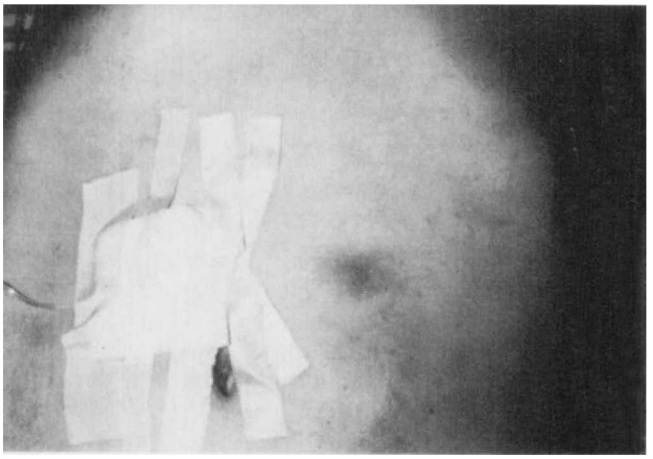

FIG. 1. A recent nodule seen above and to the right (patient's left) of the umbilicus. Two resolving nodules are below it.

pared by dilution of Squibb Regular mixed beef-pork U-100 insulin (E. R. Squibb & Sons, Princeton, New Jersey) with 0.9% saline. After about 2 mo of therapy, he began to get firm, indurated, painful, red nodules at the site of the indwelling needle (Figure 1), which came after about 24 h of infusion at a single site, and lasted several days after the needle was moved to another site. The pain necessitated moving the needle about once every 24 h. Several nodules were present at once, making it difficult to find suitable abdominal injection sites. The patient was afebrile; there were no signs of cellulitis, and erythromycin, prescribed by his general pediatrician, had no effect.

His insulin preparation was changed to Iletin I U-40 insulin (Eli Lilly and Company, Indianapolis, Indiana), which he then used without further dilution. The nodules resolved, and no new ones have occurred. The diluted insulin he had been using appeared slightly cloudy; when cultured, it grew a moderate number of Klebsiella oxytoca.

The specific cause of the nodules is not firmly established. Possible causes are the saline dilution and the bacterial contamination. The latter is of interest because of the recent report by Schade and Eaton documenting the bactericidal property of U.S.P. insulin.[2] Evidently, this property is lost on saline dilution. The brand of insulin was also changed, and this may have been a factor in the clinical improvement.

Because the patient was a child who had greatly suffered from the skin nodules, we did not rechallenge him to determine the specific cause of the untoward reaction. This case does, however, present an argument for avoiding use of diluted insulins in insulin pumps.

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Cold Weather and CSII

The unusually cold weather experienced by most of the nation during the winter of 1982 has produced a system failure of continuous subcutaneous insulin infusion (CSII) therapy that has not been described previously. A 19-yr-old man with insulin-dependent diabetes mellitus, who was working part-time as a ski-lift operator and had been using CSII for 3 mo, began reporting frequent breakage of both Monoject (Sherwood Medical Industries, DeLand, Florida) and Autosyringe (Autosyringe, Inc., Hooksett, New Hampshire) 3-cc syringes at the luer. He also reported freezing of the diluted insulin in these syringes within 15 min of exposure to the cold. The patient was using the Autosyringe AS2C infusion pump and wearing the unit on his belt. Most of the unit, including the barrel of the syringe, was covered by a medium-length nylon ski jacket. The outside temperature and wind velocity were not recorded at these times; however, local weather reports suggested that the wind-chill factor was close to 0°F.

To investigate these "cold"-related CSII system failures, we subjected Monoject and Autosyringe 3-cc syringes, both empty and filled with the insulin-saline mixture used by our patient (115 U in 3-cc normal saline), to cold (0°C to −5°C) and wind (600–2000 rpm) in a temperature-controlled centrifuge and then applied light pressure to the luer end of the syringe. Although the force applied to the syringe was not quantitated, it was similar in intensity and direction to that which could be anticipated when accidentally bumping the AS2C unit against a steering wheel, door jamb, or desk.

Monoject syringes are designed to break easily at the luer for safety reasons. Consequently, it was not surprising that these syringes broke with little pressure at both room temperature and 0°C. Autosyringe syringes, however, are designed for use with Autosyringe pumps. The AS2C design requires the luer to extend beyond the syringe cradle, and therefore be subject to forces from all directions. The Autosyringe syringes did not break easily at room temperature, but broke as easily as those designed to snap apart when exposed to 0°C for 10 min.

Filling the syringes with the diluted insulin solution did not affect the results of the fragility testing. The solution used by our patient froze solidly in both syringes when exposed to 0°C to −5°C without wind for 30 min, but did not freeze during 15-min exposure to 0°C and 600 rpm. At the same temperature but faster speeds (2000 rpm) the solution in Monoject syringes froze within 15 min while only half of the filled Autosyringe syringes froze.

Although these studies are rather simplistic and do not lend themselves to statistical analyses, they suggest that caution be used in the selection of syringes for use in CSII and that adequate warning be given to users of CSII to protect their systems from cold and wind, and cushion them from even light trauma during periods of cold weather.

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Establishing Standards for Patient Educational Publications

The quality of diabetes patient educational materials is, to be generous, uneven. Over the past two years I have reviewed some two dozen book-length publications including manuals, cookbooks, and miscellaneous works directed primarily at the person who has diabetes. These were new books, mostly softcover, recently purchased by our university's medical school library or by me directly from the publisher.

It has not been a happy experience, for I have met on those hundreds of pages purveyors of myth, outdated information, sheer falsehood, condescending, cutesy advice, and loony philosophy.

At first I was faintly amused and pleased with myself for being able to judge variations in quality. But then it occurred to me that the main reason I could tell that some of the books were terrible was that I already had a fairly extensive layman's background in diabetes literature. How, I wondered in alarm, would I be able to discern the advice of widely respected experts and persons of substantial experience from the ranting of crackpots if I were new to diabetes or had very little knowledge? Worse yet, how could I recognize that which was simply poor quality—inaccuracy, omission, mistaken judgment?

The act of publishing confers a certain legitimacy. Too often the general reader may not be skeptical enough, may tend to think that if the information is in a book—especially a book written by a doctor or a professor—it must be right. Unfortunately, that is not true of diabetes management any more than it is true of pop psychology or fad diets.

Because of the increasingly competitive publishing business and the fact that there are no general publishers' standards for medical advice books, I suggest that it is time for the diabetes community, through the American Diabetes Association, to establish a review system that publicly recognizes excellence in the field of diabetes educational materials.

How to go about it? First, physicians and educators, through the professional section of the ADA, would have to agree that (1) there is a need for some systematic evaluation of diabetes educational materials and (2) the obligation is theirs to see such a system put into practice.

Who would do the evaluating and how might the system work? I should think a sizable panel—maybe 25 or more—could, upon the recommendation of several members, award recognition (such as a sticker to be placed on book covers) to those books that meet its published criteria. By the same token, the panel could withhold recognition from works failing to meet one or more of the criteria.

Beyond that, I cannot specify. I can offer only a few assorted notions on the subject. One concerns the objectives of a materials review system. It would seem to me the charge to the panel or committee would be to ensure promulgation of diverse opinions through the use of criteria that are as objective as possible: currency of fact, high editorial standards, compatability with ADA guidelines and goals for diabetes management, etc. In no case should a review system become the handmaiden of one faction or school of thought at the expense of others.

Further, the review panel or committee should be broadly representative. Surely physicians, dietitians, and educators should be included. But there should be among its members some consumers—a teenager, a young mother, an adult who has had diabetes for a long time, an older person. And, if you will forgive my parochialism, someone with a background in the mechanics of language who can evaluate the effects of written messages—ideally a high school or college English teacher (!) or a journalist or advertising writer.

The question of how people, already burdened with business and professional obligations, can find time to read and evaluate the plethora of books in print on diabetes is the most troublesome. Perhaps they would review only materials submitted to them by authors. Or perhaps they would review only certain kinds of publications, such as books published by commercial publishers and offered for sale to the general public (as opposed to hospital manuals and other proprietary materials). Perhaps they would deal only with newly published works. Perhaps there would be a maximum number of reading assignments for each member and a minimum number of reviewers for each book.

Perhaps by making assignments and setting deadlines and using printed review sheets and a postal service the review panel could work efficiently. I shall leave the details to them.

But it is time to establish some standards in the field of diabetes patient educational materials and to acknowledge those works that measure up. It is time to provide consumers some guidance in evaluating publications that, for them, may affect their very lives. Do I hear any volunteers?

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