

Let Us Set an Example

For several years, the Lions-International Diabetes Institute at the Royal Southern Memorial Hospital, Melbourne, Australia, has been collecting unused and unneeded vials of insulin from its clients and forwarding them to countries with an insulin shortage. This insulin is forwarded through N. Decker, a pharmacist from Melbourne, who has been active in the International Diabetes Federation for many years, to Dr. F. Lester in Ethiopia.

One of the major points I want to share is that our diabetic clients have been very responsive to delivering insulin to our clinic for this project. Over the past ~3 yr a subgroup of our clients have delivered >1000 vials to us. They have not needed this insulin because they have either changed types or are non-insulin-dependent diabetes mellitus (NIDDM) patients who no longer require insulin. We were very impressed with their response, and the program was very easy to organize. All that was needed was a circular to our clients, a reminder every few months in our patient newsletter, and a box placed in a visible location in our patient waiting area.

The market value of this insulin is ~\$7000–\$10,000, and in a world very wasteful of scarce resources, here is a marvellous opportunity not to waste a life-saving medicine. Most important, all this can be done at little cost to the institution facilitating the transfer of the insulin. Any costs might be met by donations from, for example, service clubs. I would like to encourage all specialist diabetic clinics to adopt this plan. Some people will worry about the expiration dates on the insulin; a search of the literature seems to indicate there is a very gradual decline in potency of insulin over time. Of course, temperature variation is an important consideration as well. However, as long as the shipment is delivered and collected by people with appropriate knowledge of diabetes, this should not be a problem. It may be easiest and safest to airfreight the insulin, and airlines may be convinced to donate this service if suitably approached. Involvement of key people without appropriate knowledge of diabetes or insulin storage and characteristics may result in problems. It is important to send the insulin in the most direct way with as few intermediaries as possible.

We have been very encouraged by the letters from Ethiopia telling us how the collected unused insulin has been used to prolong lives, not only of children but also of adult working people whose income supports themselves and their families. We have recently started collecting other unused supplies, e.g., syringes and blood and urine reagent strips. Diabetes is a growing worldwide problem, and a plan like this would be a practical demonstration of the ability of the diabetes community to overcome national barriers to help diabetic people in need.

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CSII in Management of Insulin Allergy

Many insulin-dependent diabetic patients develop antibodies to insulin after weeks or months from beginning therapy (1). This immune response may represent a potential complication, specifically insulin allergy and/or insulin resistance (1). The incidence of allergic reactions to insulin is 5–10%, but systemic reactions only occur in 1–2% of these patients (2). Insulin-allergic clinical manifestations range from erythema, pruritus and edema in injection sites to generalized urticaria, angioedema, and systemic anaphylaxis (1). Various therapeutic schemes have been proposed for the management of insulin allergy, e.g., dexamethasone-insulin mixture (3) or desensitization with insulin-decreasing dilution injections (4). We report a case of generalized skin reaction to bovine, porcine, and human insulin resolved by continuous subcutaneous human insulin infusion (CSII).

We report on a 34-yr-old, nonatopic woman who was diagnosed as being diabetic in 1976. Three years after beginning insulin therapy with beef-pork insulin, she developed urticaria that was first localized to the neck and then extended to her limbs and trunk. Laboratory findings excluded the usual etiologies of generalized urticaria and/or pruritus (i.e., infections, malignancy, and connective tissue and hepatic diseases). Paper radioimmunosorbent test (PRIST) and radioallergosorbent test (RAST) revealed an increment in total IgE level (310 kU/L, normal value <120 kU/L), absence of IgE against the most common alimentary antigens and presence of specific IgE antibodies against bovine (8.1%) and porcine (4.3%) insulin. Antihistaminic treatment and desensitization was attempted with high-purified porcine and human insulin (Actrapid MC and Actrapid HM, Novo) without improvement. Therefore, CSII (Actrapid HM 0.5 U/kg/day) was started. With this therapeutic regimen we obtained better metabolic control (mean HbA_{1c} 5.8%), the rapid improvement of subjective symptomatology, and the gradual disappearance of allergic reactions over 2 mo.

Local allergic reactions in injection sites recurred 1 yr later, when the patient again underwent conventional insulin therapy. PRIST and RAST were performed and showed unchanged total serum IgE levels (280 kU/L) with presence of specific IgE against porcine (4%), bovine (4%), and human (4%) insulins. The patient was again treated with CSII, and we observed a rapid disappearance of allergic reactions.

Various therapeutic schemes have been proposed for the management of insulin allergy that are successful in ~90% of patients (3,4). In our patient we obtained the progressive disappearance of allergic reactions by CSII. Although the effectiveness of CSII in insulin-allergy treatment has not been described by other authors, we

based this therapeutic attempt on the supposition that the infusion of insulin microdoses at a continuous basal rate could represent an effective desensitization method. This supposition was inaccurate because the patient's immunological profile was unchanged after 1 yr on CSII.

We think that CSII is able to maintain the mast cells in chronically degranulated insulin-infusion areas and so to block the immunologic reaction liable for allergic manifestations even when greater amounts of insulin (premeal boluses) are delivered. In conclusion, CSII could be useful in the management of insulin allergy when usual therapeutic schemes are unsuccessful.

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New Devices for Patients With Diabetes Mellitus: A Reply

In reference to the letter from R. Ehrlich (1). I categorically deny any financial interest in the company marketing the hand-held computer used in our study (2). Furthermore, the study was carried out in our facility without any research funding from the company producing the device. I stand by our results, which were performed in a respected academic institution and were peer reviewed. I absolutely reject Dr. Ehrlich's slanderous insinuation that the results cannot be trusted.

I am amazed that the editors of *Diabetes Care* should allow unfounded accusations of financial interest and defamation of the scientific reputation of investigators to be published in this serious journal. I wish this re-

buttal to be offered the same prominence that Dr. Ehrlich's letter received.

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DR. EHRLICH REPLIES

The article referred to in my original letter was coauthored by Dr. Schiffrin and three other people. At the end of the article there was an acknowledgment that "one of the authors serves as a member of B.C.M.C.—Better Control Medical Computers, Inc." There was no indication of the identity of this person; it merely stated that one of the authors was associated with a corporation that is involved in the research, development, and marketing of a product used in the research in that paper.

My point, to which I am firmly committed, is that independent evaluation of newly developed medical devices is an essential part of the development of such devices. In my opinion, when a particular device is recommended in a research article coauthored by a member of the company marketing the device, then such research has to be viewed cautiously. These findings must receive independent assessment before the device can be recommended by the medical profession. This does not mean that the research data or conclusions that have been reached in the article are incorrect or were influenced by the presence on the research team of a member of the company involved in the commercial development of the device.

At no time did I intend to cast doubt on Dr. Schiffrin's reputation or integrity. I have reread my letter appearing in *Diabetes Care*, and I do not believe that there was any defamatory statement.

I did not state or infer that Dr. Schiffrin personally has an interest in the marketing of the product reviewed in the article. The name of the research team member associated with such marketing was not revealed in the article. In my opinion, it would have been preferable to have named that individual.

My remarks were intended to be global, concerning the nature of research, the methodology of verification, and the professional acceptance of new technology in the field. My views in this matter remain the same. If Dr. Schiffrin has felt personal embarrassment or concern as a result of any inadvertent comment in my letter, I