32nd WEDC International Conference, Colombo, Sri Lanka, 2006

SUSTAINABLE DEVELOPMENT OF WATER RESOURCES, WATER SUPPLY AND
ENVIRONMENTAL SANITATION

Health-based risk targets for fluorosis in tribal children of rural Madhya Pradesh, India

S. Godfrey, S. Wate, P. Kumar, A. Swami, S. Rayalu, R. Rooney, India

Conventional approaches to fluorosis mitigation and control are based on reduction of excess fluoride consumption from water. Country specific standard limits of 1 mg/l or 1.5mg/l are established and monitored by water departments based on recommendations outlined in the World Health Organization (WHO) Guidelines for Drinking Water Quality (GDWQ). With the advent of the third edition of the WHO GDWQ there is a fundamental departure from standard setting, based on dose-response affect, towards risk assessment and risk management. The water quality framework, outlined in the guidelines, consists of an iterative cycle, comprising: an assessment of risk, health targets linked to the wider public health context; risk management (with these components being informed by aspects of environmental exposure and acceptable risk) The guidelines advocate for the use of Water Safety Plans, as risk management tool, to help achieve Health Based Risk Targets. This paper presents the application of a Quantitative Chemical Risk Assessment (QCRA) method for determining health based risk targets for fluorosis control. The paper presents evidence from Madhya Pradesh, India. The findings indicate firstly that to control fluorosis total daily consumption from all exposure routes (water and food) must be considered, secondly that the most exposed population group to fluorosis are children due to lack of alternative early nutrients (e.g. exclusive breastfeeding) and, thirdly, that quantifying chemical risk is essential for appropriate risk management strategies to reduce fluorosis in children.

Introduction

Standard approaches to fluorosis mitigation are based on the identification of crystalline biotite/hornblende gneisse rocks which are laden with fluorite, tourmaline, sphene and topaz (Driscoll,1986). Mitigation measures include community and household level defluoridation units using assorted media such as ion exchange, activated charcoal, and / or charred bone meal (Gan Feng *et al*, 2005). However, despite global efforts to combat fluorosis, cases of recorded skeletal and dental fluorosis remain endemic in many developing countries including India (Dissanayake, 1996)

Recent research from East Africa and China suggests that one reason for the increasing prevalence of fluorosis is lack of knowledge about alternative routes of exposure. Recent studies by Cao *et al* (2003), Lian Feng (1995) and Mwaniki (1993) identify food as a potential hazard and states that food consumption may increase the risk of fluorosis. Indeed, studies indicate that the establishment of a water quality standard of 1 to 1.5 mg/l for fluoride consumption, through drinking water alone, is not enough to mitigate the adverse health affects of fluoride.

Furthermore, studies by *Erdal et al* (2005), in the USA, identified children as the most affected segment of the population. Thus, children are a high priority group when quantifying the health risk of excess fluoride. *Erdal et al* (2005) states that young children are more susceptible to skeletal and non-skeletal manifestations of fluorosis, than adults due to low calcium strength in early bone development in infants as well as excess exposure to fluoride in toothpaste and food/water.

However, neither *Erdal et al* (2005), Cao *et al* (2003), Lian Feng (1995) nor Mwaniki (1993) quantify levels of acceptable health based risk. Although the studies identify susceptible age groups, and alternative routes of exposure to fluorosis, neither study provides methods for quantifying the acceptable risk to children.

This paper, therefore, explores appropriate methods of quantifying the health risk of fluoride contamination, in water and food, for children. Based on the generic quantitative risk assessment paradigm outlined in the third edition of the WHO GDWQ (WHO, 2004), this paper applies risk assessment principles for establishing health based targets. While health targets and outcomes are local or national in character, they can be informed by an acceptable risk which provides a means to support the development of nationally-relevant targets, adapted to specific local conditions.

In line with similar work undertaken by Howard *et al* (2006), Jones *et al* (2005), Haas *et al* (1999) and Havelaar *et al* (2003), for quantifying microbial risk, this paper explores the use of a Quantitative Chemical Risk Assessment (QCRA) technique. Similarly, recent work undertaken by Fewtrell *et al* (2006) attempted to estimate the disease burden associated

with fluorosis. This paper reinforces the work by Fewtrell *et al* by providing a QCRA field-based assessment. This QCRA was applied in selected villages in Madhya Pradesh, India. Risk Management (Water Safety Plans) were then developed based on the findings of the QCRA.

Materials and methods

The Study was undertaken in the central Indian State of Madhya Pradesh. Data were collected from the two districts of Dhar and Jhabua in Western Madhya Pradesh. These districts have high levels of fluoride in 453 villages and 282 villages, in Jhabua and Dhar respectively. The main source of water is groundwater. This source is prone to acute shortages for the majority of the year.

To address both fluoride contamination and water availability problems, six communities were selected for the study in the two districts mentioned above. Households were selected for Quantitative Chemical Risk Assessment (QCRA) of fluoride by using the statistical t-test based on 2 comparable means from 2 variables; existing levels of fluoride contamination (mg/l) and population served. Using the t-test, the number of households required for the QCRA with 95% confidence level of estimating average levels of contamination within 2 % of the true value was calculated using Equations (1) and (2):

$$n_o = \frac{\{t\,S\}^2}{r\,Y^2} \qquad (1)$$

Where:

n_o : first approximation of sample size

t : confidence probability (t statistics). This value is 1.64, 1.96 and 2.58 for confidence probabilities of 90, 95 and 99 % respectively

S: population standard deviation

r : relative error

Y : population mean

$$n = \frac{n_o}{\left(1 + \dfrac{n_o}{N}\right)} \qquad (2)$$

Where:

n : sample size

N : population size

n_o : first approximation sample size (see Equation (1))

The QCRA is summarized as follows:
- Hazard Identification – to identify fluoride routes of transmission (e.g. from food and water)
- Dose-response assessment – characterization of the relationship between doses and incidences of adverse health affects in exposed population
- Exposure assessment – measure or estimate of the route, amount and frequency of duration of human exposure,

Table 1. t-test selected families

Village/School	Fluoride Level range (mg/l	Population (families)	t-test families
Jhabua			
Tikai Jorgie	1.7-4.16	1209	26
Charolipada	2.03-8.83	1001	21
Pithanpur	2.72-9.44	2036	39
Dhar			
Aadvi	0.6-2.6	530	30
Shikarpura	2.4-5.07	730	35
Jamanpati	4.01-8.46	768	30

- Risk characterization – integration of the above information to estimate the magnitude of the public health problem.

For data collection, water and food samples were taken by the National Environmental Engineering Research Institute (NEERI), Nagpur, India following standard AWWA/APHA (1998). The Cereals (Maize, Wheat, Rice), Pulses (Red, Green and Black grams) were collected from different households, whereas toothpaste, tooth powder, tea, tobacco, local wine, milk powder and pan masala samples of different brands were procured from local markets. See table 2 for methods.

During the QCRA survey the severity of fluorosis amongst different age groups and tolerable risks for fluoride were calculated by undertaking prescribed physical exercises (Susheela 2004). These exercises are illustrated in Figure 1.

Table 2. Materials and Methods

Sr. No	Sample Matrix	Method	Analytical Method
1	Water/ Wine	10 to 25 ml sample diluted in equal volume of TISAB buffer	Ion Selective Electrode
2	Tea	10 g dried tea sample poured in 400 ml of boiling deionized water; 25 ml of tea liquor in which TISAB solution is added	Ion Selective Electrode
3	Cereals/ Pulses/ vegetables/ Tobacco	Sample Dried, Powdered, Sieved, Digested with HCl (Conc.); dissolve in citrate buffer	Ion Selective Electrode
4	Tooth Paste/ Tooth Powder	~ 0.05 g sample diluted in 25 ml TISAB solution boiled; suspension make up with distilled water	Ion Selective Electrode

Data Analysis

Data analysis was undertaken following a four step methodology of hazard identification, exposure assessment, dose-response and risk characterization.
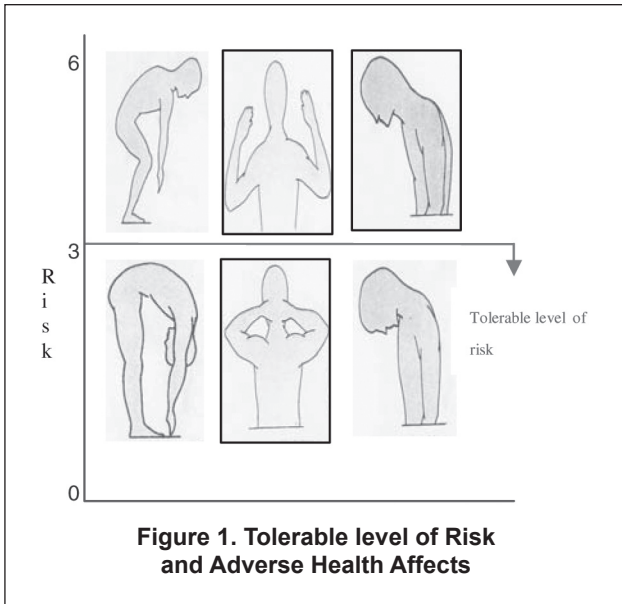
Figure 1. Tolerable level of Risk and Adverse Health Affects

Comparative fluoride concentration in food and water

Comparative fluoride concentration in food and water

Figure 2. Fluoride source

Hazard Identification

Firstly, the hazard identification indicated that the concentration of fluoride in water ranged from 0.3 to 1.5 mg/l in the communities selected. Similarly, fluoride in food samples ranged from 0.005 to 1.1 mg/kg dry weight. The comparative concentrations of fluoride in food and water are depicted in Figure 2.

Figure 2 clearly indicates that both drinking water and food contain fluoride. Further analyses of the data indicate that the intake from food or water is dependent on age groups.

Based on the findings of the QCRA the following observations were made:

- Consumption of cereal foods increased in the adolescent and young adult tribal population. This is due to the high drop out of school attendance initiation as agricultural workers which results in higher calorific demand for cereal foods during manual labour.
- Consumption of cereal foods was also noted as higher in infants (weight less than 10kg) due to the traditional practice of lower levels of breast feeding and supplementation of infant food with rice water
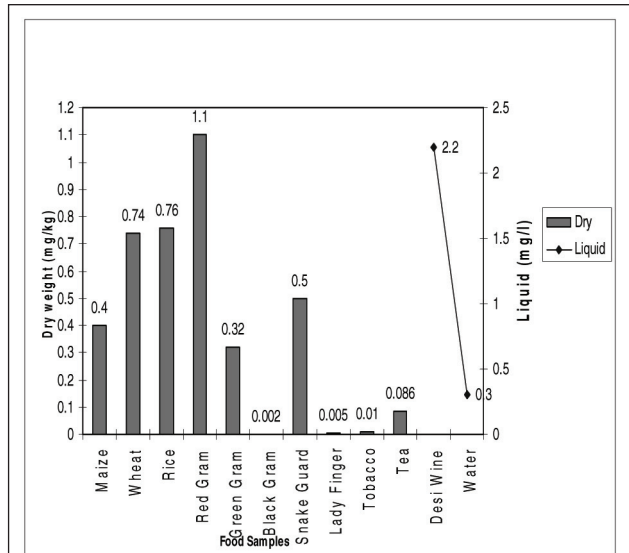- In Children (0-12 Yrs.) the ratio of 58 to 42% fluorides in food to water was observed.

Exposure assessment

Secondly, the exposure assessment is required to determine the tolerable daily intake levels, for different age groups, from food and water. An estimated total daily intake (TDI) is calculated using Equation 3:
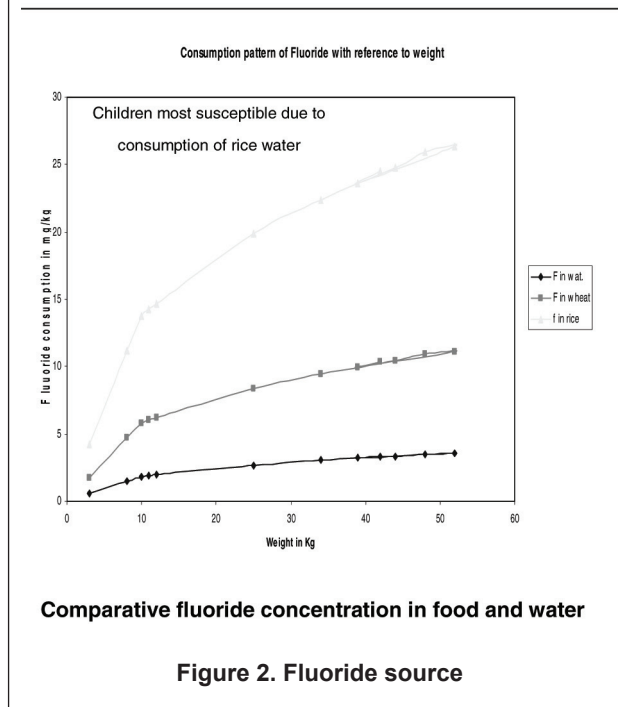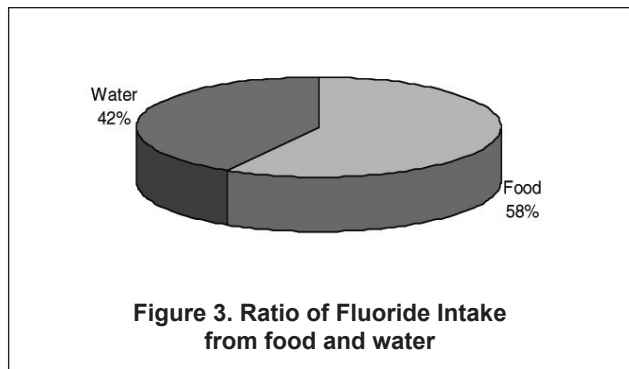
$$TDI = \frac{(NOAEL \ or \ LOAEL)}{UF} \qquad (3)$$

Where;
- NOAEL and LOAEL are not observed and lover observed adverse limits
- UF stands for uncertainty factor.

Figure 3. Ratio of Fluoride Intake from food and water

In this study the maximum TDI value for all exposure routes was observed in the range from 0.4 to 0.6 mg/kg. To determine the most susceptible age group, three age groups i.e. 0-12, 13-20 and >20 where selected. For each a guideline value was calculated using Equation: 4

$$GV = \frac{(TDI \times BW \times P)}{C} \qquad (4)$$

Where;
- GV = Guideline Value
- TDI = Total Daily Intake
- BW = Body Weight
- P = Fraction of TDI fraction allocated to drinking water
- C = Daily drinking-water consumption

The calculated guideline values for different age groups are outlined in Table 3.

Table 3. GV for age groups

Sr. No	Age groups	Guideline Values, mg/kg
1	0-12 (Children)	3.44
2	12-20 (Adolescent)	5.71
3	>20 (Adult)	5.38

Dose Response

Thirdly, the health effects associated with fluoride ingestion were described. These include symptoms such as nausea to neurotoxic effects to death (Mullins *et al.* 1998; Vogt *et al.* 1982). Dental and skeletal fluorosis is the common manifestation of high fluoride intake. Dental fluorosis occurs as permanent teeth are forming and is characterized by permanent hypo mineralization. Elevated intake of fluoride over prolonged periods of time may result in skeletal fluorosis, i.e., an accumulation of fluoride in the skeletal tissues associated with pathological bone formation.

The health survey reveals that dental and skeleton fluorosis is predominant in the study area. A LOAEL/NOAEL analysis indicates that around 90% of affected population, with prevalence of 120.7 persons per thousand persons, is above the tolerable risk level of 1:1000 outlined by USEPA (Havelaar *et al* 2003)

However acceptable risk limits may vary depending on the present health status of the population concerned. For this study, acceptable risk limits were based on a point scale methodology adapted from Susheela (2004) to ascertain DALY (Disability Adjusted Life Years). These were calculated based on methods outlined in Havelaar *et al* (2003) with background data from Murray *et al* (1996).

To calculate the DALYs a three step methodology was used. Firstly, the number (proportion) of people affected by

fluorosis was determined from field data. Secondly, the prevalence of fluorosis was calculated based on median number of years affected by fluorosis per 1000 population. Finally, the susceptibility fraction was calculated as the probability of death per symptomatic case (CFR) see equation 5.

$$\text{Prevalence level} = \frac{\text{No. of People affected above tolerable level (i.e. 3)}}{\text{Total Population}} \times 1000$$

The average life expectancy in Madhya Pradesh is 55 as a mean value for male and females (Government of India 2001). The prevalence was calculated as follows:

The formulas used for calculating the DALY are as outlined in Cooper *et al* (1998). The data can be summarized as follows:
- No of healthy life years (55) x the disability weight of full health (0) + life years with disability (25) x disability weight for fluorosis (0.33) + life years lost (30) x the weighting of death (1)
- 55 x 0 + 25 x 0.33 + 30 x 1 = 56.4 per 1000

DALY scores of 56/1000 are higher than those recorded in recent studies of Arsenic in South Asia (APSU 2006).

Discussion

Findings from the QCRA highlight the importance of establishing guideline values for fluoride intake from both food and water. A maximum Tolerable Daily Intake (TDI) value for all exposure routes was observed in the range from 0.4 to 0.6 mg/kg. The guideline value for fluoride content in drinking water in three different age group ranged from 3.4 to 5.7mg/l total tolerable daily intake dependent on age. From a health perspective, the highest risk groups were children. The study therefore suggests that specific child based fluoride levels may be required.

Additionally, food and water interventions are required to manage the risk. A 58 to 42% ratio of fluoride in food to water was observed. Therefore, to manage the risk of fluorosis a comprehensive risk management strategy is needed. This may include supplementation of food with calcium or magnesium rich vegetables and/or promotion of exclusive breastfeeding.

To ensure adequate operation and maintenance of the dilution technology a water safety plan may be adopted. The principles for a Water Safety Plan (WSP) were developed from the approach outlined in the water quality framework. The first stage is to undertake a preliminary assessment to see whether the health -based targets, as set, are likely to be met using the existing water supply infrastructure (i.e. system assessment). If the system is theoretically capable of meeting the targets, the WSP is the management tool that will assist in meeting the targets. Targets may be met by preventing contamination of source waters, using dilution techniques. Reducing or removing contamination that is present through treatment processes or preventing re-contamination during storage, distribution and handling of drinking water.

Conclusions

The conclusion of the QCRA for this tribal study area includes:

1. To control fluorosis total daily consumption from all exposure routes (water and food) must be considered,

2. The most vulnerable population group to fluorosis are children due to lack of access to alternative early nutrients (e.g. exclusive breastfeeding),

3. Quantifying chemical risk is essential for appropriate risk management strategies required for reducing fluorosis in children,

4. QCRA health based risk approach is essential for national water quality target setting.

References

Arsenic Policy Support Unit (2006) www.apsu.org

AWWA and APCF (1998) *Standard Methods for the Examination of Water and Wastewate*r. American Water Works Association. McGraw Hill: New York

Cao, J.,(2003) *Brick tea fluoride as a main source of adult fluorosis*. Food and Chemical Toxicology, Vol. 41, pp. 535-542.

Cooper, R. Osotimehin, B, Kaufman, J. Forester, T. (1998) *Disease burden in sub-saharan Africa: what should we conclude in the absence of data*. The Lancet, Vol. 351, pp 208-210

Dissanayeke, C.B, (1996) *Water quality and dental health in the dry zone of Sri Lanka, in Environmental Geochemistry and Health*. J. Appleton, D., Editor. The Geological Society: London.

Driscoll, F. (1986) *Groundwater and Wells*, Reynolds Guyar Designs; USA, 2nd edition, pp 1089

Erdal S. and Buchanan S.N., (2005), *A Quantitative Look at Fluorosis, Fluoride Exposure and Intake in Children Using a Health Risk Assessment Approach*. Environmental Health Perspectives, Vol. 113 No.1, pp. 111-117

Fewtrell, S. Smith, S. Kay, D. Bartram,, J. (2006) *An attempt to estimate the global burden of disease due to fluoride in drinking water*, Journal of Water and Health, in press

Government of India (2001), *National Human Development Report*. Planning Commission New Delhi

Havelaar, A, Melse, J, (2003) *Quantifying public health risk in the WHO Guidelines for Drinking Water Quality – A burden of disease approach*. RIVM Report 734301022

Howard, G, Pedely, S, and Tibatemwa S., (2006) *Quantitative microbial risk assessment to estimate health risks attributable to water supply: Can the technique be applied in developing countries with limited data. Journal of Water and Health*, Vol. 4, pp 49-65

Jones, MA, Stauber, J, Apte, S, Simpson, S, Vicente Becket, V, Johnson, R, Duivenvoorden, L (2005) *A risk assessment approach to contaminants in Port Curtis, Queensland, Australia*. Marine Pollution Bulletin, Vol. 51, pp 448-458

Lian-Feng, W. and H. Jian-Zhong, (1995) *Outline of control practices of endemic fluorosis in China*. Social Science and Medicine. Vol.41 No.8, pp. 1191-1195.

Mullins M, Warden C, Barnum D. (1998), *Pediatric death and fluoride-containing wheel cleaner* [Letter]. Ann Emer Med., Vol. 31, pp.523-525.

Murray, C, Lopez, A. (1996) *The global burden of disease, Cambridge Massachusetts*. Harvard School of Public Health, WHO/World Bank

Mwaniki, D., L., J. Courtney, M., and J. Gaylor, D., (1994), *Endemic fluorosis: and analysis of needs and possibilities based on case studies in Kenya*. Social Science and Medicine, Vol.39 No.6, pp. 807-813.

Susheela, (2004) *Endemic fluorosis in India*. All Indian Institute of Medical Sciences, New Delhi.

Vogt R.L, Witherell L, LaRue D, Klaucke D.N., (1982) *Acute fluoride poisoning associated with an on-site fluoridator in a Vermont elementary school*. American Journal of Public Health, Vol. 72, pp.1168-1171.

Contact address

S. Godfrey
Water and Environmental Sanitation,
UNICEF, Bhopal, India

S. Wate
National Environmental Engineering Research Institute (NEERI), Nagpur, India

P. Kumar
Water and Environmental Sanitation,
UNICEF, Bhopal, India

A. Swami
Water and Environmental Sanitation,
UNICEF, Bhopal, India

S. Rayalu
National Environmental Engineering Research Institute (NEERI), Nagpur, India

R. Rooney
South East Asia Regional Office (SEARO)
World Health Organization New Delhi, India