Follow-up Study: Protective Immunization in The Elderly

We previously reported that a group of elderly subjects given two doses of tetanus-diphtheria (Td) toxoid all achieved protective serum levels of antitoxin (≥ 0.01 AU/ml) to tetanus and diphtheria following a second dose.[1] A report describing the age-related decline in the synthesis of anti-tetanus antibody in humans[2] prompted us to follow up our study population.

From our previous study group, 14 persons (five males, nine females) were still alive four years following previous serum studies. Mean age at follow up was 78 years (range 65 to 98). Ten persons had received two doses of Td toxoid, two one dose, and two no vaccine. Sera were collected from all and antitoxin titers were performed as previously described.[1]

Protective antitoxin levels vs tetanus were present in seven of ten (70 per cent) sera from persons previously given two vaccine doses. Two persons who received only one dose of vaccine and two given no vaccine were below protective levels. Levels vs diphtheria showed that nine of ten (90 per cent) were still protective. Of two who received only one vaccine dose, one had fallen below a protective level; of two who never received vaccine, one remained below a protective titer.

A booster dose of Td toxoid was given to three persons who previously received two doses of toxoid and whose levels were below protection vs tetanus (two persons) or diphtheria (one) at follow up. None experienced any adverse reaction and all had protective levels four weeks after the dose.

These studies have implications for vaccinating the elderly against tetanus. The decline in titers to both vaccine components after four years suggests that two initial doses are not optimal for long-term protection, and a third dose is probably needed.

Tetanus continues to occur in the United States predominantly in elderly persons.[3] Any vaccine program for the elderly should take into account the reduced magnitude and duration of antibody responses of the elderly.

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Further Comments on Study by Morisky, *et al*

The recent article by Morisky, *et al*,[1] in this Journal was an important contribution to the health education literature, especially since it was a long-term follow-up study. However, the paper may mislead other investigators who emulate several of its approaches. First, the study not only evaluates the effect of the several intervention strategies on reduction of blood pressure, but also ascribes reductions in morbidity and mortality to these same interventions. Since the study was not originally designed to assess effects on morbidity and mortality, other important causal variables (family history of high BP, lack of exercise, smoking, salt intake, etc.) were not included in the study and differences in these factors between the intervened and non-intervened groups may be creating most or all of the apparent intervention effect.

Secondly, not all of the patients assigned to the various intervention groups actually received the scheduled interventions. In one group (E_1, E_2, E_3) only 13 out of 50 patients received the prescribed interventions. One would expect a considerable dilution of the intervention effect under such circumstances. Yet this study showed the second highest success in reduction in hypertension.

Thirdly, the data are presented in Tables 5, 6, and 7 at baseline, 3 years and 5 years. However, the number of individuals decreases over the follow-up period, allowing for selective drop-out of the less successful persons. A more appropriate analysis is the separate presentation of data for Baseline, 2 and 5 years for those followed 5 years, another analysis for B and 2 for those followed-up for less than 5 years but at least 2 years, and data for B alone for those who could not be followed for at least 2 years. This mode of analysis separates the selection effect from the intervention effect.

In summary, the health education intervention is credited with a marked reduction in hypertension, hypertension-related morbidity, hypertension-related mortality, and mortality from all causes. The size of the credited effect seems inappropriately large given the limited nature of the intervention techniques and may well be explained by the above mentioned methodological and analytical issues.

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Authors' Response to Kirscht and to Tuthill, *et al*

We welcome the opportunity to address the issues raised by Tuthill, *et al*,[1] as well as respond to the commentary by Kirscht[2] on our study.[3] Both express skepticism about the fact that the results are more "positive" than in previous studies with even shorter follow-up intervals (implying that the longer interval should depress rather than enhance the benefits of health eduction).[4] Also, features of our design and data are questioned that deserve more discussion that we could possibly give in the space allowed for our article.

The problem of ruling out potential threats to internal validity has been resolved by the random allocation of individuals to experimental and control groups, thereby assuring the comparability of these groups with respect to *all* factors, known and unknown, except for the one being studied.[5] Analysis of variance on baseline measures confirmed the effectiveness of the randomization process. We agree that some skepticism is warranted until comparable results are available from "other settings with other conditions," but we do not see how Kirscht would offer "a somewhat more interpretable design." The fully crossed 2 × 2 × 2 randomized factorial design allows us to answer most of the questions he raises and many more he did not raise. Larger numbers, as always, would have helped, but longitudinal analyses of individual and subgroup histories of

these patients have been reported elsewhere.[6-8]

Each commentary questions the potency of the interventions and their ability to account for the significant reductions found in blood pressure and mortality. Doubts center on the brevity of some of the educational interventions and the fact that some patients did not avail themselves of the educational sessions to which they were randomly assigned. Both the brevity and the voluntary access we regard as strengths rather than weaknesses since interventions were tailored to educational needs of a patient population, and then adapted to the needs of individuals as they were integrated with ongoing medical care, thus allowing for longer sessions with patients or family members who had difficulty comprehending or accepting specific aspects of the education. Many of the patients who declined the home visit or one or more of the group sessions or who required less than 10 minutes of counseling did so because they did not feel a need for more of that component of the educational program.[9]

Dr. Kirscht took the low, but significant, correlations among specific behavioral and blood pressure measures as a reason to doubt the validity of the results, and he speculated that these low correlations together with the sampling mortality ("selective dropout") could account for the outcomes measured as group changes. Let us be clear first that several analyses—including comparison of different groups over time, worst case analysis, and specific examination of dropouts—did not account for study results. Second, these speculations do not apply to the significant differences in death rates between experimental and control groups. The undeniable five-year mortality results can be explained as the cumulative effects of changes in various risk factors, particularly, but not exclusively, blood pressure control and weight control. Different individuals controlled different risk factors, so the group correlations are low between risk factor outcomes. Similarly, each risk factor could be controlled by changing one of several behaviors. Different individuals changed different behaviors. Hence, low correlations are found also between the group behavioral outcomes. As with self-selection in the voluntary participation of patients in the educational interventions, individual patients tended to select the behaviors they needed most to change in order to effect the great risk. Both Tuthill, *et al,* and Kirscht seem to be searching in the data for consistencies and uniformities that do not exist in reality. Moreover, the results do not at all suggest medical care is irrelevant, but rather that it can be enhanced by appropriate health education. Table 9 of our published article clearly demonstrates that appointment keeping was significantly related to medication compliance, weight loss, and blood pressure control.

Our study was designed to test the effectiveness of an *approach* to health education for hypertensive patients.[10,11] The approach was based on a diagnostic planning model which can be and has been replicated in planning alternative health education programs for other patient populations.[12-14] It is the diagnostic approach—not the specific educational interventions used in our study—that should be defended or replicated. We hope that this study will encourage other investigators to structure their educational programs on a well-researched needs assessment and tailor the educational strategies to patient needs.

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Pretesting of Questions in Visual Acuity Surveys

We read with interest "Validity of a Survey Question as a Measure of Visual Ability,"[1] which reports high specificity but low sensitivity when measures of far-vision acuity (with usual correction) are compared with responses to questions about trouble with vision even when wearing glasses or contact lenses. The authors suggest that future surveys substitute a series of task-related questions for the single general visual-ability question they studied. Other studies have also found low sensitivity rates with questions about ability to see distant objects[2,3]; one such investigation studied a graduated series of task-related questions for far-vision impairment with sophisticated scaling techniques.[4]

In the Rand Health Insurance Experiment (HIE), a general population study of adults,[5] we asked two task-related questions. Responses were compared with the relevant measures of natural (uncorrected) visual acuity (sample size approximately 3,300 adults) to estimate the validity of the questions (see Table 1).

Specificity was quite high for all levels of vision deficit, but the sensitivity was quite low except at the most severe levels of impairment. Likelihood of reporting inability to accomplish these visual tasks was directly related to the degree of vision deficit. In addition (data not shown), the items showed poor negative predictive validity despite good positive validity, meaning essentially that a sizable proportion of the HIE population claiming