

Consumerized Health Care Delivery Is Next Wave

BY JOEL B. FINKELSTEIN
Contributing Writer

WASHINGTON — The advent of health savings accounts and consumer-directed health plans has inspired entrepreneurs and academicians to design innovative delivery systems that cater to patient demand, experts said at a conference on technology and health care innovation.

“The next big change in health care will be patients managing their own care,”

said John Goodman, Ph.D., who is the president of the National Center for Policy Analysis.

“Last year, 95 million people got on the Internet to research their health problems. They didn’t always get the best information. They didn’t always get accurate information, but they were out there searching for answers,” he said.

Patients are already turning to online services for consultations, discounted drugs, simple blood tests, and even home

strep tests, said Dr. Goodman. Increasingly, patients will also demand market-based bundling and pricing of health care services.

“Most of the entrepreneurs out there in this market are people who have stepped outside the third-party payment system,” he said.

One of those entrepreneurs is Michael Howe, chief executive officer of MinuteClinic, which offers “retail health care” through more than 100 sites in 15 states.

Chain drug store giant CVS Corp. bought MinuteClinic earlier this year, and many of the health care centers are located in CVS/pharmacy stores.

The health care centers are staffed by nurse-practitioners and physician assistants trained to deal with a limited number of conditions, including routine infectious diseases, and to administer common vaccinations.

The clinics have done for health care what automatic teller machines did for banking, said Mr. Howe.

“You wouldn’t go to an ATM for a small business loan, and you wouldn’t go to a MinuteClinic to reset a femur,” he quipped.

For that reason, each location maintains a relationship with physicians’ practices where they can refer patients whose needs are beyond the scope of the clinic’s providers.

MinuteClinics are staffed by nurse-practitioners and physician assistants trained to deal with a limited number of conditions, including routine infections.

The company is also working to ensure that patients’ records can be transmitted to physicians’ offices, he said.

The clinics use technology such as electronic health records, best-practice protocols, and quality monitoring

to keep costs down, said Mr. Howe.

“On average, [our costs are] about 50% of what it cost at a primary care physician office, about 40% of urgent care, and significantly less than an emergency department,” he said. Patients also save time by coming to the walk-in clinics rather than waiting hours for medical attention somewhere else.

And private companies are not the only innovators making health care more consumer friendly.

At the Arizona Telemedicine Program’s UltraClinic, if a woman has a positive result on her mammogram, she can undergo a core biopsy, have a pathologist read the slides, and receive an oncology consult all within 4 hours of walking in the door rather than the 4 weeks it can take to go through this process, said the program’s Dr. Ronald Weinstein.

This approach saves a lot of suffering, he said. “Eighty percent of the problems I have to deal with, as the head of a large laboratory, is women waiting for their pathology results on their breast lesions.”

The program is only possible because of the availability of telemedicine technology allowing consultation between physicians at different hospitals and the development of an ultrarapid virtual slide scanner that allows a pathologist to assess the biopsy within minutes of the procedure.

“We were motivated because of the fact that consumer-driven health care is an emerging area, and that is essential to supporting these kinds of bundled services,” he said. ■

References: 1. Clobex® Lotion Prescribing Information. September 2004. Galderma Laboratories, L.P. 2. Jarratt M, Breneman D, Gottlieb AB, et al. Clobetasol propionate shampoo 0.05%: a new option to treat patients with moderate to severe scalp psoriasis. *J Drugs Dermatol.* 2004;3:367-373. 3. Data on file. Galderma Laboratories.

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CLOBEX® (clobetasol propionate) Shampoo, 0.05% Rx Only

BRIEF SUMMARY
For External Use Only.
Not for Ophthalmic Use

INDICATIONS AND USAGE:

CLOBEX® (clobetasol propionate) Shampoo, 0.05%, is a super-high potent topical corticosteroid formulation indicated for the treatment of moderate to severe forms of scalp psoriasis in subjects 18 years of age and older (see **PRECAUTIONS**). Treatment should be limited to 4 consecutive weeks because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis. The total dosage should not exceed 50 g (50 mL or 1.75 fl. oz.) per week.

Patients should be instructed to use CLOBEX® Shampoo, 0.05%, for the minimum time period necessary to achieve the desired results (see **PRECAUTIONS**).

Use in patients younger than 18 years of age is not recommended due to numerically high rates of HPA axis suppression (see **PRECAUTIONS, Pediatric Use**).

There were insufficient numbers of non-Caucasian patients to determine whether they responded differently than Caucasian patients with regards to efficacy and safety.

CONTRAINDICATIONS:

Use of CLOBEX® (clobetasol propionate) Shampoo, 0.05%, is contraindicated in patients who are hypersensitive to clobetasol propionate, to other corticosteroids, or to any ingredient in this preparation.

PRECAUTIONS:

General: Clobetasol propionate is a highly potent topical corticosteroid that has been shown to suppress the HPA axis at the lowest doses tested.

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing’s syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Conditions which increase systemic absorption include the application of the more potent corticosteroids, use over large surface areas, prolonged use, and the addition of occlusive dressings or use on occluded areas. Therefore, patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

The effect of CLOBEX® (clobetasol propionate) Shampoo, 0.05% on HPA axis suppression was evaluated in one study in adolescents 12 to 17 years of age. In this study, 5 of 12 evaluable subjects developed suppression of their HPA axis following 4 weeks of treatment with CLOBEX® (clobetasol propionate) Shampoo, 0.05% applied once daily for 15 minutes to a dry scalp before lathering and rinsing.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. (See **PRECAUTIONS - Pediatric Use**).

If irritation develops, CLOBEX® Shampoo should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noting a clinical exacerbation, as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, use of CLOBEX® Shampoo should be discontinued until the infection has been adequately controlled.

Although CLOBEX® Shampoo is intended for the topical treatment of moderate to severe scalp psoriasis, it should be noted that certain areas of the body, such as the face, groin, and axillae, are more prone to atrophic changes than other areas of the body following treatment with corticosteroids. CLOBEX® Shampoo should not be used on the face, groin or axillae. Avoid any contact of the drug product with the eyes and lips. In case of contact, rinse thoroughly with water all parts of the body that came in contact with the shampoo.

Information for patients: Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician and should not be used longer than the prescribed time period. It is for external use only. Avoid contact with the eyes.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. The scalp area should not be covered while the medication is on the scalp (e.g., shower cap, bathing cap) so as to be occlusive unless directed by the physician.
4. Patients should report any signs of local or systemic adverse reactions to their physician.
5. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, contact the physician.
6. Patients should wash their hands after applying the medication.
7. Patients should inform their physician(s) that they are using CLOBEX® Shampoo if surgery is contemplated.
8. Patients should not use more than 50 g (50 mL or 1.75 fl. oz.) per week of CLOBEX® Shampoo.

Laboratory tests: The cortrosyn stimulation test may be helpful in evaluating patients for HPA axis suppression.

Carcinogenesis, mutagenesis, and impairment of fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate.

Clobetasol propionate did not produce any increase in chromosomal aberrations in Chinese hamster ovary cells *in vitro* in the presence or absence of metabolic activation. Clobetasol propionate was also negative in the micronucleus test in mice after oral administration.

Studies of the effect of CLOBEX® Shampoo on fertility have not been conducted.

Pregnancy: Teratogenic Effects: Pregnancy Category C: Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application to laboratory animals.

A teratogenicity study of clobetasol propionate in rats using the dermal route resulted in dose related maternal toxicity and fetal effects from 0.05 to 0.5 mg/kg/day. These doses are approximately 0.1 to 1.0 times, respectively, the maximum human topical dose of clobetasol propionate from CLOBEX® Shampoo. Abnormalities seen included low fetal weights, umbilical herniation, cleft palate, reduced skeletal ossification other skeletal abnormalities.

Clobetasol propionate administered to rats subcutaneously at a dose of 0.1 mg/kg from day 17 of gestation to day 21 postpartum was associated with prolongation of gestation, decreased number of offspring, increased perinatal mortality of offspring, delayed eye opening and delayed hair appearance in surviving offspring. Some increase in offspring perinatal mortality was also observed at a dose of 0.05 mg/kg. Doses of 0.05 and 0.1 mg/kg are approximately 0.1 and 0.2 fold the maximum human topical dose of clobetasol propionate from CLOBEX® Shampoo.

There are no adequate and well-controlled studies of the teratogenic potential of clobetasol propionate in pregnant women. CLOBEX® Shampoo should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when CLOBEX® Shampoo, 0.05%, is administered to a nursing woman.

Pediatric use: Use of CLOBEX® Shampoo, 0.05%, in patients under 18 years old is not recommended due to potential for HPA axis suppression (See **PRECAUTIONS: General**).

The effect of CLOBEX® (clobetasol propionate) Shampoo, 0.05%, on HPA axis suppression was evaluated in one study in adolescents 12 to 17 years of age. In this study, 5 of 12 evaluable subjects developed suppression of their HPA axis following 4 weeks of treatment with CLOBEX® (clobetasol propionate) Shampoo, 0.05%, applied once daily for 15 minutes to a dry scalp before lathering and rinsing. Only one of the five subjects who had suppression was tested for recovery of HPA axis, and this subject recovered after 2 weeks.

No studies have been performed in patients under the age of 12. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing’s syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children.

Therefore, use is not recommended in patients under the age of 18.

HPA axis suppression, Cushing’s syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Geriatric use: Clinical studies of Clobetasol Propionate Shampoo, 0.05%, did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger patients. In general, dose selection for an elderly patient should be made with caution, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS:

In clinical trials with CLOBEX® Shampoo, the following adverse reactions have been reported: burning/stinging, pruritus, edema, folliculitis, acne, dry skin, irritant dermatitis, alopecia, urticaria, skin atrophy and telangiectasia.

The table below summarizes selected adverse events that occurred in at least 1% of subjects in the Phase 2 and 3 studies for scalp psoriasis.

Summary of Selected Adverse Events ≥ 1% by Body System

Body System	Clobetasol Propionate Shampoo N=558	Vehicle Shampoo N=127
Skin and Appendages	49 (8.8%)	28 (22.0%)
Discomfort Skin	26 (4.7%)	16 (12.6%)
Pruritus	3 (0.5%)	9 (7.1%)
Body As A Whole	33 (5.9%)	12 (9.4%)
Headache	10 (1.8%)	1 (0.8%)

The following additional local adverse reactions have been reported infrequently with other topical corticosteroids, and they may occur more frequently with the use of occlusive dressings, especially with higher potency corticosteroids. These reactions are listed in an approximately decreasing order of occurrence: hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, and miliaria.

Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing’s syndrome, hyperglycemia, and glucosuria in some patients.

OVERDOSAGE:

Topically applied, CLOBEX® Shampoo can be absorbed in sufficient amounts to produce systemic effects (See **PRECAUTIONS**).

US Patent Pending

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325068-0805

Revised: August 2005