

Editor's Note: The article below is the last scientific paper written by Dr Richard G Foulkes before his death on 3 September 2007. Originally it was submitted to the *British Columbia Medical Journal* in response to an opinion piece titled “Fear of fluoride—more bark than bite?” published in the September 2006 issue of that journal. In the following month, Dr Foulkes submitted a response to the BCMJ, and on January 4, 2007, James A Wilson, MD, editor of the BCMJ, suggested that Dr Foulkes revise and submit his response for the Premise section of the journal. On March 11, 2007, Dr Foulkes submitted his revised article, now copyedited for typesetting and printed below. Receiving no reply, Dr Foulkes inquired, and on June 11 Dr Wilson wrote rejecting the submission, stating:

“Your initial foray into the world of premise writing was quite encouraging. However, after an interesting first few pages your focus drifted back to fluoridation and never seemed to make it back to paradigm debunking. . . . I have no problem with the premise that we all need to look closely at many of our long-held non-evidence-based clinical/scientific paradigm[s] if there is good evidence denouncing [them]. However, in the same breath I have to emphasize that printing what at times appears patronizing and potentially libellous personal opinion is not the way to do it.”

Readers can judge for themselves whether what Dr Foulkes wrote was “patronizing and potentially libellous personal opinion” or whether it was backed up with solid scientific evidence. If it was “potentially libellous” as Dr Wilson contends, perhaps he would be willing to present his documentation for that view?

PARADIGMS AND PUBLIC HEALTH POLICY VERSUS EVIDENCE

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SUMMARY: A paradigm serves as a model through which our community and we view reality and may be used to form the basis for public health policy. To be valid, the paradigm must be held in place by evidence that calls for the exercise of “due diligence” on the part of those called upon in its defense. Contemporary studies and reviews must be studied and taken into account. The 60-year-old paradigm of water fluoridation and the Report of the Council on Health Promotion that defended it in the pages of the *British Columbia Medical Journal* serve as examples of such a paradigm now in retreat and requiring changes in public health policy. Fluoridation exemplifies how we must, sometimes, leave the comfort of well-established beliefs to scrutinize, re-assess, and discard them on the basis of evidence.

Keywords: Paradigm; Precautionary principle; Public health policy; Water fluoridation; Weight of evidence.

PARADIGM: A VIEW OF REALITY

Paradigms serve as patterns or models of a set of assumptions, concepts, values and practices through which our community and we view reality.¹ Accepted paradigms in medicine direct treatment, contribute to diagnosis and serve as a basis for public policy. We would like to think that well-established paradigms are held in place by evidence based on scientific inquiry. In reality, many depend on the word of “authorities” such as the World Health Organization (WHO), US Centers for Disease Control and Prevention (CDC), US Public Health Service (USPHS), and Health Canada along with various professional associations. We

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assume that these institutions base their support on the weight of evidence dealing with effectiveness and potential risks. We may be wrong.

Inaccurate data, falsehood, and misunderstanding of what constitutes “evidence” may assist in holding a paradigm in place. In addition, there is the factor that Spittle² has termed “tardive photopsia”; that is, the slowness of those seeking knowledge to see the light. The latter gives rise to the old maxim: “There are none so blind as those that will not see.”

“EVIDENCE”

With regard to “evidence,” any examination of a current paradigm must take a broad approach. This is especially true if this involves public health policy that deals not with individuals but with groups. The “gold standard” of scientific evidence is held to be the Randomized Clinical Trial (RCT) but this has severe limitations. It cannot be used to clarify cause-and-effect relationships in many spheres involving assessment of the benefits and risks of population groups. For these, the replication of associations and linkage between observations and laboratory research assume major importance.

Today, the precautionary principle must also be entered into the equation. In North America, this is based on the Wingspread Statement of January 1998.³ In the words of this statement, “[it] is necessary to implement the Precautionary Principle: when an activity raises threats of harm to human health *even if some cause and effect relationships are not fully established scientifically* (emphasis added).” Adherence to this principle does not release the researcher or those concerned with establishing public health policy from the responsibility of taking into account all of the available scientific evidence. The examination of paradigms related to medicine in its broadest sense and public health policy must direct attention to the evidence pertaining to “benefit”; that is, the efficacy of any action concerned. It must also assess the “risks”; that is, the possible adverse effects associated with the action.

“DUE DILIGENCE”

Those responsible for advocating public health policy should be held to a standard of “due diligence.” This standard applies equally to public health policy and to research and analysis done by a company or organization in preparation for a business transaction. It is the duty of those responsible to be familiar with the findings of current reviews by scientific bodies and pertinent research findings in the area of interest.

There are problems in seeking and using evidence to inform health policy. These were reviewed in the UK by McIntyre et al.,⁴ who were invited in 1997 to become an “evaluation group” to assist an independent inquiry into inequalities in health. They found that evidence from public organizations was lacking in a number of points including lack of evidence of effectiveness and information on costs and possible harm.

An examiner must have a full background in the pertinent literature to detect omissions often encountered in biased reports. It is important also to recognize

that not all journals are included in *Medline/PubMed*, generally accepted as a first line of search. The indexing of this source of information is the responsibility of the US National Library of Medicine, whose apparent policy of excluding journals perceived by its advisory committees to be in conflict with various aspects of official public health policies has long been a matter of concern.^{5,6}

A number of paradigms used in medicine could qualify as in need of re-examination. In general, we feel comfortable with them and reject contrary views. They have the support of “authorities” and are accompanied by an historical mantra and by what we are told is research that provides confirmation.

One paradigm that has persisted for more than 60 years is that of water fluoridation. This belief holds that children drinking water containing fluoride at a concentration around 1 ppm (0.7–1.5 mg/L) experience a reduction in dental caries over time with safety, save for dental fluorosis that is considered to be a “cosmetic” effect.

Many physicians probably consider water fluoridation to be an esoteric topic related more to the practice of dentistry than to medicine. However, a recent report from the Council for Health Promotion entitled “Fear of fluoride: more bark than bite?” published in the *British Columbia Medical Journal* (BCMJ)⁷ well illustrates the need to be critical of old paradigms and exercise “due diligence” when an official agency has the responsibility for promoting public health policy.

The title of the Council’s report brings into derision the serious concerns of reputable scientific researchers. The failure to ask serious questions and show evidence of familiarity with contemporary research and reviews could label this as an uncritical utterance of an old mantra.

EFFICACY

Fluoridation is the loser in a change of paradigm. A consensus is developing among scientists that fluoride, if it does reduce the prevalence of caries, works topically rather than systemically. This change in thinking was well delineated in a 2004 paper by Professor Ole Fejerskov of the Royal Dental College of Denmark.⁸ The “caries resistance” concept, he claims, is erroneous and is giving way to a second paradigm that dental caries is a transmittable infectious disease but not of the classical variety but one to be regarded as multifactorial involving the interaction of genetic, environmental, and behavioral risk factors. Others support the idea that the present paradigm is obsolete.⁹

The authors of an editorial review in the journal *Fluoride* additionally point to historical evidence indicating that water fluoridation is a paradigm in retreat.¹⁰ They are critical of the strong pro-fluoride mindset among dentists and dental health officials and the failure of researchers like Fejerskov to go further. Credit was given to the pioneering work in New Zealand of the late Dr John Colquhoun, former principal public health dental officer of Auckland and editor of *Fluoride*, who, in 1987, showed that since the 1950s increased dental health was related to improved dental nutrition and better nutritional education and dental care than to fluoridation and fluoride use.

The concept that ingestion (swallowing) of fluoride is not required to help prevent tooth decay is difficult to change even though the alleged benefits can be shown to be insignificant. A 1986–87 survey by the US National Institute for Dental Research (NIDR) of 39,207 US schoolchildren, ages 5–17, showed a decline in caries prevalence in both fluoridated and nonfluoridated areas compared to previous surveys. Analysis of these data by Brunelle and Carlos of the NIDR in 1990 showed a “benefit” of 17.7%, amounting to less than half of one tooth surface.¹¹ This figure is significantly lower than the 35% less decay quoted as a “benefit” in the report from the Council on Health Promotion. An independent review of the same NIDR data revealed there was no statistically significant difference in caries prevalence in fluoridated, partially fluoridated, and nonfluoridated populations.¹²

Since the 1960s, World Health Organization (WHO) data have shown a decline in tooth decay in both fluoridated and nonfluoridated countries. These data do not support fluoridation as being the reason for the decline. The most recent analysis by Neurath demonstrates this conclusion.¹³ His study is based on data for 12-year-olds residing in the year 2000 in 16 nonfluoridated and 8 fluoridated countries.

There is anecdotal evidence, primarily in press reports, that numerous jurisdictions that have practiced fluoridation for decades are now declaring they have a “dental crisis.” A recent Canadian report from the fluoridated City of Saskatoon published in *The Saskatoon Star Phoenix* (September 21, 2006) reports that the rate of caries among young children in the Saskatoon area has quadrupled, especially among those living in poorer neighborhoods.

With regard to the statement in the Council’s report that some communities that have stopped fluoridation have subsequently experienced an increase in the incidence of tooth decay, one needs only to look at a study of our own province, British Columbia, published by Maupome et al. in 2001.¹⁴ These authors found that when the prevalence and incidence of caries between a fluoridation-ended and a still-fluoridated community in British Columbia were examined, the prevalence of caries decreased over time in the fluoridation-ended community while remaining unchanged in the fluoridated community. There are complications in such a study but it is clear that no calamity has occurred in the community that stopped fluoridation. A significant decrease in dental caries after suspension of water fluoridation has been recorded in Japan, the Netherlands, Prague, and the former German Democratic Republic.¹⁵

There is, therefore, an evidence base sufficient to demonstrate that the systemic use of fluoride (water fluoridation) is not effective in preventing dental caries. The existing paradigm must give way to an alternative. Attention needs to be placed on dental education, nutrition, avoidance of acid beverages and sugar, supervised tooth brushing, and better access to dental services.

SAFETY

By coincidence, the paper in the BCMJ following the Council’s report is entitled “*Primum non nocere* (first do no harm): how do we improve patient safety?” This

is the theme of this issue of the BCMJ and is germane to providing an answer to the question asked in the title of the report by the Council on Health Promotion.

It is the prevalent view that approximately 50 percent of ingested fluoride is retained in the body, primarily in the skeletal system but also in other tissues, including the pineal gland. Fluoride has been shown to be a potent enzyme inhibitor and to interfere with DNA repair. Therefore, it is possible that adverse effects are ubiquitous and can, theoretically, involve all functions in the body, including the endocrine and the immune systems. An extensive bibliography of both experimental and epidemiological evidence is available on the worldwide web.¹⁶

The Council's reference to acute toxicity from fluoride is a time-tested diversion. The real problem is the possible effect of regularly ingesting relatively low amounts of fluoride over a lifetime. This intake becomes complicated when other sources of fluoride exposure are considered. The list is extensive: fluoride in foods and beverages prepared in fluoridated areas and/or contaminated by pesticide residues, dental products, pharmaceuticals, and occupational exposure. Age and genetic factors are also very important, especially when dealing with developing infants and children. Occupational exposure, excessive water intake, renal status, and individual sensitivity must be taken into account in addition to socioeconomic status and dietary deficiencies.

The Council's report states that "at the recommended levels of fluoridation and supplementation ... the only real (and small) risk is dental fluorosis." A number of "problems" are listed and the conclusion is drawn that no convincing evidence has been found to support these claims

The list of "problems" associated with fluoride presented in the report of the Council are attributed to a textbook published in 1986, edited by the University of California San Francisco's Professor of Dentistry Ernest Newbrun, now emeritus. In one of the chapters in this book these "problems" include: "cancer; Down syndrome; heart disease; osteoporosis; bone fractures; AIDS; allergic reactions; Alzheimer's disease; and, low intelligence."

The list was presented 21 years ago with a tinge of ridicule; but since that time evidence of a relationship between the majority of these "problems" and fluoride has greatly increased.

The most recent reference cited in the Council's report that could be considered scientific is the 1993 report of the US National Research Council (NRC), *Health effects of ingested fluoride*.¹⁷ There have been a number of reports on fluoride and fluoridation since 1993 with which the Council should be familiar. These include the 1999 report by David Locker for the Ontario Ministry of Health and Long-Term Care¹⁸ and the 2000 systematic review of public water fluoridation by the National Health Service (NHS) Centre for Reviews and Dissemination (CRD), the University of York (UK).¹⁹

In both of these last two reports, comments were made regarding the poor quality of research and that available data do not provide evidence that water

fluoridation is effective in reducing tooth decay. Professor Trevor Sheldon, Head of the Department and Founding Director of NHS/CRD, in a news bulletin issued January 23, 2001, made a special point of clarifying the findings. Sheldon stated that a reduction in tooth decay of 15% (sic) is neither clinically nor statistically significant; high levels of dental fluorosis are in evidence; and, that research did not show water fluoridation to be safe.²⁰

The recent report by the US National Research Council titled *Fluoride in drinking water* was released March 22, 2006.²¹ This study by a Committee of the NRC is a comprehensive review of the literature and studies available since the 1993 report.¹⁷ The 2006 NRC study is a scientific review that has its focus on the US Environmental Protection Agency (EPA) standards. Under the US Safe Drinking Water Act (SDWA) of 1974, the EPA is required to establish exposure standards for contaminants in public drinking water systems that might cause any adverse effects on human health. The NRC was called upon to evaluate the scientific basis for EPA's Maximum Contaminant Level Goal (MCLG) for fluoride currently set at 4 mg/L (to prevent crippling (stage III) skeletal fluorosis) and the Secondary Maximum Contaminant Level of 2 mg/L (to prevent severe dental cosmetic effects). In the case of fluoride, the Maximum Contaminant Level (MCL) and the MCLG are currently the same. With many contaminants, the MCLG is a "desirable" figure that may not be achievable for economic and other reasons. Examples are for arsenic and lead. For both contaminants the MCLG is zero while their MCL's are 0.10 and 0.15 mg/L, respectively.

In an editorial review published in *Fluoride*,²² Robert Carton, an environmental scientist who worked for over 30 years in the US government writing regulations and managing risk assessments on high priority toxic chemicals, gave a critical assessment of the 2006 NRC report on *Fluoride in Drinking Water*. His review includes coverage of the complex issues involved and contains personal communications from members of the NRC fluoride committee as well as his conclusions after a reading of the report.

A 12-member committee (that included the University of Toronto's Associate Professor and Head, Department of Preventive Dentistry, Dr Hardy Limeback) prepared the NRC report. According to Carton, comprehension of the report is confounded by the mandate given to the committee by EPA management and the committee's perception of their role. The committee, for example, identified health effects known only with total certainty rather than the intent of the SDWA to ascertain "whether any adverse effects can be reasonably anticipated, even though not proven to exist." In addition, the committee was instructed not to identify a new MCLG for fluoride; that is, determine a safe level of fluoride in drinking water.

The 2006 NRC report contains more than 1,000 references including many from *Fluoride*, the official journal of the International Society for Fluoride Research (ISFR) that has been denied inclusion in *Index Medicus/PubMed* for almost 40 years. The extensive text of the 2006 NRC report indicates that the committee broke new ground. It declared as adverse health effects severe dental fluorosis and

moderate (stage II) skeletal fluorosis (mobility, joint pain, and stiffness along with osteosclerosis of the spine and pelvis on x-ray).

In regard to dental fluorosis, the report suggests that moderate dental fluorosis also includes structural damage to the tooth enamel. This damage could lead to lack of protection of the dentin and pulp from decay and infection. Therefore, there is a basis for classifying moderate dental fluorosis as an adverse health effect as opposed to only a cosmetic effect.

Until this 2006 NRC report, only actual crippling by skeletal fluorosis (stage III) was regarded as an adverse effect. Recognition of stage II skeletal fluorosis as an adverse health effect means, according to Carton's interpretation, that: "fluoride exposure, then, can now be officially listed as one of the causes of arthritis."

The 2006 NRC report reviews studies of the endocrine system. There is evidence of a relationship between fluoride intake and thyroid dysfunction. Other relationships supported by evidence involve impaired glucose tolerance leading to type II diabetes and impeded sexual maturity. Studies of the effects of fluoride on the brain, especially in conjunction with aluminum, are reviewed along with other adverse effects.

Carton, in his review, points out that calculations based on SWDA guidelines have to include individual susceptibility, contribution of water ingestion, and other sources of total fluoride load. When these are considered, a number of adverse effects can be shown to occur at or below levels used in drinking water fluoridation. Carton's editorial review should be consulted for his calculations²².

When setting the MCLG, EPA must take these into consideration. A goal for fluoride of 0.0 mg/L may be justified for some adverse effects to prevent any threat of occurrence. However, as in the case of arsenic and lead, the expense (and politics) of complete removal will force the MCL, the enforceable level, to be higher. There are reasons to anticipate that, with all risk factors taken into account, a level below that currently used for water fluoridation may be enacted. If this does occur, it can be reasonably expected that Canada will follow. At present Canada's "maximum acceptable concentration of fluoride in drinking water" is 1.5 mg/L and the "optimal" concentration recommended by Health Canada for water fluoridation is 0.8 mg/L. Lowering these could end fluoridation.

The NRC review of 1993 adopted the view that the claims of opponents that water fluoridation was associated with a large number of medical problems did not have the support of credible evidence. The position taken by the 2006 committee of NRC should produce a different opinion.

The 2006 NRC committee referred in its discussion of osteosarcoma to a doctoral dissertation by Elise Bassin of Harvard University (2001) and to their anticipation of the peer-reviewed publication of the findings. This has now taken place and provides a good example of the dilemma encountered in research. In the 2006 paper entitled "Age-specific fluoride exposure in drinking water and osteosarcoma (United States)," Bassin is listed as senior author.²³ This study demonstrated that there is an association between fluoride in drinking water

during growth and development of children and the incidence of osteosarcoma for male children and adolescents. Boys who drank water with levels of fluoride considered safe by federal guidelines are about five times more likely to have the rare bone cancer, osteosarcoma. The association was not found among females.

Bassin's findings are consistent with previous studies by the National Institutes of Health (NIH) (SEER project, 1991)²⁴ and that of the New Jersey Health Department (1992).²⁵ They are also supported by a 1991 study of the effect of sodium fluoride on rats.²⁶ The authors point out that previous researchers whose conclusions were negative regarding an association did not evaluate exposure at specific ages during growth and development when cell division is occurring rapidly. Instead, previous studies evaluated fluoride exposure at the time of diagnosis or as an average lifetime exposure.

In the light of the demonstrated lack of effectiveness of fluoridation, is it prudent to ignore the implications and impose the risks inherent in this, admittedly rare, cancer of bone? The answer, surely, is "no" even though absolute proof is lacking. Similar dilemmas are presented by other "problems" on the list. The 2006 NRC review points to a number of these and serves as an update.

The Council on Health Promotion would be well advised to read recent scholarly reviews and published peer-reviewed studies of scientists on the subject of fluoride and fluoridation of drinking water. The Council may find themselves in the vanguard of those favoring a new paradigm rather than bringing up the rear offering a rhetorical question in place of an informed opinion.

Many public health policy issues and their paradigms invite questioning with regard to the evidence that supports them. Recently, for example, Tom Jefferson, coordinator of the Cochrane Vaccines Field study, has analyzed policy versus evidence for influenza vaccination.²⁷ Jefferson discovered that "the large gaps between policy and what the data tell us (when rigorously assembled and evaluated) are surprising". He introduces the concept of "availability creep." In their efforts to deal with, or be seen to deal with problems, policy makers favor intervention with what is available: in this case, registered influenza vaccines.

How many of our paradigms and public health policies require analysis to support, discard, modify, or question further?

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