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Summary Points

- Patients with eczema often report improvement with Chinese herbal creams
- There may be no indication on the label about the contents of the cream
- Eight of the 11 creams analyzed contained dexamethasone at concentrations inappropriate for use on the face or in children
- Inadvertent use of topical steroids can cause severe exacerbation of eczema herpeticum
- Closer regulation of herbal medicines is required

COMMENTARY
Adulterants in herbal products: dangerous and deceitful

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The herbal product industry in the United States is booming. Annual retail sales are approaching $4 billion and growing about 18% per year.[1] Botanicals are appearing not only in a multitude of over-the-counter pills and extracts, but also in a variety of food products including teas, soft drinks, soups, and even potato chips. Up to a third of American adults are now routinely using herbs to enhance health or alleviate illness.[1]

Because herbal products come from plants, they are often viewed as "natural" and free from serious side effects. Unfortunately, herbs are not inherently safe. Recent reports have highlighted severe reactions both to specific herbs, and to contaminants in the preparations.[2,3] Reactions range from mild side effects such as transient hepatitis or dermatitis, to severe fatal illnesses including anaphylactic shock and liver failure.[2] A recent study of 260 traditional Chinese medicine products sold in California retail herb stores found that 32% contained undeclared pharmaceuticals or heavy metals.[4] Contaminants found in herbal preparations include lead, mercury, arsenic, diazepam, thiazide diuretics, ephedrine, and caffeine. The true incidence of side effects to herbal products is not known because the systems for reporting adverse reactions are limited.

How can the consumer be sure that an herbal product is both safe and effective? In the United States, most herbs are sold as dietary supplements, and are therefore regulated by the Dietary Supplement Health and Education Act (DSHEA) of 1994. Under this legislation, herbs and other dietary supplements (including vitamins, minerals, plant-derived substances, and amino acids) may be sold and marketed without approval by the Food and Drug Administration (FDA).[5] The DSHEA specifies that the manufacturer is responsible for ensuring the safety of the herbal product. However, there is no standard describing the specific tests required to document safety, and therefore manufacturers may vary widely in the amount of testing performed. This system is in sharp contrast to that in place for standard drugs, where the manufacturer must submit adequate evidence of safety and efficacy to the FDA before the product may be sold.

The labeling of herbal products sold as supplements is even more confusing. Supplement labels may not make statements that imply that the product helps to diagnose, treat, cure, or prevent a disease. Supplements may, however, make certain "structure-function" claims. For example, a product may claim to "maintain bowel regularity" or "support immune function," but it cannot claim to "relieve constipation" or "treat the common cold." If supplements were used for these specific purposes, they would be considered drugs, and would be subject to a much more stringent regulatory process.

In this issue of *WJM,* Keane et al report a disturbing finding about the contents of a sample of Chinese herbal creams that highlights some of the problems with the regulation of the herbal products.[6]

Intentionally adding active ingredients to herbal preparations without the knowledge of patients is illegal, dangerous, and deceitful. In the United States, any agent that is used to treat a specific condition (such as eczema) is considered a drug, and must undergo approval by the FDA prior to marketing and distribution. In this study, the dose of steroids used would have required a prescription, which is yet another level of wrongdoing. Clearly this dose of steroid can be dangerous for patients, especially if used on the face or in children, as was the case in this report. And perhaps most worrisome, the practice of treating patients without telling them the active ingredients of the treatment and the associated risks and benefits is deceitful.

Chinese herbal treatments (without steroids) may indeed be effective for the treatment of eczema, as suggested

by earlier reports.[7,8] Although these studies are preliminary and not conclusive, they deserve further investigation. In general, the use of herbs in traditional Chinese medicine involves an examination by a Chinese doctor, an assessment of the patient's disorder, and the prescription of an individualized herbal treatment. While this practice is foreign to our westernized vision of medicine, it may have unique merits, and there is evidence to suggest that certain Chinese herbal remedies are effective.[7-9] Given the high prevalence of use and the potential benefit of these therapies, we must investigate their effectiveness with an open mind and with a rigorous scientific method. We must also support government efforts to locate practitioners that are exposing patients to illegal and dangerous treatments, thereby tarnishing the name of traditional Chinese medicine.

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Historical cohort study of in utero exposure to uterotonic drugs and cognitive function in young adult life

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ABSTRACT ● **Objective** To examine whether in utero exposure to uterotonic drugs effects cognitive performance in draft-age men. ● **Design** Historical cohort study based on birth registry data and cognitive function measured during evaluations for military service. ● **Subjects** 4300 Danish conscripts born between 1973 and 1975. ● **Main outcome measures** Mean score in the Boerge Prien test of cognitive function: score is the number of correct answers to 78 questions and correlates with the full scale intelligence quotient. ● **Results** The mean Boerge Prien score was similar for those exposed (n=1011) to uterotonic drugs and those not exposed (n=3289), 43.1 versus 42.9 after adjustment for confounders. ● **Conclusion** Our data indicate that exposure to uterotonic drugs does not affect cognitive function 20 years later.

Oxytocin has potent uterotonic properties that can induce tetany, rupture, and water intoxication. Inappropriately high doses can affect the fetus by inducing abnormal heart rhythms, circulatory collapse, and preterm delivery accompanied by an increased risk of respiratory distress and damage to the central nervous system.[1] Several studies have reported an association between oxytocic drugs and neonatal hyperbilirubinemia,[2] which might influence long-term cognitive function.[3] Little is known, however, of the long term consequences of exposure to uterotonic drugs. We investigated whether in utero exposure to uterotonic drugs affects cognitive performance in men of draft age.

Subjects, methods, and results

Nearly all Danish men have to register with the draft board at around 18 years of age, at which time they undergo physical and mental examinations. We studied all men who were born in Denmark after January 1, 1973 and who were drafted while residing in North Jutland and Viborg counties from August 1, 1993 to July 31, 1994.

All draftees took a 45-minute intelligence test, the Boerge Prien test, developed in 1957 for the Danish draft board.[4] The test includes four time-limited subtests covering four categories: letter matrices, verbal analogies, number series, and geometric figures. The test shows high correlations with the Weschler Adult Intelligence Scale verbal intelligence quotient (0.78), the performance intelligence quotient (0.71), and the full scale intelligence quotient (0.82). In the validation study the mean full scale intelligence quotient was 106, equivalent to a mean Boerge Prien test score of 44.2.[4]

We linked data from the draft examination with data from the Danish medical birth registry using a 10-digit unique personal identification number. The registry contains information on all births in Denmark since 1973. Oxytocin was the most commonly used uterotonic drug in