

Northland Fluoridation report analysis

This is a peer-review of the report “Pre-and Post-Water Fluoridation Oral Health Survey in Northland/Te Tai Tokerau, Final Report”, Northland District Health Board, November 2009.

Conclusion:

We conclude that this report is “just smoke and mirrors”.

The fact that the fluoridation plants did not supply the prescribed level of fluoride means that any effects observed must be from other causes, such as the various dental health improvement initiatives advised to us previously by the NDHB.

Indeed, the equipment failure makes a mockery of the whole trial and report.

The conclusion and recommendations were as written, and announced, in 2006 – the year before the trial began. The researchers pre-determined the outcome, and have not let facts get in their way.

We are not surprised that the DHB refuses to release the raw data for independent statistical analysis and peer review. It would show what a sham this study is.

Recommendation

We recommend that:

1. the FNDC note that the equipment failure renders the 2 year trial worthless as a basis for developing fluoridation policy;
2. the NDHB report be noted as being too unreliable and self-contradictory to be helpful in informing fluoridation policy; that it be classified as an “opinion piece”, to be afforded no probative value until the raw data is released to the FNDC and FANNZ for independent peer-review;
3. the FNDC note that fluoridation policy should be primarily determined by potential health risks posed by fluoride, ethical issues of enforced uncontrolled dosage mass medication, and potential legal liability of the Council for harm caused by fluoridation; not just on scientifically unsound claims of clinically minor or insignificant benefits in tooth decay in children;
4. no change to fluoridation policy (i.e. no fluoridation) be implemented until scientific research accepted as sound by independent international scientific community demonstrates beyond reasonable doubt that fluoridation is safe for all members of the community, including those with chemical intolerance or at other heightened risk from fluoride, and is effective in permanently and significantly reducing tooth decay;
5. the FNDC recommend that the NDHB focus its efforts on dental health initiatives shown to work (such as school tooth-brushing programmes) and that are less intrusive on individual rights.

Size of the study.

The total number of subjects was 540 baseline and 516 followup. These were split between two age groups. By comparison, Armfield and Spencer, 2004, studied 9988. The US National Institutes of Health data covered over 30,000 children. The latest analysis of this, published in October/November 2009, showed no benefit from fluoridation.

With DMFT rates ranging from 1 to 5, small percentage changes will be difficult to detect in such a comparatively small sample.

No assessment is made of how much weight should realistically be given to the Northland study in relation to this body of (often contradictory) evidence.

Study design

The data section (2.3) omits any reference to data on confounding factors advised by the NDHB under the Official Information Act. Most notable is any reference to dental health programmes operating in schools during this time. This confounding factor is not allowed for in the analysis. More importantly, the NDHB confirmed that various groups (mainly those supporting the study) implemented their own initiatives, but the NDHB did not allow for these in its data collection or analysis. This fact alone negates the possibility of determining what effect fluoridation was having.

Moreover, co-researcher Dr Croucher has described a school tooth-brushing programme run during the trial as highly successful. Consequently it is impossible to say what caused any benefit if this is not controlled for in the analysis.

Socioeconomic status was recorded by the school decile rating. This is invalid. It is well accepted that SE status must be determined on an individual basis. Further, the school TEFA ratings have been widely criticised as inaccurate. In the Lee and Denniston study, for example, one school supposedly moved from decile 3 to decile 8 in one year. This is not possible.

The Report does not identify eruption rates of the 5 year olds. This is a fundamental flaw in any study for two reasons:

1. There is a significant body of evidence that fluoridation delays eruption of both permanent and deciduous teeth by approximately one year on average. If correct, age comparison of children is therefore irrelevant, and gives a false impression of benefit;
2. European's teeth erupt at different ages than non-Europeans'. Again, this makes age comparisons irrelevant. Non-European data must be separated from European data.

Some children lived in unfluoridated areas but went to school in fluoridated areas. It is not explained how these children were categorised.

As with Dr Thomson's 2005 Southland study report, various statistically meaningless demographic slices are reported. For example male and female impacts are reported.

But this is meaningless unless controlled of other confounding factors. So we would need to see results for each of the following male/female splits (yielding six sets of data, or more if all confounding factors were analysed for):

- European
- non-European
- Socioeconomic status (high/low at least)

Similarly, for ethnicity we would need to see these by:

- Male
- Female
- Socioeconomic status (high/low at least)

With such a range of subsets required for reliable analysis, the overall sample size is too small to provide sufficient subjects in each subset. No assessment of the possibility of multivariate analysis is discussed in the report.

Fluoridation levels

The fluoridation levels achieved were significantly below target according to the report.

Kaitaia only had the level of fluoride the NDHB believes reduces dental decay for 5 months of the trial, the Kaikohe Taraire Hills plant had the required levels for only 2 months, and the other Kaikohe plant *never* had the required level!

If the benefit were real, this would negate fluoridation promoters' claim that 0.7 ppm is the minimum level that will have benefit.

Another perspective is that with such low levels of fluoride exposure, any benefits seen are unlikely to have been caused by fluoridation in light of 60 years of fluoridation promoters' claims and research focused on a minimum added delivery of 1 mg/day, and the demonstrated absence of any topical benefit at concentrations below 1.5 to 2 ppm. The Report's recommendation is seen as unjustifiable and disingenuous in this context.

Absence of independent peer-review

The "peer reviewer" was Dr Thomson, of Otago Dental School. Dr Thomson has been involved in this medical experiment from the outset. His position and salary are dependent on his support for fluoridation. As such he cannot be considered an independent peer-reviewer. The NDHB has steadfastly refused to allow any independent peer-review of its data. We consider that this report demonstrates why it does not what proper scrutiny of the data – such scrutiny would expose the total inadequacy of the trial, and illegitimacy of the conclusion and recommendation – repeated exactly as stated by the researchers the year before the trial even began – a clear demonstration of pre-determination.

Intervention or observation study?

The information in section 1.4, pages 7 and 8, demonstrates that this was an intervention study – the Far North District Council was persuaded to fluoridate two

communities only on certain bases, including the study on dental health and full subsidies for this period. Fluoridation was to continue only for the period of the study. Yet the researchers' application to the Northern Y Ethics Committee claimed that the FNDC decided, independently of the NDHB, to implement fluoridation as a public health measure. This report goes a long way to confirm that the application misrepresented the nature of the study –as an observation study when it was actually an intervention study. The researchers' failure to advise residents of potential adverse health effects from the fluoridation therefore breaches published standards for intervention studies (National Ethics Advisory Committee, 2009). More importantly, this strengthens the case that this exercise was a breach of section 10 of the NZ Bill of Rights Act 1990 – the right to not be medically or scientifically experimented on without informed consent.

Omissions from the literature review

The literature review was derived from two medical databases. The Public Health Commission, to which the researchers refer, identified that these databases rarely list research adverse to fluoridation. With this knowledge, to limit the search to these databases is academically dishonest.

The report references the York Review (McDonagh et al) but omits its relevant findings. The York Review conducted a systematic review of all published population studies available at that time (2000). It found that 90% were scientifically worthless. The remaining 10% were only graded "B: moderate reliability". The Northland report does not identify which grading was given to the pre-2000 studies it quotes, but none is scientifically sound according to York.

The York Review reported on only B grade studies regarding caries impact of fluoridation, as follows:

- 1 found an increase in decay from fluoridation
- 10 found no effect
- 19 found some benefit, ranging from minimal to a claimed 64%

It concluded that no firm conclusion in allegations of benefit could be drawn from any of these studies, or from a simple average, given the divergence of results.

The Report refers to studies by De Liefde, but omits her 1998 study published in the NZ Dental Journal. This study found no clinically significant difference in decay rates between fluoridated and unfluoridated communities. It also found that decay rates had been declining at exactly the same rate in both fluoridated and unfluoridated communities.

The Report refers to Lee and Denniston, 2004; a study never accepted by any international journal. Yet it omits Armfield and Spencer's Australian study published the same year, in the international journal *Community Dentistry and Oral Epidemiology*. This is arguably the best study published since York, and is highly relevant to NZ. It found no benefit from fluoridation beyond age 12 (without considering the possibility of delayed eruption as a cause of apparent benefit). It also found that socioeconomic status was the key determinant of dental health regardless of fluoridation status.

To omit these studies is simple academic dishonesty.

In 2005, an article in the medical journal *Lancet* stated that fluoridation promoters continue to quote unreliable studies to support their cause. The literature review is a further example of this.

Misrepresentation of quoted studies.

The Report quotes MacKay and Thomson 2005, and Kanangaratnam 2009, as finding benefit from fluoridation. This is incorrect.

Both studies found a doubling in the incidence of dental fluorosis resulting from fluoridation.

Kanangaratnam reported no consistent benefit from fluoridation.

MacKay and Thomson’s study found no benefit by the standard measures of DMFT or percent caries-free. They then did a “multivariate analysis”, which miraculously claimed to show a 50% benefit. This is simply not credible.

The executive study mentioned only the result of the multivariate analysis; not the other data. This is academically dishonest.

It is important to note that “Thomson” is the same Thomson involved in the Northland study design, where he has used the same strategy. There was no benefit shown in the dental data, so radiographic detection of lesions was used to claim a benefit. But if the lesions had not become detectable by sight, they may well have self-repaired – there are always spots on the teeth that can turn into decay – or not. To claim benefit based on this one, non-standard, method while standard data show no benefit is scientifically unsound.

Dental health in the Far North is not the worst in New Zealand as incorrectly claimed on page 7. Other areas such as Tairāwhiti, which includes *fluoridated* Gisborne, have similar or higher levels of decay according to national data published by the Ministry of Health (prepared by Dr Gowda).

Ministry of Health data

Ministry of Health figures over the same period are as follows:

Year 8 children

	F	non F	All		F	non F	All
2006			2.42				
2007	3.97	2.13	2.40				-0.9%
2008	1.31	2.04	1.84	-67.1%	-4.5%		-23.4%

5 - 6 year old children

	F	non F	All			
2006			3.99			
2007	4	4.55	4.53			13.5%
2008*	5.86	3.56	3.79	39.3%	-21.7%	-16.3%

Study only	2009	5.60	47.7%
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* only 63 fluoridated children in this sample.

First we note these were compiled by Dr Gowda, who wrote the study Report.

The alleged decrease from 3.97 DMFT to 1.31 DMFT (Year 8 children) from 2007 to 2008 is simply not credible as anything other than a natural statistical variation. It certainly could not be due to fluoridation, as the majority of DMFT would have already been evident by age 11, at the start of fluoridation.

If the study data are correct for 5-6 year olds, there was a 48% increase in decay in the second year of the study. This is a 40% increase since 2006 – the year before the study began.

These variations dwarf those recorded in the study Report. On this ground alone we consider that no reliable conclusion can be drawn from the Northland study data.

Study results

A highlight of the report was the results from unfluoridated Kawakawa and Moerewa. These showed a remarkable improvement compared with the fluoridated towns, which showed far less. Specifically, unfluoridated Kawakawa/Moerewa went from 36% higher to 20% lower in dmfs rates than fluoridated Kaitaia over the study period.

By all decay measures, there were both increases and decreases in decay in both fluoridated and unfluoridated groups. The results varied by 30 or 40%. To talk of 5% or 15% claimed improvements from fluoridation, when annual variation is up to 40%, is nonsensical.

The large percentages quoted reflect relatively small changes in small numbers. In such circumstances, percentages are meaningless without absolute values being quoted simultaneously.

We do not consider that there is any value in discussing individual figures when the results are so internally inconsistent. This is especially so when the methodology and equipment failure make any results scientifically worthless.

This critique was prepared by Mark Atkin BSc(Chem), on behalf of Fluoride Action Network NZ Inc.