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SOME STATISTICAL OBSERVATIONS ON FLUORIDATION TRIALS.

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THE suggestion that domestic water supplies should be fluoridated, with the aim of partially preventing the development of dental caries, has gained wide support, and moves are being made in Australia for the widespread introduction of this measure. Much confusion of thought clouds the issue of the desirability, the method of action and the safety of this process. This uncertainty is reflected in two recent events. In November, 1956, a Reference Committee of the American Medical Association (1957) stated that "there is a definite need for a re-evaluation of the problem of fluoridation",[1] and in March, 1957, after a public hearing, the proposal to fluoridate the water supply of New York was not put into practice (Nesin, 1957).

Apart from these considerations, an examination reveals that there are aspects that call for a very careful appraisal of the figures presented in the reports of the experimental trials which have been conducted in Brantford, Canada, and in Grand Rapids, Newburgh and Evanston, U.S.A., and upon the results of which proposals to fluoridate domestic water are almost entirely based.

A preliminary survey of the methods used, of the published figures and of the method of their presentation discloses some disturbing facts. Some of these are as follows. (i) In the clinical examinations no attempt was made to devise a randomization procedure, which would have eliminated bias on the part of the examiners. However, the necessity for such a precaution was recognized by Ast, Bushel, Wachs and Chase (1955) in the Newburgh-Kingston trial, when they instituted a combined clinical and X-ray study eight years after the commencement of the ten-year investigation. (ii) No estimate was made of variability between examiners, although in some studies several operators were employed, some being changed from year to year (Blayney and Tucker, 1948; Arnold, Dean and Knutson, 1953); some of the examinations in Kingston were made by two dental hygienists (Ast, Finn and McCaffery, 1950). Furthermore, there appears to be no estimate of variability within the examiner—that is, the variability of individual examiners from inspection to inspection. (iii) The importance of random variation in the DMF rate (decayed-missing-filled permanent teeth rate) does not appear to have been recognized, or else it has been ignored. (iv) Bias is suggested by the presentation of some results, so that the casual reader may be misled (Ontario Department of Health, 1956).

The following observations will serve as illustrations.

1. In each of these studies it has been emphasized that the maximum benefits of fluoridated water are seen only in those subjects who have consumed it during the total period of enamel formation. Therefore, it would be expected that only a slight decrease (due to the possible topical effect of the fluorine) would be seen in the DMF rate between successive years during approximately the first six years of the project, until the first permanent teeth which had been completely formed under its influence had erupted, and that the advent of these "resistant" teeth would thereafter produce a greater drop in DMF rate between succeeding years. However, in the first three years of each project there is a marked relative fall in the reported DMF rate, particularly in the younger age groups; while in the six-years-old group in Brantford the rate reached after ten years is no lower than it was after only four years of fluoridation (Ontario Department of Health, 1955; Hutton, Linscott and Williams, 1956). It would appear that the results reported are not those which would be expected if the theory mentioned above is correct.

2. In four of these studies (Hutton *et alii*, 1956; Hill, Blayney and Wolf, 1956; Arnold, Dean and Knutson, 1953; Ontario Department of Health, 1956) the method of expressing changes in caries experience was the same. The final rate was subtracted from the baseline rate, and the difference was expressed as a percentage of the latter rate. It is obvious, therefore, that with this method, relatively small variations in the baseline values will produce substantial alterations in the percentage reduction obtained. For instance, in the seven-year-old children in Evanston, during the last five years reported, the increase in caries-immune deciduous dentitions was 361%, but for the whole of the nine-year period 1946-1955 the increase was only 58% (Hill *et alii*, 1956). The authors claim that "difference between 1946 and 1955 rates is statistically significant". However, such a claim is not warranted, owing to the marked variation in the values observed in the intervening years. The effect of variations between years is seen in the six-year-old group in Brantford. By the use of this method of calculation the reduction in the DMF rate for the period 1944-1950 was 82%, but the apparent benefit had dropped to 52%, a decrease of 30%, after an additional two years of fluoridation (Ontario Department of Health, 1956). An improved method of indicating relative changes in the DMF rate would seem to be desirable—in particular, one which would permit statistical tests to be applied.

3. As an instance of the divergent results which can be reported by different examiners, those from the two independent trials in Brantford may be compared (Ontario Department of Health, 1956). The National Health and Welfare authors reported a reduction in the DMF rate in the six to eight years age group of 69% from the inception of their examinations in 1948 to the 1954 results. However, in the same city, in the same age range and between the same years, the reduction in the DMF rate obtained by the City Health Department examiner was only 25%, less than half of that claimed by the authors of the other study. The Health Department DMF figures for 1954 were given for individual age groups without statement of the number of children involved in each group. The 25% reduction is based on a DMF rate obtained by simple averaging of the six, seven and eight year DMF rates. For 1948 the actual numbers of children are available (Hutton, Linscott and Williams, 1951).

The uncertainty in the computed reduction of 25% is most unlikely to account for the gross difference between it and the figure of 69% quoted by the National Health and Welfare authors.

4. In Table II of the Report of the Ontario Department of Health (1956) to the Ontario Minister of Health, the mean numbers of decayed or filled deciduous teeth are shown. In the column headed "% Reduction Since 1948", there are dashes opposite the control cities of Sarnia and Stratford. These, surely, would lead the reader to suppose that no reductions had taken place in these cities, particularly as the footnote states that "the rates for Stratford, which has had natural fluoridation for 30 years, and Sarnia, which has no fluoride in its water, have remained about the same". However, in the nine to eleven years age group in Stratford there was a slight decrease of 5% (by the use of the DMF rate reduction method common in these studies), and in Sarnia the same age group showed a decrease of no less than 16%. One would like to know the reason for the omission of these figures, particularly as the latter reduction is almost as high as the 18% claimed for children of the same age in the test city.

Whilst we do not question the integrity of workers in this field, it must be pointed out that the evidence tendered in favour of fluoridation reveals two disturbing features. The first is that what must be essentially a statistical study does not appear to have been planned as such. The second is that even when sufficient information is presented, no comprehensive attempt at statistical evaluation has been considered.

It is possible that a case for fluoridation can be solidly based, but until adequate statistical treatment of all the pertinent factors has been carried out—and this would be quite a major undertaking — the question should not be regarded as settled. In the meantime, claims concerning the amount of caries reduction are open to doubt.

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[1] In December, 1957, the American Medical Association endorsed the principle of fluoridation, but that decision cannot affect the facts which have been stated in this paper.

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