, along with the costs incurred in these 2 disease categories. Although the rates of depression in the 2 groups did not differ significantly, noncompliant patients had significantly more depression-related office visits. However, noncompliant and compliant patients did differ in terms of the incidence of heart disease. The noncompliant patients had a significantly higher rate of new myocardial infarctions and related office visits, as well as a significantly higher rate of congestive heart failure and follow-up visits.

Figure 2. Compliant Versus Noncompliant Patients: Prescription and Total Healthcare Costs



Source: Reference 15.

Not surprisingly, PP/PM costs for depression, myocardial infarction, and congestive heart failure were all greater in the noncompliant patients, and the costs were significantly greater in terms of infarctions. "As would be expected, PP/PM prescription costs were greater in the compliant patients (approximately \$75) than in the noncompliant group (approximately \$55)," Dr. Heaton said. "But total PP/PM healthcare costs were greater in the noncompliant patients (\$252) than in compliant patients (\$220). Thus, the \$20 extra spent in prescription drugs resulted in a \$32 difference in total PP/PM healthcare costs, or a difference of \$1230 per patient during the study period" (Figure 2). Thus, HRT compliance had a significant impact on both health and economic outcomes, resulting in lower rates of myocardial infarction and congestive heart failure with a correspondingly lower number of medical visits for heart disease as well as for depression, all of which translated into significantly lower healthcare costs per patient.

... REFERENCES ...

1. Henshaw SK. Unintended pregnancy in the United States. *Fam Plann Perspect* 1998;30:24-29, 46.
2. Heaton AH. Understanding the hormone continuum: From menarche to menopause. Optimizing outcomes through effective patient counseling and contemporary therapeutic strategies. Paper presented at: Meeting held in conjunction with Academy of

Managed Care Pharmacy's 13th Annual Meeting and Showcase; April 18, 2001; Tampa, FL.

3. Hatcher RA, Guillebaud J. The pill: Combined oral contraceptives. In: *Contraceptive Technology*. 17th rev ed. New York, NY: Ardent Media, Inc; 1998:405-466.

4. Franks AL, Beral V, Cates W Jr, Hogue CJR. Contraception and ectopic pregnancy risk. *Am J Obstet Gynecol* 1990;163:1120-1123.

5. Trussell J, Leveque JA, Koenig JD, et al. The economic value of contraception: A comparison of 15 methods. *Am J Public Health* 1995;85:494-503.

6. Klein NA, Soules MR. Endocrine changes of the perimenopause. *Clin Obstet Gynecol* 1998;41:912-920.

7. Treloar AE, Boynton RE, Behn BG, Brown BW. Variation of the human menstrual cycle through reproductive life. *Int J Fertil* 1967;12:77-126.

8. Münster K, Schmidt L, Helm P. Length and variation in the menstrual cycle—A cross-sectional study from a Danish county. *Br J Obstet Gynecol* 1992;99:422-429.

9. Consensus Development Conference: Diagnosis, prophylaxis, and treatment of osteoporosis. *Am J Med* 1993;94:646-650.

10. Lindsay R, Tohme J, Kanders B. The effect of oral

contraceptive use on vertebral bone mass in pre- and post-menopausal women. *Contraception* 1986;34:333-340.

11. Enzelberger H, Metka M, Heytmane G, Schurz B, Kurz C, Kusztrich M. Influence of oral contraceptive use on bone density in climacteric women. *Maturitas* 1988;9:375-378.

12. Kleerekoper M, Brienza RS, Schultz LR, Johnson CC. Oral contraceptive use may protect against low bone mass. *Arch Intern Med* 1991;151:1971-1976.

13. Kritz-Silverstein D, Barrett-Connor E. Bone mineral density in postmenopausal women as determined by prior oral contraceptive use. *Am J Public Health* 1993;83:100-102.

14. Taechakraichana N, Limpaphayom K, Ninlagarn T, Panyakhamlerd K, Chaikittisilpa S, Dustitin N. A randomized trial of oral contraceptive and hormone replacement therapy on bone mineral density and coronary heart disease risk factors in postmenopausal women. *Obstet Gynecol* 2000;95:87-94.

15. Heaton AH, Flinner A, Martin SL, et al. Effect of compliance on health and economic outcomes: Role of conjugated estrogen on depression and cardiovascular disorders. Paper presented at: International Society for Pharmacoeconomic and Outcomes Research; May 27, 1998; Philadelphia, PA.