

# Patients Can Control Medical Records

Americans can take control of their personal health records with iHealthRecord, a service created by a coalition of national health care industry leaders.

The system is an interactive personal health care record system that electronically connects patients with their physicians. iHealthRecord houses critical personal health data for physicians or emergency departments to access information on medical conditions, medications, past surgeries and allergies. This program can be used to increase medication adherence, enhance continuity of care and improve patient-physician communication.

Patients also benefit from the program, which makes programs specific to their medical conditions available, and also sends them automated reminders regarding medications and conditions. Patients can control who views their

records. The system also provides a history of each use.

iHealthRecord and its patient education programs are developed in conjunction with the American Heart Association, the American Cancer Society, the Food and Drug Administration (FDA) and other national experts. The program is an effort led by the physician-patient communication network Medem, which includes the American Medical Association.

The iHealthRecord allows health information to be updated by patients, electronic medical records systems or by health plans. The interoperability helps to facilitate information exchange between health care providers, a key focus of the national health care infrastructure and regional health information organizations.

For more information, visit [www.ihealthrecord.org](http://www.ihealthrecord.org).

## National Recall, Correction Issued by Two Companies

Qualitest Pharmaceuticals, Inc (Huntsville, Ala) and LifeScan Inc (Milpitas, Calif) announced deficiencies in their products. Qualitest issued a voluntary nationwide recall of AccuSure Insulin Syringes 1 cc, 28 ga 0.5 inch that may have been mislabeled. LifeScan, Inc initiated a worldwide notification to patients using OneTouch, Ultra InDuo and OneTouch FastTake meters as their blood glucose testing systems.

1-cc syringes distributed between October 2004 and June 2005 may be labeled as 0.5-cc syringes on the plastic inner wrap holding 10 individual syringes, according to a news release. This could potentially result in confusion by the patient or caregiver and allow an incorrect dose or administration amount. No injuries have been reported to date.

The products were distributed to drug wholesalers/distributors and pharmacies within the United States. Qualitest is notifying all customers who received the product to arrange for return of the product. This recall is being conducted with the full knowledge of the FDA.

LifeScan's notification occurred because its machines were reported to be misinterpreting results, and therefore shipment of these systems has been temporarily stopped.

Because the machines display two different units of measurement, it is possible for patients to accidentally change the measurement to misinterpret their blood glucose results. Other malfunctions may occur if the machine is dropped while in use. Such an event may change the unit of measurement and/or change the coding number.

Users should continue to test their blood glucose, howev-

er, and LifeScan Inc is suggesting that patients confirm their meter's unit of measure and the code number each time they test. Patients are urged to contact LifeScan, Inc to confirm their meter is set to the proper unit of measurement. They can call 800-515-0915 to speak to a customer service representative. For more information on Qualitest, call 800-444-4011.

## Long-Acting Insulin Approved

The FDA has approved Novo Nordisk Inc's (Princeton, NJ) Levemir (insulin detemir [rDNA origin] injection) for the treatment of type 1 and 2 diabetes. Levemir is a novel, long-acting form of insulin that provides up to 24 hours of action and has been shown to cause little weight change.

"Experts agree there is a significant need for consistent good control of patient glucose levels, which is associated with a reduced risk of diabetes complications," said Peter Atrup, MD, vice president of the clinical development, medical, and regulatory affairs department, in a news release. "The results seen to date with Levemir affirm the value that the product will provide to patients who struggle to manage their diabetes."

Additionally, a New Drug Application for Levemir for pediatric indication is currently under review by the FDA. The safety and efficacy of Levemir given once or twice daily was compared to NPH human insulin or insulin glargine in controlled clinical studies involving 3,724 type 1 and 2,280 type 2 diabetic patients. In a treat-to-target efficacy study of 475 patients using Levemir or NPH insulins, 70% of those treated with Levemir achieved an HbA1c of approximately 6.6%. There was no significant difference between the two treat-

ment arms. In other studies, Levemir achieved a level of glycemic control similar to that provided by other basal insulins, as measured by HbA1c.

Levemir is indicated for once- or twice-daily subcutaneous injection, depending on blood glucose control and insulin requirements. Levemir provides a relatively flat action profile. Levemir can be used in monotherapy, added to oral antidiabetic agents, or used with a rapid-acting insulin.

Hypoglycemia is the most common adverse effect of insulin therapy, including Levemir. Adverse events commonly associated with human insulin therapy include allergic reactions, injection site reaction, lipodystrophy, pruritus and rash. Levemir is contraindicated in patients hypersensitive to insulin detemir or its excipients.

Full prescribing information for Levemir is available at [www.novonordisk-us.com](http://www.novonordisk-us.com).

## Microcyn Cleanses, Debrides Acute and Chronic Wounds

Oculus Innovative Sciences (Petaluma, Calif) has received 510(k) clearance from the FDA to market Dermacyn Wound Care, formulated with Microcyn Technology, as a medical device for cleaning and debriding of acute and traumatic wounds and burns.

Microcyn Technology is a super-oxidized, pH-neutral solution that is ready for use with no dilution or mixing and requires no special handling or disposal, according to the company. It is manufactured using a multichamber electrolysis process that produces and isolates ionic species. This process allows for the production of a pH-neutral solution while minimizing the level of chlorine in the final product.

Dermacyn Wound Care, the first Microcyn Technology product for human use in the United States, is available. For more information, visit [www.oculusis.com/us/is/microcyn.html](http://www.oculusis.com/us/is/microcyn.html).

## Merrem IV Receives Approval for Skin Infections

The FDA has approved the antibiotic Merrem IV (meropenem for injection, AstraZeneca, Wilmington, Del) to treat adults and children with complicated skin and skin structure infections (cSSSI).

The approval is based on results from a study that examined hospitalized patients with cSSSI. A 500-mg dose every 8 hours was well tolerated and effective in patients including the elderly and patients with diabetes who have cSSSI, according to the company. This international, phase 3, randomized, double-blind, multicenter clinical trial of 1,037 patients with cSSSI compared the efficacy, safety and tolera-

bility of Merrem and imipenem-cilastatin. The primary efficacy endpoint was clinical outcome at follow-up in the clinically evaluable (CE) and modified intent-to-treat populations.

The success rates in the CE patients at the follow-up visit were 86% in the Merrem arm and 83% in imipenem-cilastatin arm (95% CI, -2.8, 9.3). They were 73% (Merrem) and 75% (imipenem-cilastatin; 95% CI, -8.4, 4.7) in the MITT population. Among those with diabetes, 86% of patients treated with Merrem had a satisfactory clinical response at follow-up compared with 72% of patients treated with imipenem-cilastatin. For more information, visit [www.astrazeneca-us.com](http://www.astrazeneca-us.com).

## FDA Approves Zemplar for Earlier Treatment of CKD

The FDA has approved Zemplar Capsules (paricalcitol, Abbott, Abbot Park, Ill), an oral, activated vitamin D therapy for the prevention and treatment of secondary hyperparathyroidism (SHPT). It is indicated for the prevention and treatment of SHPT in stages three and four chronic kidney disease (CKD), before dialysis or transplantation, according to the company.

SHPT is a major complication associated with CKD that if left untreated may impact bones and vital organs including the heart, muscles and nerves, according to a news release. It can occur when kidneys lose their ability to activate vitamin D obtained through diet and other sources. About 20 million people in the United States have CKD. Another 20 million are at risk for developing CKD from underlying causes such as diabetes and hypertension.

Results from three phase 3 clinical trials showed that the capsules are safe and effective in reducing parathyroid hormone levels in stage three and four kidney disease. After 24 weeks, 91% of patients treated with Zemplar Capsules had significant and sustained reduction in PTH levels compared to 13% of placebo patients. Significant reduction in PTH was defined as achievement of at least two consecutive,  $\geq 30\%$  reductions in PTH. Additionally, patients had a  $>30\%$  mean reduction in PTH by week 9, with a sustained reduction in PTH noted throughout the remainder of the study.

Data were further analyzed to evaluate consistency with the National Kidney Foundation in the Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines for calcium and phosphorus targets. Calcium, phosphorus and calcium and phosphorus product (Ca X P) values were maintained within the K/DOQI targets for calcium (91% paricalcitol vs 95% placebo), phosphorus (70% paricalcitol vs 75% placebo) and calcium and phosphorus combined (94% paricalcitol vs 96% placebo). Maintaining appropriate levels of calcium and phosphorus is critical for the effective management of SHPT. For more information, visit [www.zemplar.com](http://www.zemplar.com). ■