

# Local Health Information Networks Share Data

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Contributing Writer

SAN DIEGO — A few pioneering health care organizations have set up local information networks to share electronic health data, and there are interesting lessons to be learned from these examples, according to Gordon J. Apple, a health lawyer based in St. Paul, Minn., who spoke at the annual meeting of the American Health Lawyers Association.

He compared the Santa Barbara Care Data Exchange with the Indianapolis Network for Patient Care, two projects that have similar goals but are using very different technologies and organizational structures.

The Santa Barbara project developed as a public/private collaboration, and today is organized as a nonprofit with a "community stakeholder" board of directors, including physicians, chief financial officers, chief operating officers, a chief in-

formation officer, and a consumer and business advocate.

It uses peer-to-peer Internet technology, the same method college students use to share music files. "This is a pointer system," Mr. Apple said. It can identify where data are stored within the system, and "it provides the physician with a patient-centered view of both clinical and administrative results. However, it is not an electronic medical record."

Efforts like these are expensive, and the

Santa Barbara project has run into problems. Insufficient grassroots support has been an issue, Mr. Apple said. The data exchange received a \$10 million grant from the California HealthCare Foundation and \$400,000 from the federal government. Although it started development work in 1999, it is expected to be up and running this summer.

The Indianapolis Network for Patient Care has been functioning for more than 7 years. "Five hospital systems that at one time were probably fierce competitors are now cooperating," Mr. Apple said.

Indianapolis started with a small project, one everyone could agree was really needed. At first, when a patient came into the emergency department, physicians could access limited data from participating hospitals. This effort was originally funded through a National Library of Medicine grant, but when the grant expired, the participants chose to continue the project.

Today, the much-expanded Indianapolis network can be used for any treatment purpose. With the patient's permission, physicians can access a complete medical history, including all previous care.

Indianapolis uses a data warehouse system. Each institution stores its data in a separate database, but all the databases use the same structure and the same coding processes. The system can pull out and combine information as needed.

The Regenstrief Institute, a nonprofit affiliated with Indiana University, Indianapolis, manages the network. Indianapolis didn't set up a separate entity to deal with these issues; instead, the network is governed by a contractual agreement signed by all users. "Regenstrief acts as the hub of the wheel," Mr. Apple said.

Before it went into effect, this draft agreement was reviewed and approved by clinicians, compliance officers, lawyers, risk managers, and information system personnel in a cooperative, consensus-building process. "That's the most important point," Mr. Apple said. "This wasn't something where the information technology folks said, 'let's put this out and make the doctors use it.' They actually spoke with the physicians and looked at all the issues before rolling this out."

He pointed out a second key difference: The Santa Barbara network allows doctors to pull up computer files so they can access each other's information, but the information is unstructured. Physicians are, in effect, accessing copies of paper files. In Indianapolis, the data are entered in a structured format, so it's possible to search for and compare key data items. Test results are tagged so that other computers in the network can recognize them.

Neither network offers a truly interoperable electronic health record, and Mr. Gordon told this newspaper that it will be years before we get one: "When you get all the different players in a community together, you see just how difficult it can be to reach agreement. Do we want to drive a Porsche or a VW?" Some hospitals and health systems will seek more robust technology, storing larger amounts of data with higher levels of security. Others will say they can't afford that level of sophistication. ■

## Luxiq® (betamethasone valerate) Foam, 0.12%

BRIEF SUMMARY For Dermatologic Use Only Not for Ophthalmic Use

**INDICATIONS AND USAGE** Luxiq is a medium potency topical corticosteroid indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp. **CONTRAINDICATIONS** Luxiq is contraindicated in patients who are hypersensitive to betamethasone valerate, to other corticosteroids, or to any ingredient in this preparation. **PRECAUTIONS General:** Systemic absorption of topical corticosteroids has caused 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 augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. 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 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. 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, Luxiq 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 Luxiq should be discontinued until the infection has been adequately controlled. **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. 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 treated scalp area should not be bandaged or otherwise covered or wrapped so as to be occlusive unless directed by the physician. 4. Patients should report to their physician any signs of local adverse reactions. 5. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, contact the physician. **Laboratory Tests:** The following tests may be helpful in evaluating patients for HPA axis suppression: ACTH stimulation test; A.M. plasma cortisol test; Urinary free cortisol test. **Carcinogenesis, Mutagenesis, and Impairment of Fertility:** Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of betamethasone valerate. Betamethasone was genotoxic in the *in vitro* human peripheral blood lymphocyte chromosome aberration assay with metabolic activation and in the *in vivo* mouse bone marrow micronucleus assay. **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 in laboratory animals. There are no adequate and well-controlled studies in pregnant women. Therefore, Luxiq should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time. **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 breast milk. Because many drugs are excreted in human milk, caution should be exercised when Luxiq is administered to a nursing woman. **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established. 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. Hypothalamic-pituitary-adrenal (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. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children. **ADVERSE REACTIONS** The most frequent adverse event was burning/itching/stinging at the application site; the incidence and severity of this event were as follows:

Product	Total incidence	Incidence and severity of burning/itching/stinging		
		Mild	Moderate	Severe
Luxiq Foam n=63	34 (54%)	28 (44%)	5 (8%)	1 (2%)
Betamethasone valerate lotion n=63	33 (52%)	26 (41%)	6 (10%)	1 (2%)
Placebo Foam n=32	24 (75%)	13 (41%)	7 (22%)	4 (12%)
Placebo Lotion n=30	20 (67%)	12 (40%)	5 (17%)	3 (10%)

Other adverse events which were considered to be possibly, probably, or definitely related to Luxiq occurred in 1 patient each; these were paresthesia, pruritus, acne, alopecia, and conjunctivitis. The following additional local adverse reactions have been reported with topical corticosteroids, and they may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximately decreasing order of occurrence: irritation; dryness; folliculitis; acneiform eruptions; hypopigmentation; perioral dermatitis; allergic contact dermatitis; secondary infection; skin atrophy; striae; and miliaria. Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. **OVERDOSAGE** Topically applied Luxiq can be absorbed in sufficient amounts to produce systemic effects. (See **PRECAUTIONS**) **DOSAGE AND ADMINISTRATION** Note: For proper dispensing of foam, can must be inverted. For application to the scalp invert can and dispense a small amount of Luxiq onto a saucer or other cool surface. Do not dispense directly onto hands as foam will begin to melt immediately upon contact with warm skin. Pick up small amounts of foam with fingers and gently massage into affected area until foam disappears. Repeat until entire affected scalp area is treated. Apply twice daily, once in the morning and once at night. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary. Luxiq should not be used with occlusive dressings unless directed by a physician. **HOW SUPPLIED** Luxiq is supplied in 150 gram (NDC 63032-021-01), 100 gram (NDC 63032-021-00) and 50 gram (NDC 63032-021-50) aluminum cans. Store at controlled room temperature 68-77°F (20-25°C). **WARNING FLAMMABLE. AVOID FIRE, FLAME OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION.** Keep out of reach of children. Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

Manufactured for: Connetics Corporation, Palo Alto, CA 94303 USA  
For additional information: 1-877-821-5337 or visit www.luxiq.com  
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R<sub>x</sub>only

## OLUX® Foam, 0.05%

BRIEF SUMMARY For Dermatologic Use Only Not for Ophthalmic Use

**INDICATIONS AND USAGE** OLUX Foam is a super-potent topical corticosteroid indicated for short-term topical treatment of the inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses of the scalp, and for short-term topical treatment of mild to moderate plaque-type psoriasis of non-scalp regions excluding the face and intertriginous areas. Treatment beyond 2 consecutive weeks is not recommended and the total dosage should not exceed 50 g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis. In a controlled pharmacokinetic study, some subjects experienced reversible suppression of the adrenals following 14 days of OLUX Foam therapy (See **ADVERSE REACTIONS**). Use in children under 12 years of age is not recommended. **CONTRAINDICATIONS** OLUX Foam 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 super-potent topical corticosteroid that has been shown to suppress the adrenals at 7.0 g of OLUX Foam per day. Lesser amounts of OLUX Foam were not studied. Systemic absorption of topical corticosteroids has caused reversible adrenal 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 augment systemic absorption include the application of more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of adrenal suppression. If adrenal 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 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. 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, OLUX Foam should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than by 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 OLUX Foam should be discontinued until the infection has been adequately controlled. **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 treated area should not be bandaged or otherwise covered or wrapped so as to be occlusive unless directed by the physician. 4. Patients should report to their physician any signs of local adverse reactions. **Laboratory Tests:** The following tests may be helpful in evaluating patients for adrenal suppression: ACTH stimulation test; A.M. plasma cortisol test; urinary free cortisol test. **Carcinogenesis, Mutagenesis, and Impairment of Fertility:** Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate. Clobetasol propionate was non-mutagenic in three different test systems: the Ames test, the *Saccharomyces cerevisiae* gene conversion assay, and the *E. coli* B WPM2 fluctuation test. Studies in the rat following subcutaneous administration of clobetasol propionate at dosage levels up to 0.05 mg/kg per day revealed that the females exhibited an increase in the number of resorbed embryos and a decrease in the number of living fetuses at the highest dose. **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. Clobetasol propionate has not been tested for teratogenicity by the topical route; however, it is absorbed percutaneously, and when administered subcutaneously, it was a significant teratogen in both the rabbit and the mouse. Clobetasol propionate has greater teratogenic potential than steroids that are less potent. Teratogenicity studies in mice using the subcutaneous route resulted in fetotoxicity at the highest dose tested (1 mg/kg) and teratogenicity at all dose levels tested down to 0.03 mg/kg. These doses are approximately 1.4 and 0.04 times, respectively, the human topical dose of OLUX based on body surface area comparisons. Abnormalities seen included cleft palate and skeletal abnormalities. In rabbits, clobetasol propionate was teratogenic at doses of 0.003 and 0.01 mg/kg. These doses are approximately 0.02 and 0.05 times, respectively, the human topical dose of OLUX based on body surface area comparisons. Abnormalities seen included cleft palate, cranioschisis, and other skeletal abnormalities. There are no adequate and well-controlled studies of the teratogenic potential of clobetasol propionate in pregnant women. OLUX Foam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time. 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 breast milk. Because many drugs are excreted in human milk, caution should be exercised when OLUX Foam is administered to a nursing woman. **Pediatric Use:** Safety and effectiveness of OLUX Foam in pediatric patients have not been established; therefore, use in children under 12 years of age is not recommended. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of adrenal suppression and Cushing's syndrome when they are treated with topical corticosteroids. Pediatric patients are therefore 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. Adrenal 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. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children. **ADVERSE REACTIONS** The most frequent adverse event was burning/itching/stinging at the application site; the incidence and severity of this event were as follows:

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