

data. In order to accommodate the child's needs, the diet must be strictly adhered to. This necessitated a dramatic modification in family life-style. Therefore it is unclear whether the improvement in the children was due to the diet or to the additional care given the children in these particular circumstances. In addition, the severely restrictive diet has been criticized by many nutritionists as being nutritionally inadequate.

Other investigators have designed projects to determine if a relationship exists between food additives and hyperactivity.

One preliminary attempt to investigate the hypothesis is the study designed by Connor, of Pittsburg's School of Medicine. This study involved 15 children diagnosed in accordance with the American Psychiatric Association's definition of hyperkinetic reaction of childhood.

In this study, both parent and teacher ratings showed a statistically significant difference between measurements made at baseline and those made after the children had been on the K-P diet. It is interesting to note that, when the K-P diet was measured against a control diet, teacher ratings showed a statistically significant difference, but parental ratings did not.

Dr. Connor concludes that "the special diet may reduce hyperkinetic symptoms" but warns, and I quote:

... it would be hazardous at this point to draw too many conclusions from this experiment, given the small size of the sample and the lack of complete consistency in the results. Any thoughtful observer will understand that a major intervention into dietary habits of a family will produce behavioural effects, regardless of the specific diets, a phenomenon well understood in the management of such conditions as juvenile diabetes. The results would have been substantially clarified if it had been possible to have objective measures of function uncontaminated by the psychological factors which are bound to operate in the family-school-child system. At this point, the results point to the need for considerable further investigation.

Perhaps the most significant of all studies is that conducted by a team at the University of Wisconsin. This represents the first systematic investigation of the hyperactivity-food additive hypothesis. It includes objective psychologic, psychophysiological and classroom observational data in addition to parent and teacher ratings of behavioural change associated with dietary manipulations. The study was designed in such a way that teachers, parents, clinical investigators, and classroom and laboratory observers of the children's activity level were unaware throughout the course of the investigation whether the child was on the special diet or on a diet containing artificial colours and flavours. Both the experimental and control menus were prepared from commercially available food stocks.

Available results indicate that of the 36 mothers with boys in the 6-12 year group, 13 rated their son's behaviour as improved on the special diet, while 6 rated their child's behaviour as worsened. Seventeen of the maternal ratings showed less than 10 per cent change due to effects of diet. Of the 30 fathers rating the behaviour of this same age group, 14 rated their son as improved, 3 as worsened and 13 essentially unchanged. In contrast, only 6 of the 36 teachers rated those on the special diet as less hyperactive, 10 rated them as showing more active behaviour while on the experimental diet, and 20 of the teacher ratings showed little change between the

### *Artificial Food Additives*

two diet conditions. Agreement between parent and teacher ratings of improved behaviour while on the experimental diet occurred in only 4 of the 36 children.

The observational data collected on a number of behaviours in the classroom and in a standardized laboratory task yielded very few ratings of improvement in association with the experimental diet. Preliminary statistical analysis of these data has been completed and no statistically significant effect was apparent.

However, the younger children (age 3-6) showed a greater positive response on the experimental diet as indicated by parent rating. All 10 mothers in this group rated their child's behaviour as improved, as did 4 of the 7 fathers in this sample.

Thus, with the possible exception of the youngest age sample, the preliminary analysis completed to date in the Wisconsin study does not appear to offer strong support for the efficacy of the experimental diet, at least with respect to group effects. The University of Wisconsin research team, however, has repeatedly emphasized the still incomplete status of their project saying that a number of the objective measures obtained on the subject have not yet been tabulated.

A study was recently conducted at the University of Western Ontario to determine the relative effectiveness of dietary and drug management of hyperkinesis. Preliminary findings suggest that the effect of diet was ambiguous. Parents and teachers were of the opinion that dietary infractions involving artificial food colours and flavourings had minimal and insignificant effects.

The aforementioned studies conducted to date clearly indicate the potential difficulties in any attempt to test the food additive-hyperactivity hypothesis. The small sample size used reduces the significance of all findings and makes the use of statistical analysis extremely difficult. Furthermore, the use of outpatients in all these projects makes difficult the control of compliance. Also, specificity of responsiveness must be studied by challenging subjects with individual groups of substances, such as artificial colours or flavours or salicylates. Finally, results are meaningless if strict adherence to guidelines is not preserved throughout the entire duration of an experiment.

Several other studies currently under way have been funded by the U.S. Food and Drug Administration. These include a study on the hyperkinetic syndrome in children being conducted at the Kaiser Permanent Foundation Research Institute in California. The study should be completed in about 1 year. A second study, at the University of Wisconsin, is designed to identify children who respond to the K-P diet.

Much more definitive scientific information is needed to determine if the consumption of food additives is related to the hyperactive syndrome in children and the ultimate effects in adults. This is very expensive.

A study sponsored by the Department of National Health and Welfare is now underway in a Canadian hospital.

**Mr. Yewchuk:** Which hospital?