

## C12: Other Adverse Effects: Individual Study Results

### 1. Cohort and Ecological Studies

#### a. Studies which present adjusted outcomes

Study Details	Outcome	Group	Exposure	Crude Risk Males/ 100 000	Crude Risk Females/ 100 000	Summary Measure (CI):	
						Details	Male
Erickson (1978)	Deaths from all causes classified into 34 categories	Group 1: Control:	>0.7 <0.7	3572.8 3160.8		<b>Measure used:</b> Rate ratio <b>Variables controlled for:</b> Age-sex-race standardised mortality rates controlled for city population density and median education, weighted for black and white 1970 populations,	1.01 1
Forbes (1997)	Alzheimer's disease reported as the underlying cause of death	Group 1: Group 2: Control:	>=0.98 0.5-0.98 <0.5			<b>Measure used:</b> Odds ratio <b>Variables controlled for:</b> Aluminium, iron and silica content of drinking water, water pH and water source	1.22 (1.00-1.47) 0.80 (0.59-1.07) 1.0
	Rate of impaired mental functioning	Group 1: Control:	>=0.8 <0.8		38035.3 48611.1	<b>Measure used:</b> Odds ratio <b>Variables controlled for:</b> Water concentrations of aluminium and iron, water pH and source	0.49 (0.27-0.89) 1.0
Griffith (1963)	Anaemia during pregnancy	Group 1: Group 2: Group 3: Control:	1.0 <0.1			<b>Measure used:</b> Rate difference <b>Variables controlled for:</b> Not controlled for any variables	2.03 (SE = 3.57)

#### b. Studies which present standardised results

Study Details	Outcome	Group	Exposure	Exposure Level	Crude Risk Males/ 100 000	Crude Risk Females/ 100 000	Standardisation				
							Methods	SMR		Standardised rate	
								M	F	M	F
Erickson (1978)	Deaths from all causes classified into 34 categories	Group 1: Control:	Water fluoride level	>0.7 <0.7	3572.8 3160.7	<b>Method used</b> Indirect <b>Standard population</b> Deaths and populations of all cities pools	1156.0 1102.4				
Erickson (1980)	Births with congenital malformations	Group 1: Control:	Water fluoride level	>=0.7 <0.7	650.5 650.4	<b>Method used</b> Indirect <b>Standard population</b> Age-specific rates in all study areas combined		65.1 65.0			
	Births with Down's Syndrome	Group 1: Control:	Water fluoride level	>=0.7 <0.7	41.1 44.1		4.1 4.4				
Hagan (1954)	Average yearly deaths from all causes	Group 1: Control:	Water fluoride level	>=0.7 <=0.25		<b>Method used</b> Direct <b>Standard population</b> 1950 US population, results standardised for age, sex and race (stated that used indirect, but actually used direct method)	1010.6 1005.0				

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### c. Studies which present crude results only

Study Details	Outcome	Group	Exposure	Exposure level	Crude Risk /100 000	
					Male	Female
Berry (1958)	Number of births with Down's syndrome per 1000 births	Group 1:	Water fluoride level	0.7-1.1	159.0	
		Group 2:		1.9-2.0	122.4	
		Group 3:		0.9	137.0	
		Group 4:		<0.2	190.2	
		Group 5:		<0.2	164.0	
		Group 6:		<0.2	164.8	
		Group 7:		<0.2	107.6	
		Group 8:		<0.2	131.0	
		Group 9:		<0.2	153.4	
Erickson (1976)	Number of births with Down's syndrome per 10 000 births: data from Metropolitan Atlanta (1960-1973)	Group 1:	Water fluoride level	High	9.9	
	Number of births with Down's syndrome per 10 000 births: Data from NIS surveillance areas (1961-1966)	Control:		Low	8.5 (p<0.05)	
		Group 1:		High	4.9	
	Number of births with All congenital malformations per 10 000 births: data from Metropolitan Atlanta (1960-1973)	Control:		Low	5.1 (p<0.05)	
Number of births with All congenital malformations per 10 000 births: Data from NIS surveillance areas (1961-1966)	Group 1:	High	292.6			
	Control:	Low	270 (p<0.05)			
Needleman (1974)	Cases of Down's syndrome	Group 1:	Water fluoride level	1	153.1	
		Control:		<0.3	133.8	
Rapaport (1957)	Prevalence of Down's syndrome	Group 1:	Water fluoride level	0.1-0.2	6.0	
	Prevalence of Down's syndrome	Control:		0.0	3.9	
		Group 1:		>3	34.8	
	Control:	<3		15.2		
	Prevalence of Down's syndrome	Group 1:	2.8	30.3		
		Group 2:	1.4	32.5		
		Group 3:	0.5	25.4		
		Control:	0.1	13.5		
Prevalence of Down's syndrome	Group 1:	1.6-2.6	Water fluoride level	1.6-2.6	14.4	
	Group 2:	1.0-1.2		1.0-1.2	11.4	
	Group 3:	0.4-0.7		0.4-0.7	12.2	
	Control:	0.3		0.3	6.6	
Rapaport (1963)	Infant mortality	Group 1:	Water fluoride level	>2.0	979.7	
	Incidence of Down's syndrome per 100 000 births	Control:		<1.0	775.0	
Group 1:		1.0-2.6	71.6			
Group 2:		0.3-0.7	47.1			
Group 3:		0.1-0.2	39.2			
Control:	0.0	23.6				
Jooste (1999)	% Prevalence of goitre	Group 1:	Water fluoride level	2.6	28961.7	
		Group 2:		1.7	27659.6	
		Group 3:		0.9	18390.8	
		Group 4:		1.1	5263.2	
		Group 5:		0.3	15294.1	
		Group 6:		0.5	17322.8	
Farkas (1983)	Median age at menarche	Group 1:	Water fluoride level	1.09		12.78
		Control:		0.17		12.79

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Study Details	Outcome	Group	Exposure	Exposure level	Crude Risk /100 000	
					Male	Female
Jacqmin – Gadda (1994)	Cognitive impairment (used as major clinical sign of Alzheimer's)	Group 1: Group 2: Group 3: Control:	Water fluoride level	0.6-2.03 0.11-0.6 0.07-0.11 0.03-0.07		23801.9 24417.8 22906.4 25511.8
Still (1980)	Primary degenerative dementia	Group 1: Group 2: Control:	Water fluoride level	4.18 0.49 0.61	26.1 159.2 140.3	31.6 171.5 133.6
Zhao (1996)	IQ	Group 1: Control:	Water fluoride level	4.12 0.91	98.1 (13.2) 105.8 (15.0)	97.3 (12.9) 105.0 (15.0)

## 2. Before-After Studies

Study Details	Outcome Presented	Group	Fluoride level	Outcome 1	Outcome 2	
Briner (1966)	Crude mortality rates (per 10 000) for 1953 and 1963				<b>Mortality (SE)</b>	
		<b>Baseline:</b>				
		Group 1:	low		180	
		Group 2:	0.6-0.7		130	
		Control:	low		140	
Overton (1954)	Incident rate per 1000 live births for infant mortality and per 100 live and still births for still births				<b>Infant mortality (SE)</b>	<b>Still births (SE)</b>
		<b>Baseline:</b>				
		Group 1:	low		36.4	27
		Control:	low		43.1	27.7
		<b>Final:</b>				
Group 1:	1-1.2		27.6	18.7		
Control:	low		30.6	18.8		
Rogot (1978)	Average mortality ratios for deaths from all causes, indirectly standardised for age, sex and race using US specific rates for 3 year period 1959-61				<b>Mortality (SE)</b>	
		<b>Baseline:</b>				
		Group 1:	Low		1.13	
		Group 2:	>=0.7		1.19	
		Control:	<0.7		1.16	
<b>Final:</b>						
Group 1:	>=0.7		0.97			
Group 2:	>=0.7		0.96			
Control:	<0.7		0.99			

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Study Details	Outcome Presented	Group	Fluoride level	Outcome 1	Outcome 2	
Schatz (1976)	Number of deaths per year for 1954 and 1964			<b>Mortality (SE)</b>		
		<b>Baseline:</b>				
		<i>Group 1:</i>	low	837		
		<i>Group 2:</i>	0.67	596		
		<i>Control:</i>	low	441		
		<b>Final:</b>				
Schatz (1976) (continued)	Average yearly number of stillbirths and infant deaths per 1000 total births (number of subjects = number of births)			<b>Mortality (SE)</b>		
		<b>Baseline:</b>				
		<i>Group 1:</i>	low	335		
		<i>Group 2:</i>	0.67	275		
		<i>Control:</i>	low	198		
		<b>Final:</b>				
Weaver (1944)	Crude death rates for deaths from all-causes			<b>Mortality (SE)</b>		
		<b>Baseline:</b>				
		<i>Group 1:</i>	1.4	12.9		
		<i>Control:</i>	<0.25	11.9		
		<b>Final:</b>				
		<i>Group 1:</i>	1.4	13.4		
<i>Control:</i>	<0.25	12.1				

### 3. Case-Control Studies

Study Details	Outcome	Number of Subjects per Group	Exposures	Level of Exposure in Cases	Level of Exposure in Control 1	OR for Exposure
Dick (1999)	Postneonatal deaths attributed to SIDS	379	<b>Exposure 1:</b> >80% of population served with fluoridated water (artificially fluoridated to 1ppm) <b>Exposure 2:</b> <20% of population served with fluoridated water (artificially fluoridated to 1ppm)	227 152	944 606	1.19 (0.82-1.74) 1.0

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### 4. Cross –Sectional Studies

Study Details	Outcome Details	Exposure	Water Fluoride Level	Number of Subjects	Results (% prevalence)
Jolly (1971)	Skeletal fluorosis (%)	Fluoride level	0.7-9.4	Not stated	The prevalence of skeletal fluorosis showed an increase with increasing water fluoride levels. The prevalence of skeletal fluorosis ranged from 45 at water fluoride levels of 0.7ppm to 70% at levels of 9.4ppm
Gedalia (1963)	% with enlarged thyroid	Fluoride level	<0.1 <0.3 0.3 0.7 – 0.9	692 979 604 410	17 30 2.6 4.7
Lin (1991)	Goitre	Fluoride level	0.88 0.34	250 256	91 82