Paper to the North West PCT Chief Executives Meeting – June 2008

Report of	Peter Rowe – Chief Executive, Ashton, Leigh and Wigan Primary Care Trust, and Lead North West PCT Chief Executive for Water Fluoridation Evaluation
Paper prepared by	Anna Delves – Fluoridation Evaluation Group Project Manager Will Blandamer – Director, GM Public Health Network
Date of paper	23rd June 2008
Subject	Outcome of the North West PCTs Evaluation Group on Water Fluoridation
From which group does this paper come?	North West Fluoridation Evaluation Group
History of paper	All North West PCT Chief Executives in March 2007 supported the establishment of the North West Fluoridation Evaluation Group
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Purpose of paper	To report on the work of the North West PCTs Fluoridation Evaluation Group, and to ensure each PCT in the North West has sufficient information to consider the option of fluoridating the water supply as part of their oral health strategy.
Outcome Required (E.g. for decision, for information)	NWFEG recommend that; 1. That the North West PCT Chief Executives meeting receive this report. 2. That the North West PCT Chief Executives meeting note the initial review of potential water fluoridation schemes. 3. That PCT boards consider whether they wish to request the SHA to explore the possibility of fluoridation of the public water supply. 4. That in the event a PCT does request the SHA explore the possibility of fluoridation they express a view on the potential water fluoridation schemes presented in this report. 5. That PCT boards frame a response to the SHA in accordance with the SHA guidance issued 6. That following the production of this report, the NWFEG is disbanded

REPORT OF THE NORTH WEST PCTS FLUORIDATION EVALUATION GROUP

23rd June 2008

Lead PCT Chief Executive: **Peter Rowe**
Ashton Leigh and Wigan PCT

Executive Summary

Primary Care Trusts (PCTs) are responsible for assessing the oral health needs of their population and for commissioning services or interventions required to address identified needs. The executive decision making role for water fluoridation following public consultation lies with the Strategic Health Authority (SHA). In discharging their duty to improve the oral health of their population and in particular to reduce health inequalities in oral health, PCTs are encouraged by the Chief Dental Officer to consider the option of fluoridating their water supplies. (Ref:1 – p 11 para 38)

Following discussion at a meeting of Chief Executives of all North West PCTs' in December 2006, all PCTs in the North West agreed to contribute a relatively small amount of money to the establishment of the North West PCTs' Fluoridation Evaluation Group (NWFEG). This was in recognition of the fact that water flows cross many PCT boundaries and any consideration of water fluoridation requires PCTs to work together. PCT Chief Executives in the North West received confirmation in March 2007 that all PCTs in the North West had agreed to support the work of NWFEG. This report is the outcome of the work of NWFEG and is provided in the first instance for the North West PCT Chief Executives' group as the meeting that commissioned the work.

The report is intended to support each PCT in the North West in meeting the expectation on them to consider the option of water fluoridation as one possible intervention to improve dental health. Every PCT will receive the main report and relevant appendices and each PCT will also receive maps and information of the possible water fluoridation scheme/s identified by NWFEG specific to that PCT. The PCT is thereafter invited to consider whether they would request the SHA to explore the possibility of fluoridation, to include procuring a more detailed cost assessment from the water provider in the North West and also managing any potential subsequent public consultation.

This report provides the following information:

- An overview of the latest DH/Chief Dental Officer Guidance (February 2008)
- An understanding of the population's dental health in the North West
- A summary of the literature surrounding evidence of effectiveness of fluoridation
- An overview of the available evidence on the safety of fluoridation
- An overview of the ethical issues of fluoridation
- A review of public opinion of fluoridation
- An assessment of the technical feasibility of fluoridation in the North West through the consideration of 4 possible fluoridation schemes
- An indication of cost for possible fluoridation schemes.
- Identification of next steps

On the basis of the information provided, the North West Fluoridation Evaluation Group makes the following recommendations:

1. That the North West PCT Chief Executives meeting receive this report.
2. That the North West PCT Chief Executives meeting note the initial review of potential water fluoridation schemes.
3. That PCT boards consider whether they wish to request the SHA to explore the possibility of fluoridation of the public water supply.
4. That in the event a PCT does request the SHA explore the possibility of fluoridation they express a view on the potential water fluoridation schemes presented in this report
5. That PCT boards frame a response to the SHA in accordance with the SHA guidance issued.
6. That following the production of this report, the NWFEG is disbanded.

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Chapter 1 - Background and Context

1.1 Purpose of Paper

In April 2006, PCTs in England were given responsibility through local commissioning for securing primary dental services and improving oral health. The Government had recently produced a document, "Oral Health Plan for England" (Ref 2), which identified the actions required by SHAs, PCTs and primary care professionals to deliver further improvements in oral health. The NHS North West subsequently identified some key measures for PCTs to focus on.

- Improving population oral health in children – measured by the amount of dental decay in children at 5 years old and 11 years old.

- Improving access to dental services measured by the proportion of the population receiving care in a 2 year period, the supply of NHS dental provision and the success of local measures to manage demand for NHS dentistry.

In discharging their duty to improve the oral health of their population and in particular to reduce health inequalities, PCTs

> *"are encouraged to consider the option of fluoridating their water supplies"* (Ref1 – p11 para 38).

PCTs in the North West have noted as part of their oral health strategies that they are awaiting the outcome of the North West Fluoridation Evaluation Group (NWFEG) to inform their consideration of fluoridation as one potential intervention to improve dental health.

This report has brought together, for the benefit of all the PCTs in the North West, background and supporting information about water fluoridation in the North West. This includes:

- Placing the report and background information in the context of the guidance received in February 2008 from the Chief Dental Officer (Ref 1)
- An assessment of the technical feasibility of fluoridation in the North West through the analysis of 4 possible schemes
- Providing an overview of population dental health and dental health inequalities in the North West
- A report commissioned by NWFEG on a summary of the literature surrounding evidence of effectiveness of fluoridation and comparing that with the benefits derived from other possible interventions
- An overview of the available evidence on the safety of fluoridation
- A brief overview of the ethical issues surrounding fluoridation
- A review of public opinion on fluoridation
- An indication of cost for possible fluoridation schemes.
- Identification of next steps

This report is to be received in the first instance by the North West PCT Chief Executives' meeting, as that is the group that commissioned the work of NWFEG.

1.2 Legislative Framework and Chief Dental Officer Guidance February 2008

Arrangements for all existing water fluoridation schemes were made before 1985. The Water (Fluoridation) Act 1985 consolidated in the Water Industry Act 1991 was intended to regularise the legislative framework but it proved ineffective. Section 87 of the Act stated that when requested by Health Authorities, water undertakers (water companies) *"may increase the fluoride content of the water supplied by them within that area".* No new schemes were introduced under this legislation. Water undertakers did not feel equipped to make decisions on what they considered to be a public health issue. New measures were introduced in the Water Act 2003 which included wide ranging

amendments to the provisions on fluoridation of the Water Industry Act 1991. Most significantly an obligation was imposed on water providers and Section 87 now reads

> *"if requested in writing to do so by a relevant authority a water undertaker shall enter into arrangements with the relevant authority to increase the fluoride content in the water supplied by that undertaker to premises within the area specified in the arrangements".* (Ref 3 and with thanks to Ref 12)

In February 2008, the Chief Dental Officer for England, Barry Cockcroft, circulated guidance (1) intended specifically to:

- *"show how fluoridation offers a realistic option of reducing health inequalities which PCTs are encouraged to include in their consideration of measures to improve the oral health of their populations*
- *give updated guidance on the respective roles of strategic health authorities and primary care trusts in planning, consulting upon and implementing fluoridation schemes*
- *provide guidance on the legislative framework governing the consultations and assessment of public opinion that SHAs need to undertake where they propose to make arrangements with a water undertaker to increase the fluoride content of a water supply; and*
- *provide guidance on the technical and legal issues SHAs need to address in conducting consultations and making arrangements with water undertakers including the means by which water undertakers may be indemnified against any liabilities arising from the fluoridation of water."* (Ref 1 – p 1 para 1)

It is recommended that PCTs familiarise themselves with this guidance. This report is consistent with the guidance provided in relation to the duties and responsibilities of individual PCTs which are recognised to be the following:

- Para 10, p5 – "PCTs are responsible for assessing the oral health needs of their population and commissioning the services required to meet their needs"
- Para 11, p5 – "PCTs should consider developing an oral health strategy" and "are under a statutory obligation to undertake epidemiological surveys of the dental health of their populations"
- Para 39, p11 – "In discharging their duty to improve the oral health of their populations and in particular to reduce inequalities in oral health, PCTs are encouraged to consider the option of fluoridating the water supplies "
- Para 12, p5 – "after reviewing local oral health needs and considering the options for reducing tooth decay, the PCT may conclude that fluoridation of water could be the most effective solution to reducing the prevalence of dental disease and reducing inequalities in oral health. The PCT may then approach the SHA in order to discuss the commissioning of a study from the water company to assess the technical feasibility and cost of a fluoridation scheme"
- Para 15, p6 – "PCTs are encouraged to cooperate closely where a water distribution system covers the areas of a number of PCTs"
- Para 34, p10 – "the SHA receives a request from a PCT to explore the possibility of fluoridation"

The guidance indicates that the SHA in discussion with PCTs should work with the water undertaker to develop a technically viable and affordable scheme upon which any consultation will be based. A number of factors related primarily to the complexities of the water distribution system (for example potential fluoridation concentration levels) will inform this judgement.

There is a statutory obligation to monitor the impact of existing and potential water fluoridation schemes. The Water Act 2003 Section 90A Review of Fluoridation states

"*a relevant authority which has entered into arrangements… shall monitor the effects of the arrangements on the health of persons living in the area specified in the arrangements… publish a report… within the period of four years".* *(Ref 3)*

The Department of Health has asked the West Midlands Public Health Observatory to make recommendations for the standardisation of a monitoring process for current fluoridation schemes. Guidance is expected on this issue.

1.3 PCT Responsibilities

Prior to consideration by the PCT Board it is necessary for the PCT to engage with key stakeholders on this matter irrespective of the SHA's statutory obligations regarding public consultation should such a stage be reached in the future. During all discussions assessing the technical feasibility and cost of proposals for water fluoridation schemes.

> *"it is essential that all parties understand and make clear to the public that those discussions are an aid to understanding whether or not a fluoridation scheme may be technically viable and affordable. They are therefore an essential pre-requisite to making a decision subsequently as to whether or not the SHA should undertake a formal (statutory) public consultation"* *(Ref1 – p 6 para 16).*

The public consultation phase of this process, should it progress that far, is to be managed by the SHA. The purpose of any communication at this stage is to obtain views of key stakeholders, in line with normal PCT practice and as a contribution to a Board's decision on whether to request the SHA undertakes further work on fluoridation. NWFEG would recommend the following are key stakeholders as a minimum:

- The local authority
- Local Overview and Scrutiny Committee
- Local dentists
- MPs
- Patient Forums

These stakeholders are listed as a minimum and PCTs are advised to follow their normal practice.

The legislation gives the SHA (in this case NHS North West) the executive role on the issue of fluoridation. Therefore, PCTs supportive of fluoridation as an intervention they wish to pursue based on their assessment of needs must discuss this with the SHA and suggest the SHA undertakes further work. The further work the SHA may do upon receipt of such a request from a PCT would involve commissioning the water provider to undertake a more detailed feasibility study than that provided here, and must involve managing a public consultation on the issue.

1.4 Water Fluoridation

Fluorine is a comment element in the earth's crust and can be detected in all natural waters. The concentration is usually expressed in parts per million (1 ppm = 1 mg per litre). Concentrations of fluoride in the "drinking water" of the North West, and most of England, tend to be lower than 0.3 ppm. Some areas, for instance Hartlepool, have a naturally occurring concentration of fluoride of about 1ppm. In some parts of the world rainwater can contain up to 1ppm fluoride.

In the first half of the twentieth century it was noted that the populations in some US cities had lower levels of tooth decay than others; these cities were found to have naturally occurring concentrations of fluoride greater than 1 ppm. The first trial of artificially raising the concentration of the drinking water supply to 1.0 - 1.2 ppm was started in 1945, in 4 pairs of US cities (1 control and 1 artificially fluoridated city in each pair). Significant reductions in tooth decay were found in subsequent years. This led to the widescale adoption of water fluoridation as a public health measure.

Cheng, Chalmers and Sheldon (2007) (4 – Box 2) noted that

> "Limited fluoridation trials were introduced in England from the mid 1950s but resistance from water companies curtailed their spread. Currently, 1.5 million people receive water containing fluoride drawn from ground that is relatively high in the mineral. Another five million people in parts of the West Midlands, Yorkshire and Tyneside receive water with added fluoride (1mg/l)"

Dental caries is a common preventable condition. It is a disease of the teeth in which micro-organisms convert sugar in the mouth to acid. This acid then erodes teeth.

Fluoride acts topically ie it acts on the tooth surface once it has erupted. It prevents caries by acting in two main ways:

1. It reduces the loss of calcium and phosphate (mineral) from the tooth surface when it is under acid attack.
2. It promotes the remineralisation of any damage by enhancing the movement of calcium and phosphate (that is at high concentrations in saliva) back into the tooth. In other words it repairs the damage. The other benefit that the fluoride goes into the tooth as part of the repair process and makes the tooth more resistant.

There is a suggestion that fluoride also kills the bacteria that cause the problem (weak evidence). Fluoride has a caries preventive effect on both children's and adult's teeth. (Ref 5)

1.5 Background to the North West Fluoridation Evaluation Group

Water fluoridation is one of a number of interventions that have the potential to improve dental health and reduce dental health inequalities. It is a population wide intervention of public interest and needs special consideration. In addition, as a consequence of the water flows around the North West, the matter is best considered by the North West PCTs working together. So the North West Fluoridation Evaluation Group (NWFEG) was formed. This paper is the report of the NWFEG. All 24 PCTs in the North West have funded the work of the group for the year 2007/08 at an average cost per PCT of £5000. This funding has supported project management and the commissioning of expert advice and guidance. The group is chaired by the Chief Executive of Ashton Leigh and Wigan PCT on behalf of the 24 PCT Chief Executives in the North West.

The NWFEG conducted its work from a position of being neutral on fluoridation. Financial commitment to the work of the group has not implied a position of any individual PCT being in favour or against fluoridation. It has however allowed PCTs to be in a position to undertake their responsibility to consider water fluoridation as one of a number of possible interventions available to improve dental health. The aim of NWFEG group has been to assemble as much information and guidance as possible to allow individual PCTs to consider the relative merits and feasibility of fluoridation as one intervention aimed at improving dental health and dental health inequalities.

The terms of reference of the group are attached as **Appendix 1**. It should be noted that the terms of reference of the group from March 2007 primarily focused on providing sufficient information to individual PCTs such that they were in the position to consider whether they wished to *request the SHA for a public consultation on the matter of fluoridation*. However in the light of the revised national guidance of February 2008, the terms of reference were amended in March 2008 to highlight that PCTs need to consider whether or not they wish the SHA to "*explore the possibility of fluoridation*" (Ref 1 – p 10 para 34).

1.6 Current Assessment of Dental Health in the North West

The following information is provided as an explanation of the state of dental health in the North West compared to other parts of England. Information is provided for children and adults.

1.6.1 Children

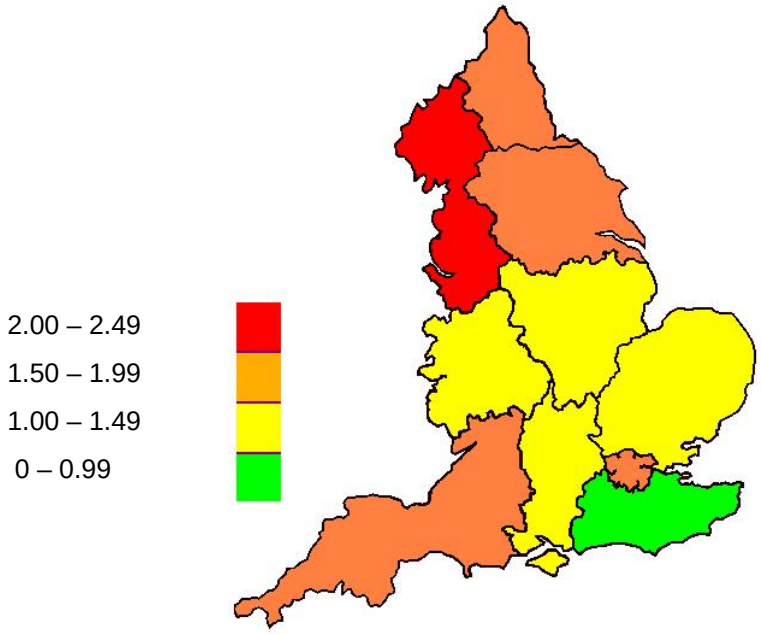
1.6.1.1 decayed, missing and filled tooth (dmft) scores

Regular surveys of children's oral health allow for comparisons both within the North West and with the rest of England (Ref 6)

During the 2005/06 school year, trained examiners undertook a full visual examination of 5 year old children in the sample and recorded the numbers of deciduous teeth affected by decay (d), missing due to decay (m) or filled (f). These were added to produce the decayed, missing and filled tooth (dmft) score. The scores were then averaged to produce a mean score for each PCT.

The results show that at 5 years of age, children in the North West have the highest levels of dental disease with an average of 2 teeth each affected by decay. This compares poorly with the South East of England where the same age group have only half the level of the disease.

Figure 1 Mean number of **d**ecayed, **m**issing and **f**illed **t**eeth (dmft) among 5 year old children in England by SHA 2005/06.



The percentage of children affected by tooth decay and the mean number of teeth affected by SHA are shown in **Figures 2** and **3** respectively. The North West has the worst dmft figure and the second worst prevalence figure.

Figure 2 Percentage of 5 year old children affected by tooth decay in 2005/06 by SHA.

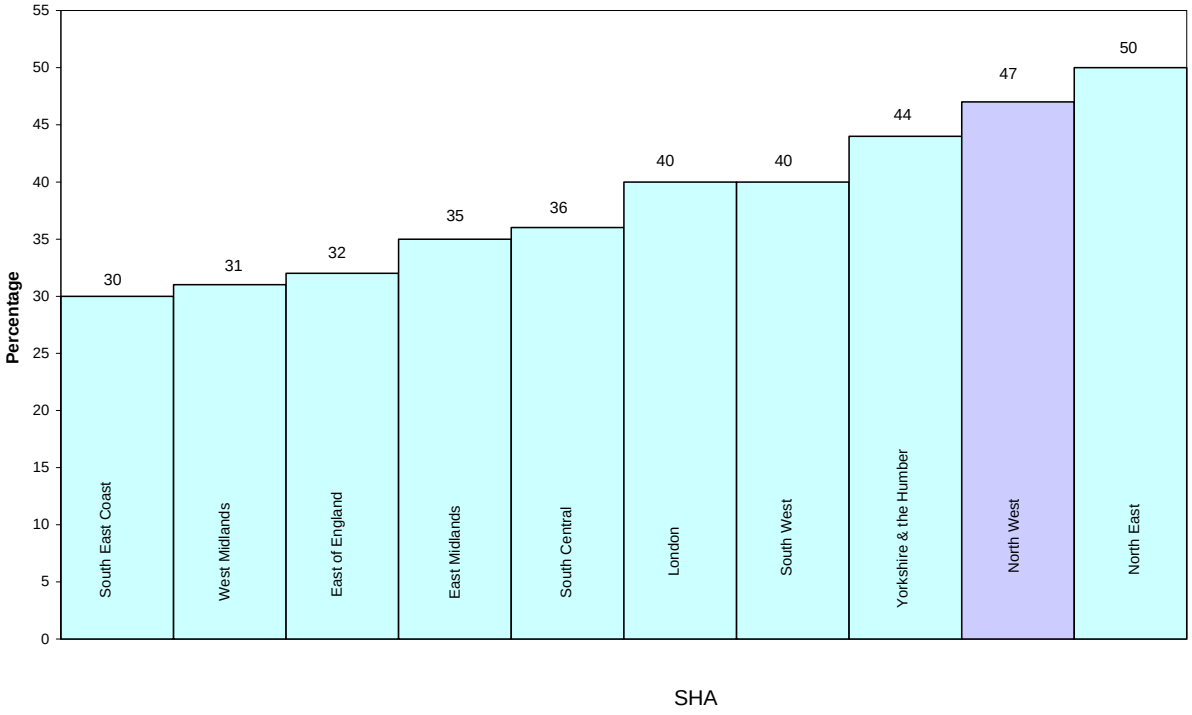
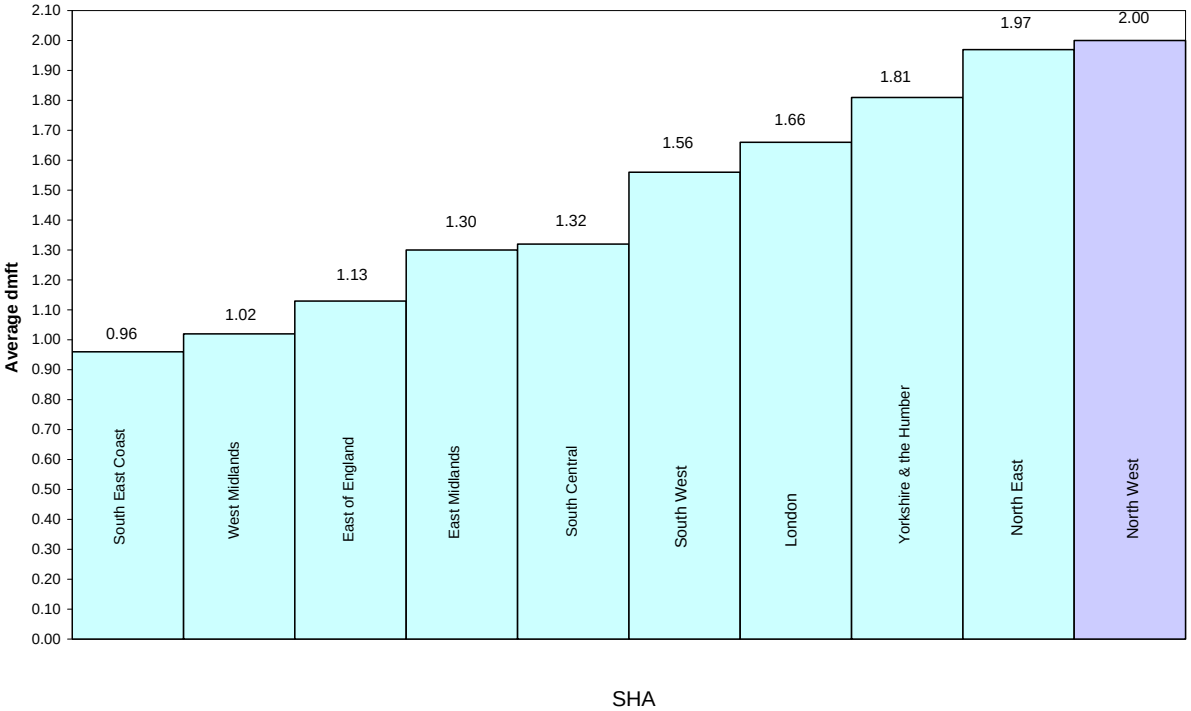
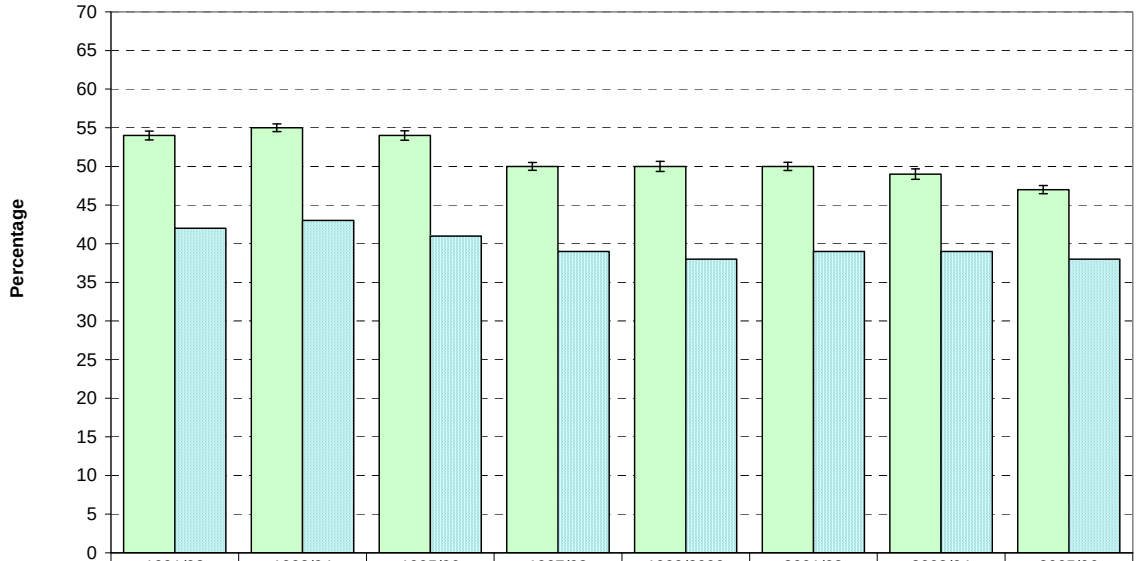


Figure 3 Mean numbers of **d**ecayed, **m**issing and **f**illed **t**eeth among 5 year old children in 2005/06 by SHA.



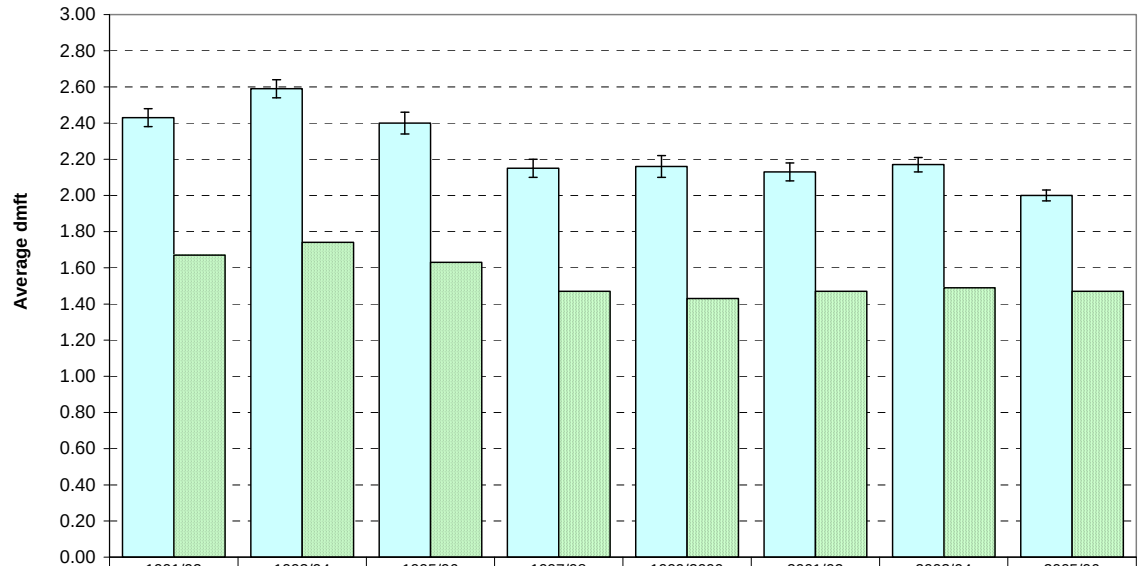
Figures 4 and **5** show the trends in dental decay experience in the North West from 1991/92 to 2005/06, against the trends for England as a whole. Until 2005/06 there had been no significant change in the dental decay of North West 5 year old children since the decrease in 1997/98.

Figure 4 North West trends in percentage of 5 year old children affected by tooth decay including 95% confidence intervals.



	1991/92	1993/94	1995/96	1997/98	1999/2000	2001/02	2003/04	2005/06
North West	54	55	54	50	50	50	49	47
England	42	43	41	39	38	39	39	38

Figure 5 North West trends in mean numbers of **d**ecayed, **m**issing and **f**illed **t**eeth among 5 year old children including 95% confidence intervals.



	1991/92	1993/94	1995/96	1997/98	1999/2000	2001/02	2003/04	2005/06
North West	2.43	2.59	2.40	2.15	2.16	2.13	2.17	2.00
England	1.67	1.74	1.63	1.47	1.43	1.47	1.49	1.47

Figures 6 and **7** show the results by the 24 PCTs in the North West. In 21 PCTs more than 38% of children had been affected by tooth decay, the mean for England as a whole. The figures show considerable variation across the North West. For example, 5 year old children in Central and Eastern Cheshire PCT had a mean dmft of 1.16 while children in Blackburn and Darwen Teaching PCT had a mean of 3.21.

The results by local authorities are shown in **Figure 8**. As expected these mirror the PCT values but they also show the value of smaller area data. For example, Central Lancashire PCT 5 year

old children had a mean dmft of 1.84. However, in Chorley LEA the mean dmft was 1.21, in West Lancashire LEA, 1.78, in South Ribble, 1.80 and in Preston LEA 2.46.

Figure 6 Percentages of 5 year old children affected by tooth decay in 2005/06 in the North West by PCT.

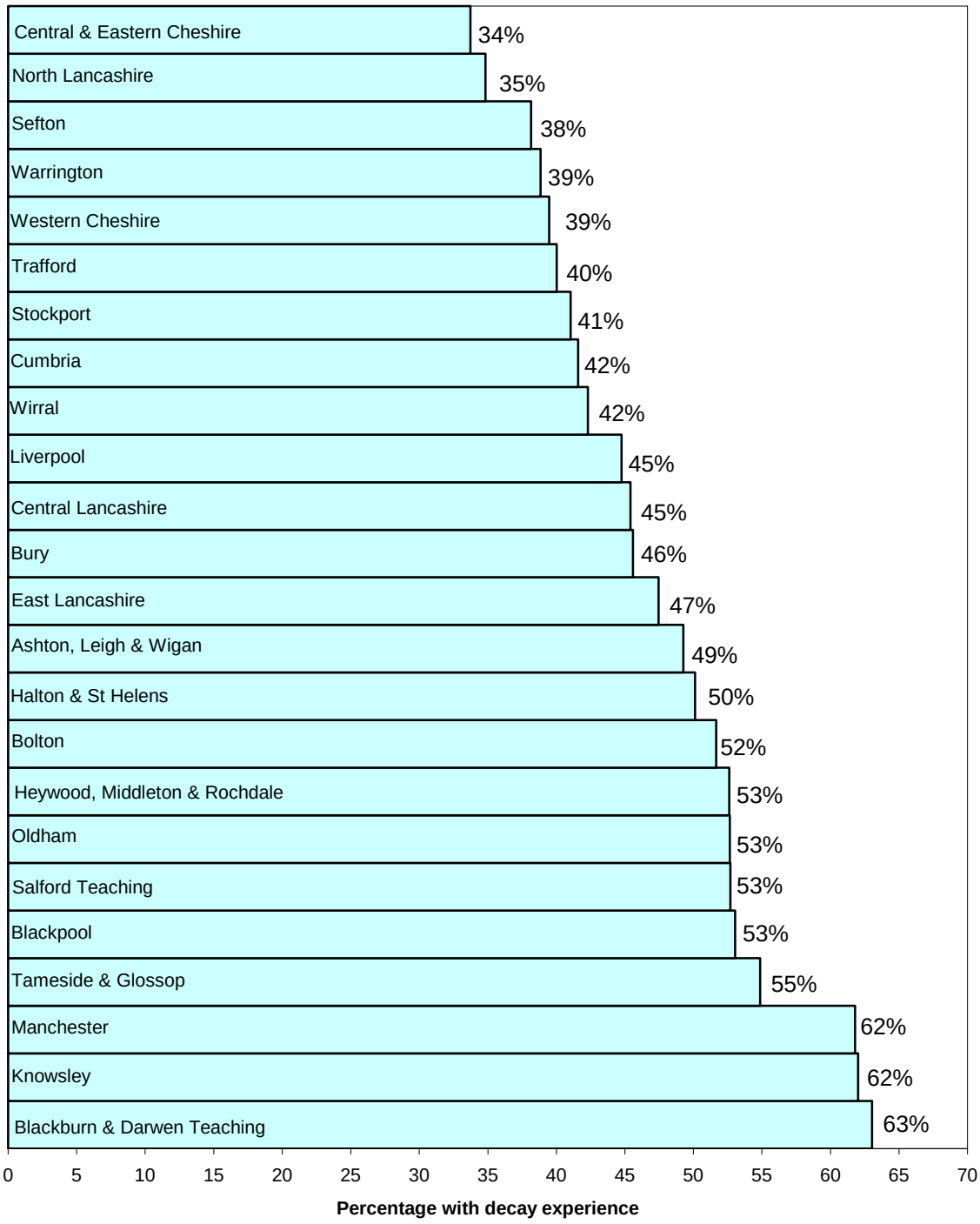


Figure 7 Mean numbers of **d**ecayed, **m**issing and **f**illed **t**eeth among 5 year old children in 2005/06 in the North West by PCT.

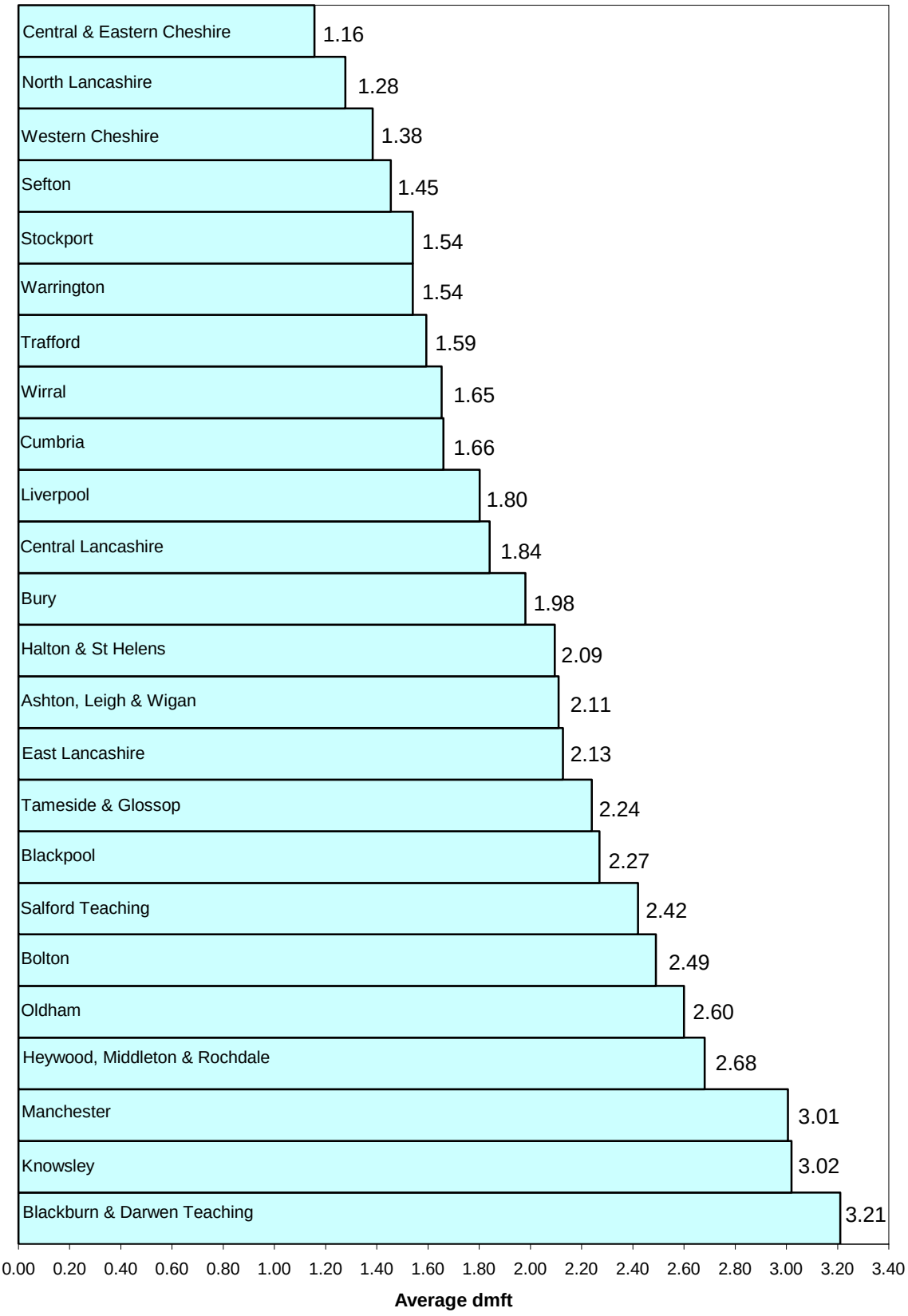
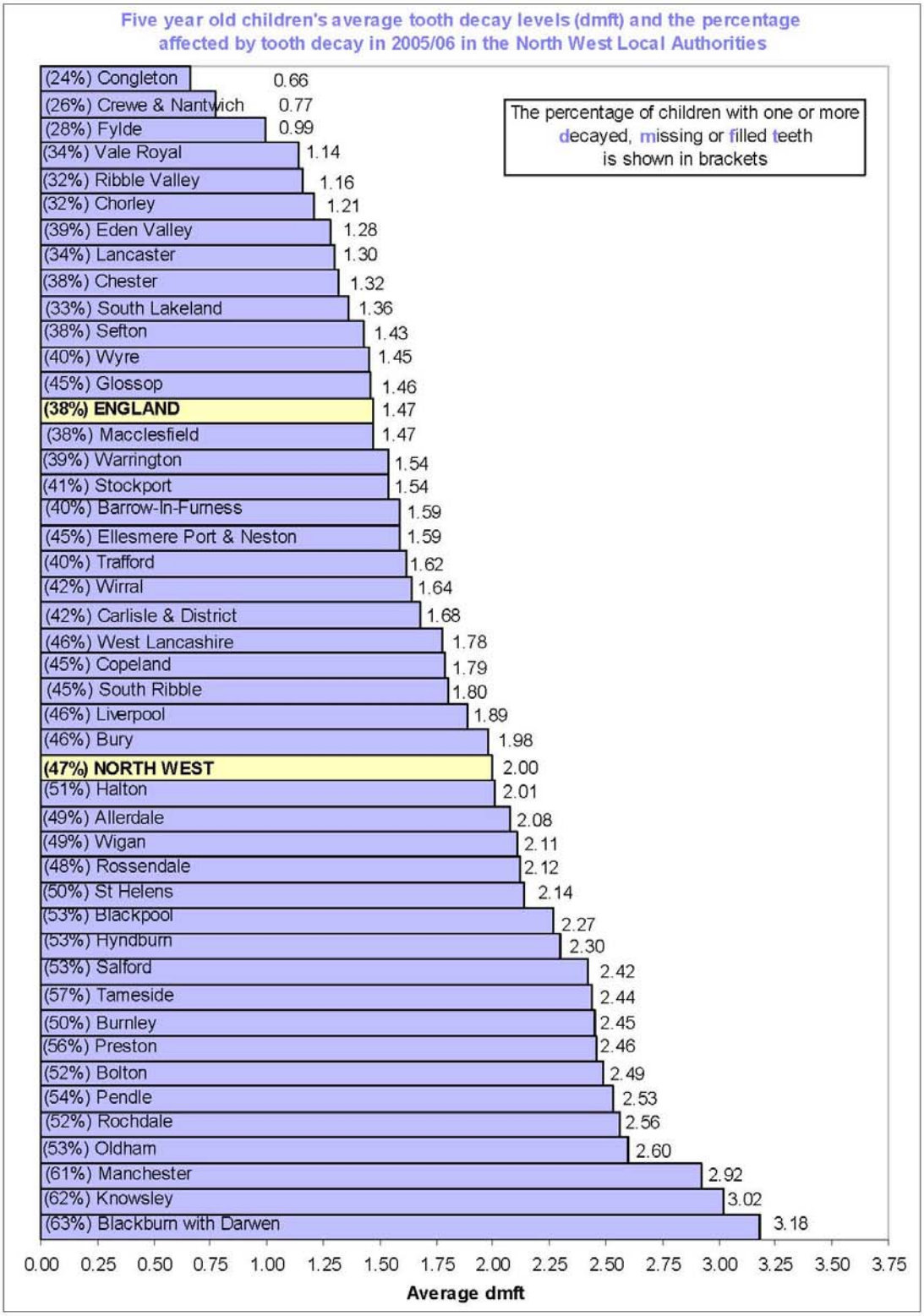


Figure 8 Mean numbers of **d**ecayed, **m**issing and **f**illed teeth among 5 year old children in 2005/6 in the North West Local Authorities.



Acknowledgements : Schools involved in the training and calibration of the dentists (Longsands County Primary - Preston, St. Stephen's C of E Primary - Burnley, St Gerard's R C Primary - Widnes); the schools where the survey was carried out; the dentists & recorders who collected the information: Project Manager - Janet Neville; Administration - Julie Flicker

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August 2007

1.6.1.2 - Extraction of children's teeth under General Anaesthetic

The majority of dental extractions resulting from gross dental decay are carried out under local anaesthetic in general dental practice or by PCT salaried dental services. Referral to hospital for extraction is undertaken when a child either needs multiple extractions or would be unlikely to co-operate with the procedure without general anaesthetic, or both. Admission of children to hospital for extraction of teeth is a significant consequence of dental decay. The costs for these procedures to the NHS are considerable and the impact of these surgical procedures on the children and their parents is also an important factor.

Data on dental extractions performed under general anaesthetic are available from two sources:

- The Hospital Episode Statistics (HES) database held by The Information Centre for Health and Social Care. This holds information on finished consultant episodes (FCEs) for all children and adolescents aged 0-19 years who had main procedure codes F09 – surgical removal of tooth or F10 – simple extraction of tooth.
- Dental general anaesthetic services are also provided by PCT Dental Services (PCTDS) that are not captured by the HES database. For this service it is currently not possible to identify which cases had general anaesthesia, sedation or local anaesthetic alone as there are no national standards for recording anaesthetics. The resulting data therefore describes the total numbers of children being admitted for the extraction of teeth because of caries, regardless of the means of anaesthesia. Information from the clinical directors of PCTDS suggest that the majority of these cases are general anaesthetic extractions.

Table 1 compares the number of FCEs for simple and surgical extractions with commonly occurring hospital episodes performed on children. Two codes referring to extraction of teeth appear in this table; F10 for simple extraction and F09 for surgical removal of tooth. Together they total 9555 episodes for 2005/6; by far the most common reason for children to be admitted to hospital.

Table 1 The most frequent procedures for children and adolescents aged 0-19 in 2005/06 in the North West (HES dataset)

Children's procedures		
OPER3	**Procedure**	**FCEs**
F10	F10 SIMPLE EXTRACTION OF TOOTH	7479
F34	F34 EXCISION OF TONSIL	5829
R24	R24 NORMAL DELIVERY	4851
D15	D15 DRAINAGE OF MIDDLE EAR	3895
W26	W26 OTHER CLOSED REDUCTION OF FRACTURE OF BONE	3041
X29	X29 CONTINUOUS INFUSION OF THERAPEUTIC SUBSTANCE	2924
X36	X36 BLOOD WITHDRAWAL	2762
X35	X35 OTHER INTRAVENOUS INJECTION	2087
F09	F09 SURGICAL REMOVAL OF TOOTH	2076
N30	N30 OPER ON PREPUCE	2048
H01	H01 EMERGENCY EXCISION OF APPENDIX	2002
S06	S06 OTHER EXCISION OF LESION OF SKIN	1640

Table 2 provides the HES data plus the data provided by the PCTDS by PCT for the whole of the North West. During 2005/6 15,817 children were admitted to hospital for extraction of teeth, either by a hospital based surgical team or by a PCT Dental Service team. Some hospital based services are run by PCT DS staff, and there is variation between services regarding the inclusion or exclusion of these extraction episodes with HES figures. To avoid the possibility of over-estimating the number of episodes, the calculation of the totals include only those episodes performed by PCTDS that were not included in hospital statistics. This may have resulted in an under-recording of PCT service episodes which were believed to have been included in hospital statistics, but which in fact were not.

Table 2 Extraction episodes for children and adolescents aged 0-19 in North West Region admitted to hospital for extraction during 2005/06, by PCT of child residence (surgical removal or simple extraction of tooth)

	Hospital Episode Statistics					PCT DS figs	
PCT of Residence	0-4 yrs	5-9 yrs	10-14 yrs	15-19 yrs	All child ages	Ext'n episodes excluded from hosp stats	Total number of extraction episodes
ASHTON, LEIGH AND WIGAN PCT	123	514	164	52	853	0	853
BLACKBURN WITH DARWEN PCT	149	262	78	39	528	0	528
BLACKPOOL PCT	66	187	70	34	357	0	357
BOLTON PCT	43	131	130	49	353	651	1004
BURY PCT	62	217	149	59	487	280	767
CENTRAL AND EASTERN CHESHIRE PCT	12	52	125	87	276	574	850
CENTRAL LANCASHIRE PCT	151	426	170	94	841	0	841
CUMBRIA PCT	32	89	101	50	272	966	1238
EAST LANCASHIRE PCT	90	283	164	86	623	0	623
HALTON AND ST HELENS PCT	23	60	69	54	206	900	1106
HEYWOOD, MIDDLETON AND ROCHDALE PCT	79	249	136	67	531	0	531
KNOWSLEY PCT	34	49	49	30	162	0	162
LIVERPOOL PCT	83	128	147	81	439	168	607
MANCHESTER PCT	209	457	191	117	974	0	974
NORTH LANCASHIRE PCT	53	177	80	47	357	520	877
OLDHAM PCT	19	52	66	44	181	0	181
SALFORD PCT	104	279	140	50	573	0	573
SEFTON PCT	23	56	69	30	178	0	178
STOCKPORT PCT	26	91	122	81	320	0	320
TAMESIDE AND GLOSSOP PCT	22	50	77	44	193	145	338
TRAFFORD PCT	60	190	134	57	441	0	441
WARRINGTON PCT	7	22	24	28	81	285	366
WESTERN CHESHIRE PCT	5	19	55	36	115	1029	1144
WIRRAL PCT	9	29	118	58	214	744	958
TOTAL for NORTH WEST	1484	4069	2628	1374	9555	6262	15817

1.6.2 Adults

Information on tooth decay in adults is sparse in comparison with that of children. There are few local surveys of adult oral health and the NHS is reliant largely on the ten yearly national adult oral health surveys funded by the Department of Health. The last survey was undertaken in 1998 (6) and data are only available for the North of England as a whole. The 1998 survey demonstrated that adult dental health of adults in England had improved in the 10 years since the previous survey. In 1998, 13% of all adults had no teeth at all compared to 21% in 1988. Total tooth loss was more common in the elderly, affecting 46% of adults 65 and over and 0% of adults aged 25-34. Differences in dental health were evident between social groups; 8% of social class I,II,IIIA adults had no natural teeth compared to 22% of adults from social class IIIB,IV,V . There were also regional variations in dental health, with residents of the North of England having the worst dental health. For example, almost two-thirds (65%) of dentate adults in the North had at least one decayed or unsound tooth compared with just over half of those living in the Midlands (52%) and the South (51%).

Attitudes towards dental health also changed over successive surveys. The proportion of dentate adults who reported going to the dentist for regular check-ups increased from 43% in 1978, to 50% in 1988, and to 59% in 1998. This was reflected in treatment preferences and expectations. There was a marked increase in the proportion of respondents saying they would prefer a back tooth to be filled rather than extracted, from 65% in 1978 to 79% in 1998. Among dentate adults 81% expected to retain some of these for their lifetime; 61% thought that the need for complete replacement of their teeth by dentures would be very upsetting and 27% found the idea of partial replacement by dentures very upsetting.

So although dental health of adults is improving, there are social and geographical inequalities in oral health. Due to falling disease patterns and growing reluctance to have extractions and dentures, people are keeping their teeth longer, which means that there are more teeth at risk of decay and large numbers of heavily restored teeth which need expensive long term maintenance by dental services.

The York Review (Ref 7) only included one study that examined the effects of water fluoridation on adults, this study reported the proportion of adults with false teeth to be statistically significantly greater in the low fluoride control compared with the fluoridated test area. A more recent systematic review, which investigated the effectiveness of fluoride in preventing tooth decay in adults (8) included nine studies which examined the effectiveness of water fluoridation. The authors reported that water fluoridation has a beneficial impact on the dental health of adults. (Summary-prevented fraction of the studies was 27.2% (95%CI: 19.4%-34.3%.)) (The preventive fraction is the difference in caries increments between the fluoridated and non-fluoridated groups expressed as a percentage of the increment in the non-fluoridated group.)

1.7 Current Fluoridation Schemes in the North West

United Utilities and its predecessors have operated three fluoridation schemes for more than thirty years. These are at Cornhow, Ennerdale and Hurleston Water Treatment Works and together they supply fluoridated water to a population of 265,000, slightly less than 4% of the total population served by United Utilities in the North West. Geographical coverage is indicated in the map below.

North West Water Fluoridation Evaluation
Currently Fluoridated Water Zones (March 2008)

NATCANSAT
www.canceruk.net
0870 840 8033

1.8 Analysis of existing schemes on dental health

There are three water treatment works in the North West that provide fluoridated water to the populations in their catchment areas. Hurleston supplies Nantwich and part of Crewe, whilst the two works in Cumbria together supply an area of West Cumbria which includes Workington and Whitehaven. The Hurleston scheme has been running uninterrupted since 1971. However the West Cumbria scheme has had lengthy period when it was decommissioned due to comprehensive refurbishment

Table 3: Fluoridation programmes in the North West

Water treatment works	PCT	District Council	Population covered	Start date
Cornhow	Cumbria PCT	Copeland and Allerdale	70000	1968
Ennerdale	Cumbria PCT	Copeland	64000	1971
Hurleston	Central and Eastern Cheshire PCT	Crewe & Nantwich Borough Council	135000	1971

Analyses of the impact of these schemes has been completed for 5 year old children. Data from the last surveys of 5 year old children that examined all children in living in fluoridated areas were used to ensure that sufficient numbers of children living in fluoridated areas were included in the analyses.

The analysis of the Hurleston scheme used Cheshire data from the 2001/02 survey of 5-year-olds which included Warrington, Halton, Vale Royal, Neston, Crewe & Nantwich, Macclesfield and Chester, in total 9771 children were examined. The analysis of the Cumbria scheme involved data produced from the 2003/04 survey of 5-year-olds for West Cumbria, Carlisle & District, Eden Valley, Barrow & South Lakes. In total 2990 children were included in the analysis.

The outcome variable was dichotomous; children were categorised as having caries or carious free. Children were also categorised as living in a fluoridated or non-fluoridated area by reference to their home postcode.

Analyses consisted of simple cross tabulations and multiple logistic regression analysis. The latter analyses were completed to explore the relationship between caries and fluoridation status after controlling for socio-economic status. It was important to control for socio-economic status as this is a proxy measure of the possible confounding variables sugar consumption and fluoride toothpaste use. Socio-economic status was measured using the Index of Multiple Deprivation (IMD) score of the Super Output area in which the child lived, identified by reference to each child's postcode. For the purposes of the regression analyses the IMD score was converted into quintiles of deprivation.

The effect of the existing fluoridation schemes in Cheshire and Cumbria are presented in tables 4 and 5 respectively.

Table 4: The relationship between caries prevalence and water fluoridation in 5-year-old children resident in Cheshire 2001/02

	Children living in a non-fluoridated area N (%)	Children living in a fluoridated area N (%)	Total N (%)
Children caries free	5367 (64.9)	1043 (76.6)	6410 (66.5)
Children with caries	2907 (35.1)	319 (23.4)	3326 (33.5)
Total	8274	1362	9636

Some 135 records in Cheshire had missing or errors in the postcodes leaving 9636 children who were included in the analysis. In Cheshire there was a highly significant difference ($p<0.0001$) in the prevalence of caries between children living in fluoridated and non-fluoridated areas after controlling for socio-economic status. Table 4 shows that 35 percent of children had caries in the non-fluoridated part of Cheshire compared to 23 percent in the fluoridated part, so a 12 percent absolute difference and a 33 percent relative difference in an area with a relatively low prevalence of tooth decay.

Table 5: The relationship between caries prevalence, water fluoridation and social deprivation in 5-year-old children resident in Cheshire 2001/02

	Living in Non Fluoridated Area			Living in Fluoridated Area		
IMD Quintiles	Caries free N (%)	Caries N (%)	Total	Caries free N (%)	Caries N (%)	Total
1 (most deprived)	370 (53.2)	326 (46.8)	696	22 (62.9)	13 (37.1)	35
2	792 (56.1)	621 (43.9)	1413	132 (67.0)	65 (33.0)	197
3	688 (60.5)	450 (39.5)	1138	205 (75.1)	68 (24.9)	273
4	1063 (66.7)	530 (33.3)	1593	160 (69.3)	71 (30.7)	231
5 (most affluent)	2384 (71.5)	951 (28.5)	3335	524 (83.7)	102 (16.3)	626
Total	5297 (64.8)	2878 (35.2)	8175	1043 (76.6)	319 (23.4)	1362

Table 5 presents an analysis on the Cheshire epidemiological data to compare the prevalence of dental caries in 5-year-old children in different socio-economic strata. The population has been split into quintiles of deprivation using the Index of Multiple Deprivation. The results demonstrate the strong relationship between tooth decay and social deprivation with higher prevalence figures in the more deprived quintiles compared to the more affluent. Comparing fluoridated and non-fluoridated areas the table shows higher prevalence of caries in every stratum of socio-economic status. Even in the most affluent quintile there was a 42 percent difference between fluoridated and non-fluoridated children. The prevalence of decay (37.1%) in the most deprived quintile of the children living in the fluoridated part of Cheshire was similar to that of children living in the middle quintile in the non-fluoridated part (39.5%).

Table 6: The relationship between caries prevalence and intermittent water fluoridation in 5-year-old children resident in Cumbria and North Lancashire 2003/04

	Children living in a non-fluoridated area N (%)	Children living in a fluoridated area N (%)	Total N (%)
Children caries free	875 (55.8)	813 (57.1)	1688 (56.5)
Children with caries	692 (44.2)	610 (42.9)	1302 (43.5)
Total	1567	1423	2990

In Cumbria 44 percent of children had caries in the non-fluoridated parts of the county compared to 43 percent in the fluoridated area (Table 6). This different was not statistically significant.

However the fluoridation was intermittent – no fluoride was added to the water at Ennerdale between May 2002 and September 2004 or at Cornhow between October 1996 and December 2004. Therefore the children examined had not been exposed to fluoridated water from birth to the time when the examinations took place.

Chapter 2 – Key Issues on Water Fluoridation

The October 2007 BMJ article by Cheng et al (Ref 4) intended to reduce the potential for a polarised debate on fluoridation by providing a constructive framework for the debate. They suggested five areas for consideration: known benefits, potential harms, alternative ways to prevent caries, whether fluoride is a medicine, and ethical implications.

The NWFEG has considered each of these in turn for the benefit of individual PCTs in the North West. In addition NWFEG has undertaken a systematic review of public opinion polls on fluoridation in order to provide further context.

2.1 Summary of Potential Benefits

The NWFEG commissioned the Office for Public Management (OPM) to undertake a review of the literature for the purposes of considering the relative benefit of water fluoridation compared with other interventions and this is included as **Appendix 2**. The section on benefits is repeated here in its entirety. (NB references can be found in the main report in appendix 2)

Effectiveness in reducing the prevalence of dental caries

Systematic review evidence

Numerous studies outline the broad benefits of adding fluoride to water as a public health measure aimed at reducing the prevalence and severity of caries. The York Review found that the 'best available evidence suggests that ***fluoridation of water supplies does reduce caries prevalence****' , both as measured by the proportion of children who have no obvious decay experience and by the mean change in the dmft/DMFT score.*

In addition the review found that the ***reduction in dental caries experience is greater in areas with higher levels of dental caries*** *prior to water fluoridation. The change in the prevalence of dental caries was estimated to be a 15% increase in the proportion of children with no dental caries and a decrease of 2.2 in the mean dmft/DMFT.*

The Review stresses that the ***degree to which caries is reduced is not definitive*** *and reports a wide range in results for both of the outcome measures:*

- *Mean difference in proportion of caries free children ranges from -0.5% to 64%*
- *Mean change in dmft/DMFT score ranged from 0.5 to 4.4*

It also found that the 'best available evidence' showed that caries prevalence rises following the withdrawal of water fluoridation. However, the authors stress that the evidence of a benefit of water fluoridation in terms of reducing caries should be considered 'together with the increased dental fluorosis'. Fluorosis as a risk factor is discussed in the ***limitations*** *section below.*

Other relevant evidence

An earlier review of 100 studies found that the reduction in caries levels between fluoridated and non-fluoridated communities was between 40-50% in the deciduous dentition and 50-60% in the permanent dentition (Arens, 1999). More recently, a number of studies have substantiated this by suggesting that adjusting the level of fluoride in the water supply to 1ppm could result in a reduction of dmft/DMFT levels in British children of at least 50%.

A number of studies compare fluoridated areas in the UK with non-fluoridated areas or artificially fluoridated areas. A 'naturally occurring experiment' involving non-fluoridated Salford and Trafford as control group, artificially fluoridated Newcastle and North Tyneside and naturally fluoridated Hartlepool allowed for the comparison of differences in dmft in 5 year olds by electoral ward. The multiple linear regression analysis of this study's results showed a 'significant interaction' between Jarman score for ward, mean number of teeth affected by decay and both natural and artificial types of water fluoridation. The authors note that this result 'confirms that the more deprived an area, the greater benefit derived from fluoridation, whether natural or artificial .

This finding was supported by three other identified studies reporting lower level of caries experience as measured by dmft in Newcastle, which is artificially fluoridated, relative to the surrounding non-fluoridated area of Northumberland. These studies, which are fairly similar in methodology and sample size, also identified a difference between the caries experienced in children from the non-fluoridated area and those from the fluoridated area. The study published in 1988 found that children from fluoridated areas experienced 54% lower mean dmft score and 60% reduction in dmfs, However, the study published in 1996 reported smaller differences between fluoridated and non-fluoridated communities – reporting that children from fluoridated areas experienced 48% fewer dmft and 54% dmfs than those in non-fluoridated areas.

*The **differences between the findings** in these two studies for the same areas mean that the translated benefits of water fluoridation 'in absolute terms' are both positive but the more recent studies finds a lower potential benefit. The1988 study found that the benefit was on average two teeth less with caries, whereas the 1996 study found a potential benefit of a child in the fluoridated area experiencing one tooth less having caries. The 1996 authors suggested that the 'power of water fluoridation' to reduce caries experience in absolute terms between social classes within fluoridated areas had diminished, but the differences between fluoridated and non-fluoridated areas 'still persist' .*

A study looking at the effect of residence and social class on caries experience of 15 to 16 years olds in fluoridated (both artificial and natural) and non fluoridated towns uses the results from Newcastle and Hartlepool to argue that as naturally fluoridated Hartlepool had the lowest DMFT values (32-35% lower than in artificially fluoridated Newcastle), it 'confirms the importance of continuous residence in a fluoride area to achieve maximum effect'. However, it has also been suggested that the benefit of lower DMFT levels in Hartlepool resulted from the slightly higher fluoride level of the water in that area, where fluoride naturally occurs at 1.0 to 1.3ppm. Newcastle is artificially fluoridated at 1.0ppm.

This is supported by an assessment of the effectiveness of water fluoridation in Ireland which found that the results from an oral health survey of adults in 1990 showed subjects who had lived in fluoridated communities for many years had better dental health than those in non-fluoridated communities. Among those aged between 25 and 34 years, the average DMT in those resident in fluoridated areas was 14.7 compared with 16.9 in those resident in non-fluoridated communities.

Much of the evidence included in systematic reviews and original studies looks at the effectiveness of fluoride in preventing caries in children. One study identified looked at the effectiveness of water fluoridation and other fluoride interventions in adults, both over the age of 20 years and 40 years. A meta-analysis found a prevented fraction for water fluoridation of 27% which led the authors to conclude that fluoride prevents caries among adults of all ages.

Effectiveness in reducing dental health inequalities

Although the absolute benefit of fluoridation has decreased over the last twenty years, as caries levels have dropped, the relative benefits remain, particularly with regard to addressing health inequalities . A 2002 report on water fluoridation and health found that there is 'almost universal agreement' that an additive effect of social class and water fluoridation exists. As a public health measure water fluoridation differs from other fluoride interventions in terms of its intervention level; water fluoridation has the potential to reach everyone in a geographically contained population who is served by a public water supply. Water fluoridation therefore has the additional benefit in that it does not require individuals to change their behaviour or to spend additional resources, two issues which have been presented as potential barriers for reducing caries in the most at risk sections of the British population.

The evidence referenced in the sections above suggests that there is a consensus that one of the main benefits of water fluoridation is its potential in reducing severity of caries in socially disadvantaged children as unlike other fluoride interventions, as water fluoridation overcomes compliance issues. For example, a paper published in 2002 argues that given the behavioural

factors related to social economic status and dental health such as lower dental attendance and lower frequency of tooth-brushing, disadvantaged sections of the community are likely to have less exposure to fluoride from professional applications and from toothpaste than do people in higher social-economic status group. It is this argument which has led the authors to conclude that this 'essentially leaves fluoridated water as the only practical method of bringing fluoride exposure to the whole population'.

Systematic review evidence

The York Review noted that of the 15 sources of evidence relating to social inequality, 14 of these sources found that 'for all ages and all social classes the proportion of caries-free children is higher in fluoridated than non-fluoridated area. While there was no evidence that water fluoridation reduced the social gradient overall, it did find some evidence that water fluoridation reduces inequalities in dental health across the social classes in 5 and 12 year old children when measured by dmft/DMFT. The York Review found that the effect of water fluoridation in reducing the differences in dental health between social classes to be varied and the evidence around reducing inequalities of relatively low quality as all but four were classes as quality level C (the lowest acceptable quality for inclusion).

While the York Review found limited evidence to suggest a difference in social gradient when examining caries prevalence in fluoridated/non-fluoridated areas, there was a marked distinction when examining the severity of caries experience. So when the indicator for caries is measured by the ***proportion of children without caries,*** *there are higher numbers of caries-free children in fluoridated areas but no variation in the differences in the inequality between the social classes in low or high fluoride areas. Therefore when measured by proportion of caries-free, there is no evidence that fluoridation reduces the gradient between children in high and low social classes. However, when the indicator for caries severity is measured by the* ***mean difference in dmft/DMFT****, the authors found that water fluoridation 'does appear to be having an impact on reducing the differences between the social classes among children aged five years' as well as for 12 year old children*

The York Review also suggested that there did appear to be some evidence that water fluoridation had a greater benefit in reducing caries for children in more deprived areas than children in less deprived areas.

Other relevant evidence

There is also evidence to suggest that the benefits of water fluoridation in terms of reducing dental decay in 5 year olds are shown to be ***greater for more deprived areas*** *as deduced from the predicted reductions in decay based upon Jarman underprivileged area scores. Similarly, another study that measured deprivation using the Townsend Deprivation Index found that water fluoridation reduces dental caries experiences to a greater degree in materially deprived areas than in affluent areas, which lead the authors to conclude that introducing water fluoridation would 'substantially reduce' inequalities in dental health.*

A report published in 2002 following on from the York Review found that the majority of studies reported reductions in dental caries inequalities resulting from water fluoridation and that no study reported water fluoridation increasing inequality.

These findings suggest that both the ***indicators used for measuring caries*** *and the methods for* ***measuring social class*** *are important considerations. For example, classifications of social class based on occupation could be considered to be blunt instrument leading to the assertion that more work is needed on 'refinement of the instruments for classifying socio-economic position in accordance with the view that more refined instruments might reveal greater inequalities.*

Cost effectiveness of water fluoridation

A study published in 1998 by the York Health Economics Consortium argued that there were four key variables which should be considered when evaluating the cost-effectiveness of water fluoridation. These variables are:

- *The size of the population served by the water supplier*
- *The level of tooth decay in this population*
- *The age and condition of the water treatment works*
- *Type of fluoride to be used*

*An earlier study published in 1990 focused on two of these variables; the **pre-existing level of caries** in the community and the **size of the catchment population** of the water supply. This study found 'marked differences' in the cost effectiveness of water fluoridation for communities of different sizes and with differing levels of dental caries. Fluoridating the water supply of a community with a low fluoride intake from other sources and a high level of caries among children is likely to have a **greater effect** than the fluoridation of a similar community with a lower level of caries , both in terms of the relative benefits of water fluoridation in reducing experience of dental caries and in terms of cost-effectiveness. For example, fluoridation has been found to be more effective in reducing dental decay in social classes IV and V, than in it is in classes I, II and III . Further regression analysis of these studies shows that the more deprived an area, the more positive the effects upon reducing caries, with an a estimated 44% reduction in caries incidence in five year old children, climbing to 54% in very deprived wards. In terms of costs this is illustrated by the study's estimate that in 1989 reducing caries prevalence in a high caries large population costs an estimated value of £1.60 per dmft per person per year compared with an estimated value of £6.50 in a similar area but with low caries.*

*Further evidence to this effect is provided a more recent study published in 1998 in which it is commented that the effectiveness of water fluoridation would depend upon the baseline level of caries, and that the capital costs were sensitive to **economies of scale**. The report concluded that water fluoridation would be best targeted at districts where local water treatment works supply water to at least 200,000 residents with high levels of caries and with mean dmft greater than 2.0 for five year olds. A report by the British Fluoridation Society describes these areas in the UK as including 'most or all of Scotland, Wales, Merseyside and North West England, plus some parts of Yorkshire' .*

This leads to the recommendation that decisions related to water fluoridation should not be taken on the basis of dental caries alone, as the cost per unit benefit associated with fluoridating a small population of high caries levels is roughly of the same magnitude as for fluoridating a population ten times as large but with low caries level .

<u>Costs of water fluoridation</u>
*In terms of actual costs and cost benefits of fluoridating water supplies, there is limited evidence and evidence that is available is relatively old. A paper published in 1990 noted that previous work on the costs of water fluoridation expressed costs in terms of the cost per person. However, the authors argue that this way of calculating costs 'fails to recognise' that the benefits of water fluoridation are not spread equally across the population within a fluoridated area. The author therefore concludes that it is important to express project benefits in a population context and compare with the total cost of water fluoridation for that population. It also notes that fluoridation of water sources needs to be **assessed on an individual case basis.***

The following costs are taken directly from the sources of evidence and not attempt has been made to compare the costs as they refer to different years, different local contexts and measure different types of costs.

*In **1990**, the initial capital and annual running costs of water fluoridation in three hypothetical communities are estimated as being:*

- *For a population of size 60,000, the initial capital cost is estimated as £125,000 with an annual cost of £17,000.*
- *For a population of size 120,000, the initial capital cost is estimated as £135,000 with an annual cost of £24,000*

- *For a population of size 600,000, the initial capital cost is estimated as £163,000 with an annual cost of £80,000*

The same source of evidence concludes that in 1990, using a discount rate of 5% the present value of fluoridating a high caries area of 60,000 people is estimated to be £310,280 and that such a project would produce dental caries at an average of £4.80 per dmft person year avoided .

*A later source of evidence, published in **1998**, looked at the estimated costs for fluoridating non-fluoridated UK water treatment works in selected regions serving populations of 200,000 or more . For the North Western water works, the 5 year old mean dmft (as in 1885) is given as 2.7. The largest population is Watchgate with a 1,920,000 population leading to an estimated capital cost of £1,102,000 and an annual revenue cost of £221,000. The smallest area in the North Western area given is Rivington (population of 240,000) with an estimated capital cost of £407,000 and an annual revenue cost of £63,000.*

*An even older study, published in **1988**, compared the costs of water fluoridation (the indirect cost and cost savings in terms of spending on dental care for children) with fluoridated Newcastle compared to non-fluoridated Northumberland. It found that the difference in cost between these two areas (according to NHS October 1986 scale of fees) was £9.91 per child, less in the fluoridated area than the non-fluoridated area.*

Limitations
Impact of water fluoridation on different sections of the population
*An issue raised in many of the sources of evidence is the lack of available information on **exposure to fluoride from a range of sources** and the impact that this has on different sections of the community, for example the possible disproportionate risk of fluorosis for those who have a higher intake of fluoride, particularly with regard to socio-economic status. The Medical Research Council argues that because of this lack of information on confounding factors in relation to fluoride intake, there is a need for greater understanding of **total exposure** to fluoride .*

2.2 Summary of Potential Harms

The NWFEG commissioned OPM to undertake a review of the literature for the purposes of considering the relative benefit of water fluoridation compared with other interventions and this is included as **Appendix 2**. The section on risks is repeated here in its entirety.

Risks associated with the intervention
A recently published article highlighting the issues raised by water fluoridation from the York Review stressed that evidence on the potential benefits and harms of adding fluoride to water is relatively poor and there is 'no absolute certainty on safety' .

Fluorosis
*With this in mind however the York Review report that of all the possible adverse risk factors associated with of water fluoridation, the effect on **fluorosis incidence** is most apparent although it would appear that the vast majority of this is mild and does not constitute a public health problem. The Review estimated that the prevalence of fluorosis would be 48% in 1ppm artificially fluoridated areas and 15% in non-fluoridated areas.*

The York Review found a positive relationship between fluoride level in water and prevalence of fluorosis in that 'there are relatively large differences in the prevalence of dental fluorosis at the level of water fluoridation 0.7-1.2ppm when compared with an area of relatively low water fluoride content (0.4ppm) ' and that fluoride levels also impact on dental fluorosis causing aesthetic concern. However it was reported that the studies included in the analysis of the effects of water fluoridation on fluorosis had a mean validity score of 2.8 out of 8, indicating that there may be a shortage of high quality research on the impact of the relationship between fluorosis and water fluoridation.

Differences in the prevalence of fluorosis were also reported in an additional study published in 1990, which compared the prevalence of developmental defects of enamel in eight year old children living in fluoridated and non-fluoridated communities in Cheshire. 60% of children in the fluoridated community had enamel defects compared to those in the non-fluoridated community.

As noted, there are differing levels of fluorosis and mild fluorosis is not considered to be aesthetically significant. The York Review makes this distinction between aesthetically problematic fluorosis and non problematic fluorosis and estimates that the prevalence of aesthetically problematic fluorosis would be12.5% in fluoridated areas, compared with 6% in non-fluoridated areas. This data, when compared with the much higher general estimates for fluorosis prevalence cited above, would suggests that aesthetically problematic fluorosis is less of a risk than fluorosis per se.

Some of the evidence also looked at the way in which fluorosis is measured and the potential subjectivity of a measurement. For example, a study conducted in the North West and published in 2000 compared the normative and subjective assessments of the child prevalence of fluorosis living in Crewe and found that there are differences in the perceptions of dental professionals and 12 year old children on both the 'presence and relevance' of fluorosis.

In addition, the MRC report notes that the York Review included studies in countries with hotter climates than the UK and do not factor in considerations about the impact of climate on the level of water consumption. Because of this the MRC report suggests that the prevalence of aesthetically problematic fluorosis in the UK is 'probably lower' due to lower water intake and corresponding lower risk of fluorosis.

The York Review addressed incidence of fluorosis over time and found no positive relationship, but concluded that these findings were 'counterintuitive' and the measures used to assess fluoride levels resulting from other interventions were insufficiently robust.

<u>Bone health</u>
*In addition to fluorosis as a possible risk associated with water fluoridation, the York Review analysed studies examining the relationship between fluoridation and **bone fractures** and bone development problems. Of the 29 studies that met the inclusion criteria, 14 analyses found hip fractures decreased with increased fluoride levels and 15 studies found hip fractures increased with increased fluoride levels. The review found that there was 'no clear association of hip fracture with water fluoridation.'*

However, the MRC report published following the York Review discussed the validity of the York Review's conclusions regarding the relationship between fluoride and bone health. The MRC report states that 'the York Review suggests the evidence base on fluoride and bone health is weak, but this conclusion may be misleading because the criteria by which studies were classified were not entirely appropriate'. This is due to the York Review's methodology of classifying evidence according to the length of the time in which fluoridation had either been initiated or discontinued. Classifying evidence in this way means that the studies classified by the review as high level would not be 'informative about the long-term risks of bone disorders.

<u>Cancer</u>
*The York Review also examined possible associations between water fluoridation and **cancer**. 26 studies were included with an average validity of 3.8 out of 8. The report suggests there is insufficient evidence to draw conclusions on the links between cancer and water fluoridation, as variation in results showed 11 studies presented a positive relationship (lower cancer rates), and 9 studies were negative (increased cancers) and that 'the findings of cancer studies were mixed, with small variations on either side of no effect.' This finding is generally supported by the MRC report which found that 'overall, the current evidence does not support the hypothesis that exposure to artificially fluoridated water causes an increase in risk for cancer in humans' within a 35 year period time frame of exposure. The report notes however that it is still too early to conclude whether*

longer term exposure increases the risk of cancer particularly as most cancers occur in old age. While it is very difficult to form robust conclusions on the impact of artificially fluoridated water supplies due to this lack of evidence, the MRC report does note that studies of populations who have had a lifetime of exposure to high levels of naturally occurring fluoride in water supplies do not report an increase in cancer risk.

Other possible risks
In addition to fluorosis, bone fractures and cancer, the York Review assessed other potential adverse effects however they were all of evidence level C and as such the authors suggest treating results with caution. Evidence in this area is weak due to the small sample of studies and the 'lack of control for confounding factors' impacting on adverse effects.

Other studies look at the risk of chronic and acute ***toxicity*** *from fluoride ingestion from water. One study dismisses the risk in that acute toxicity is 'highly unlikely' because of the large volume of water that would have to be drunk to provide a sufficiently large dose of fluoride .*

2.3 Alternative dental ill health preventative measures

The NWFEG recognises Fluoridation as one potential intervention to address dental health. There are others. **Appendix 2** of this report provides a detailed comparison of the different interventions available.

2.4 Fluoride as a medicine or food supplement

Debate on adding fluoride to the water can hinge on consideration of fluoride as a medicine. On the one hand fluoride occurs naturally at concentrations comparable to those used in fluoridation programmes and is not therefore a medicine. On the other hand adding fluoride is intended to have a biological effect to prevent disease. The distinction is important: if considered to be a medicine, fluoride should be subject to the same standards of proof as other medicines. However, the UK Medicines and Healthcare Products Regulatory Agency (MHRA), which licences medicinal products in the UK, has indicated that fluoridation of water is not within remit: "As drinking water is quite clearly a normal part of the diet the MHRA does not regard it to be a medicinal product." (9 – p 130 Box 7.6)

Therefore, it might be concluded that fluoride in water can be consider a food supplement. The legal situation is that while in principle drinking water is considered a food, the addition of fluoride is not considered a food supplementation process. This is because, from a legal viewpoint, water provided by the local water supply is only considered a food once it emerges from the taps that are normally used for human consumption. Further "fluoridation of water at the water treatment stage also does not fall in the remit of the Food Standards Agency as a fortified food". (9 – p 130 Box 7.6).

2.5 Ethical Implications

There is an ethical consideration to the debate on fluoridation, focused primarily on issues of informed consent and autonomy to make a decision to accept an intervention and the balance with public health priorities.

All drinking water contains some fluoride. Water fluoridated at an optimal or near optimal level has the potential to reduce dental health inequalities and reduce ill health in both the child and adult population, although the best available evidence on the extent of benefits is relatively weak. Additionally, the nature of water fluoridation schemes is such that whole areas either receive the intervention or do not and it is therefore impossible to give any one individual the choice of whether or not to participate.

It might be argued that because of the impossibility of securing individual consent the implementation of water fluoridation schemes should therefore in principle be ruled out. In the context of public health decision making however, a careful balancing exercise needs to be

undertaken between individual preference on the one hand and opportunities for the wider population to access important health benefits on the other.

If there were unequivocal evidence that water fluoridation was associated with a substantial likelihood of significant detriment to individuals, individual consent would certainly be required. Equally, if there are no harms, but clear benefits, it could be argued that fluoride should be added by default without individual consent, in the same way that chlorine is currently added to drinking water to remove harmful bacteria. Water fluoridation is not characterised by such certainty. There is some evidence of possible detriment and stronger evidence of benefit, though the extent of each is difficult to quantify.

Thus both action (fluoridating drinking water) and inaction (not fluoridating) are likely to disadvantage some sections of society, either through limiting personal choice or denying health benefit.

The acceptability to a community of water fluoridation should be considered in relation to the balance of risks and benefits. A decision to introduce a water fluoridation scheme and a decision not to fluoridate require justification and a mechanism is needed for considering the views of the public in providing a mandate for either option. Ultimately, the most appropriate way of deciding whether drinking water should be optimally fluoridated is a transparent consultation process conducted within the legislative framework put in place by a democratically elected government. Such decisions should be taken within the context of local circumstances, although because of the nature of the drinking water distribution network, account should also be taken of the views of larger constituencies. Relevant evidence including dental health needs, the degree of anticipated benefit, local perceptions of the measure and the cogency of the arguments put forward should all be considered, and the process of engagement should be transparent.

Although occasionally the Human Rights legislation is quoted in support of arguments against water fluoridation as a means of improving dental health, to date there is no case law on this.

2.6 Review of Public Opinion

Proposals for water fluoridation are often controversial and generate significant public debate. For the benefit of PCTs in the North West the Evaluation Group considered there was merit in providing a review of public opinion on the issue. This work was led by Melanie Catleugh, consultant in Dental Public Health, East Lancs PCT and member of NWFEG and was undertaken in conjunction with Professor Paul Bellaby, Professor of Sociology. Salford University.

This is included in this report not to pre-empt any engagement undertaken locally by individual PCTs or by any subsequent formal public consultation co-ordinated by the SHA. However it is provided in order to provide a further component of information that PCTs may wish to consider. The complete review is at **Appendix 3**. The executive summary is as follows:

1. *This review has been commissioned to gather, quality assess and summarise those relevant opinion polls which may inform discussions to be held in the North West PCTs.*

2. *The objective was to review and critically quality assess opinion polls relating to water fluoridation, of relevance to potential fluoridation schemes which may be implemented in the North West of England.*

3. *Opinion polls were identified through a computerised search of MEDLINE, EMBASE, Google and the UK Data Archive. In addition hand searching and professional contacts were used.*

4. *All polls meeting the following criteria were considered: opinion polls consistent with the Oxford Dictionary definition of opinion poll; carried out between 1st June 1977 and 1st June 2007 in any population in the United Kingdom; reported in any language.*

5. *All searching efforts yielded reports, summaries, or knowledge, of 35 opinion polls, carried out in the UK between the chosen dates.*

6. *All opinion polls were described using a tool, based on a critical appraisal tool for use with surveys developed for use in this review. Where possible polls were quality assessed using agreed criteria based on sampling methodology, sample size and respondent selection methods.*

7. *Of the 35 opinion polls identified, 11 were considered to be relatively methodologically robust. These were either carried out using quota or random samples. The majority of the polls represented a wide variety of respondents, based on standard socio-demographic variables.*

8. *In general terms respondents appeared to think that fluoride reduced tooth decay; there was a limited knowledge of the fluoridation status of the water received by respondents; the majority of better quality polls found respondents to be generally in favour of water fluoridation; of the four polls that posed a question relating to decision making, the majority felt that the decision should be made by a health body.*

9. *The reviewers identified a number of issues which question the validity of past opinion polls conducted in the UK, relating to water fluoridation, between 1977 and 2007.*

10. *Whilst some of the higher quality polls identified in this review suggest that there has been has been public support for water fluoridation, it is not necessarily safe to conclude from these results they would corroborate contemporary public opinion. The authors recommend that an informed consultation, based on the real possibility that fluoridation may be introduced would be a more accurate measure of public opinion.*

This research on opinion polls was external validated by Dr Gail Topping Programme Director of Dental Caries Control Research, and Hon Consultant in Dental Public Health, Dental Health Services Research Unit, from Dundee University who judged it

> *"In conclusion, the review and critical appraisal of literature on opinion polls about water fluoridation undertaken by the North West Fluoridation Evaluation Group appears to have taken a thorough and systematic approach to sourcing and assessing information about polls conducted in the past three decades. The conclusions which have been drawn are well founded and appear to be without bias."*

Chapter 3 - Technical Considerations

3.1 Water flows in the North West

United Utilities is the main operator of the water distribution system in the North West. It operates upwards of 80 water treatment works (WTW) throughout the North West of England. These plants supply the whole of the population of the North West SHA footprint with the exception of two small water zones, Holt near Chester and Alston in Cumbria, which receive potable water from imported water supplies and therefore would not be affected by any scheme involving United Utilities. Thus it is with United Utilities alone that studies have been undertaken to identify possible and feasible fluoridation schemes in the North West.

United Utilities does not supply water on the basis of PCT or SHA boundaries but on the basis of available reserves and gravity, so any fluoridation scheme is unlikely to deliver the optimal dose of 1ppm across a whole PCT area consistently for 365 days a year. The introduction of fluoridation at any given site is likely to miss out a number of desired target areas while also spilling over into other areas already enjoying relatively good dental health.

There are however 2 cross boundary issues to be aware of. United Utilities provide an emergency supply from Oswestry WTW in Shropshire, feeding about 31,800 customers. Severn Trent Water used the supply in the summer of 2007 to meet peak demand. In the long term they do not plan to use this supply at all, and improvements to supply security are planned.

There are a few properties that fall within the Welsh border that are fed off the large diameter trunk main. There may be an opportunity to connect them to Severn Trent Water's network. United Utilities and Severn Trent Water are working up the scope of work required to connect the concessionary supplies fed from the raw water aqueduct onto their network. It is likely that with both these border issues, there will be a cost to transfer to Severn Trent Water which will need clarifying before proceeding with any fluoridation scheme.

It is highly recommended that, if in the case of proceeding with a water fluoridation scheme, United Utilities are requested to check their supplies at the borders of the SHA to confirm that they do not provide fluoridated water to populations outside the SHA.

3.2 Potential Fluoridation Schemes

The health organisations in Greater Manchester were the first to begin evaluation work on water fluoridation schemes. It became apparent in this work that due to the integrated nature of the water supply system, it would be technically difficult and maybe impossible to develop schemes solely for small, discrete areas of Greater Manchester. Neighbouring areas outside the Greater Manchester border in Merseyside and Cheshire would be affected.

With the reconfiguration of the NHS in 2006 and the formation of one North West SHA, this issue ceased to be a problem so work continued to develop possible schemes across the North West area. 3 schemes were identified as being technically feasible; Greater Manchester and areas of Merseyside, this area plus some other key locations to give added coverage, and a scheme to cover the whole region adding fluoride at 80 WTWs. This third scheme, whilst described here as the Whole Region, indicates the number of WTWs involved rather then 100% geographical coverage of the North West, as some areas received water from imported water supplies.

These 3 schemes each provide a dosage of fluoride at a rate of 1 ppm, considered to be the optimal level, to a good proportion of the population covered.

In considering these 3 schemes if became apparent that in each case the costs were skewed by the disproportionate cost per litre of water delivered by the smaller plants which were contained in the schemes. United Utilities therefore identified details of a further scheme whereby a relatively

small number of WTWs could achieve coverage of almost all the major centres of population. This fourth scheme concentrates on the largest plants that offer the most economical installation and operating opportunities, but given that these plants would in some case supply water mixed with non-fluoridated supplies, this option would supply water to some of the population at less than the optimal 1 ppm.

This however left several significant population centres without fluoridated water, so further work was done to identify the size of this problem and steps which could be taken to address it, hence a further 'sub-option' to address the shortcomings.

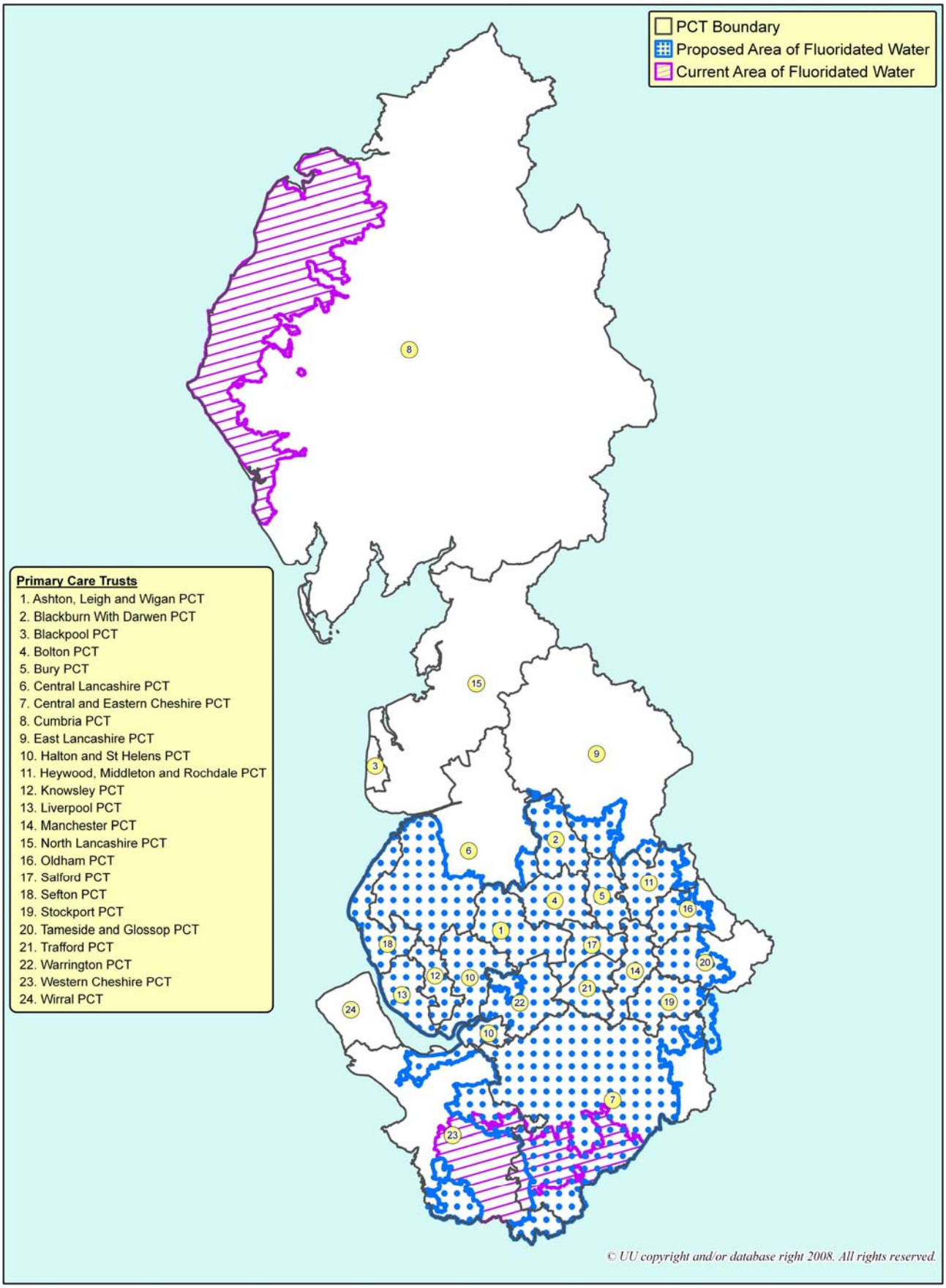
Consequently the NWFEG have identified 4 possible schemes in the north west having regard to water flows, population and prevalence

(i) a scheme for Greater Manchester and Merseyside (26 WTWs)
(ii) a scheme for Greater Manchester and Merseyside, plus some other key locations (additional 21 WTWs)
(iii) a scheme for almost the Whole Region (80 WTWs)
(iv) a scheme based on fluoridating most of the largest sites to take advantage of economies of scale (a. Woodgate Hill), together with a sub-option (b. Watchgate) adding a small number of sites in areas of particularly poor dental health (18 WTWs)

NWFEG would advise that these are not the only possible fluoridation schemes available but are included to demonstrate the necessity of balancing economies of scale, water flows and relationship to prevalence of poor dental health. Should proposals for water fluoridation progress to the point at which the SHA wishes to undertake a public consultation, it will be for the SHA to identify a technically viable scheme upon which to consult.

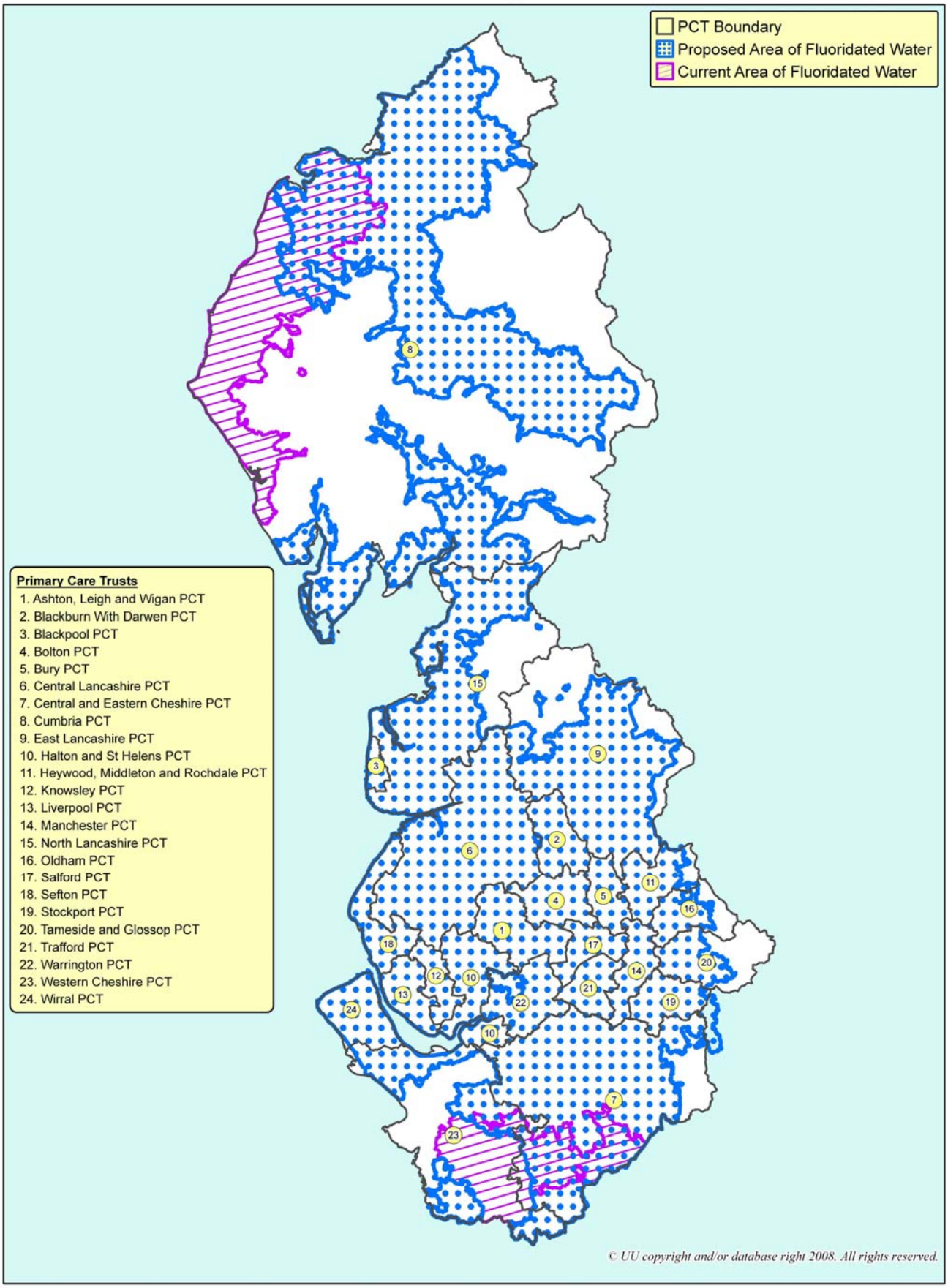
NHS North West Water Fluoridation Evaluation
Scheme 1 - Greater Manchester and Merseyside

NATCANSAT
www.canceruk.net
0870 840 8033



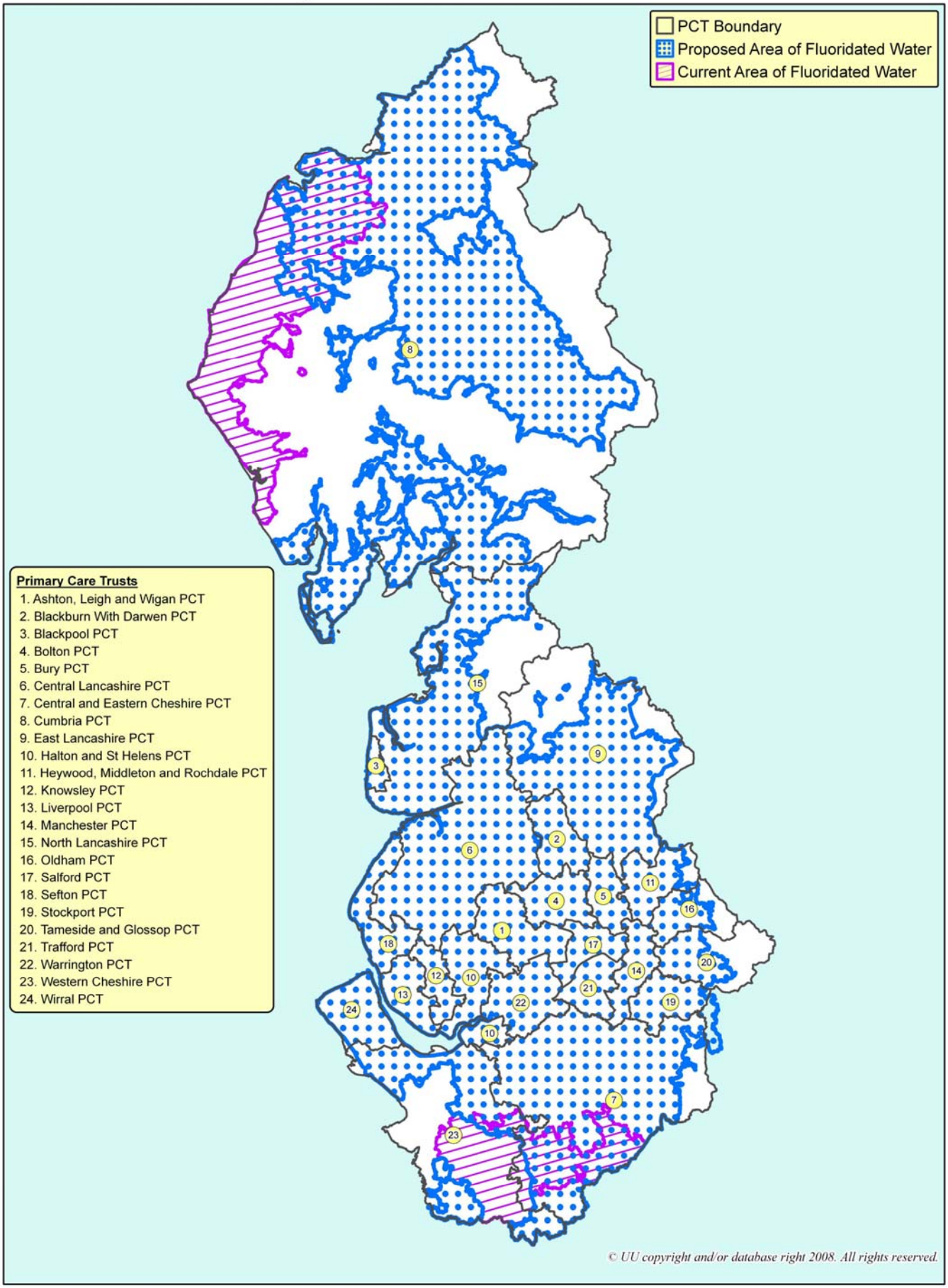
NHS North West Water Fluoridation Evaluation
Scheme 2 - Greater Manchester and Merseyside Plus

NATCANSAT
www.canceruk.net
0870 840 8033



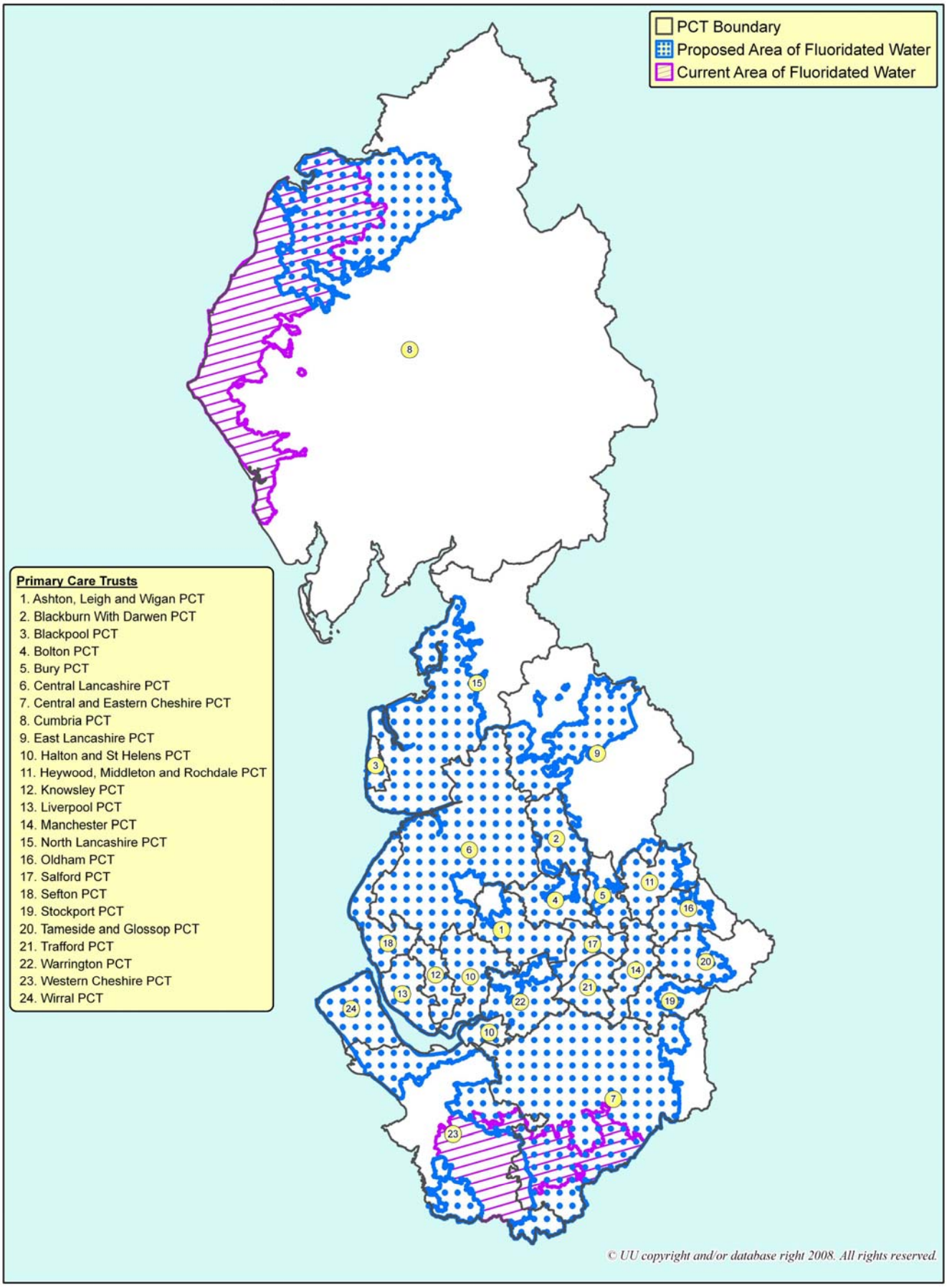
NHS North West Water Fluoridation Evaluation
Scheme 3 - Whole Region

NATCANSAT
www.canceruk.net
0870 840 8033



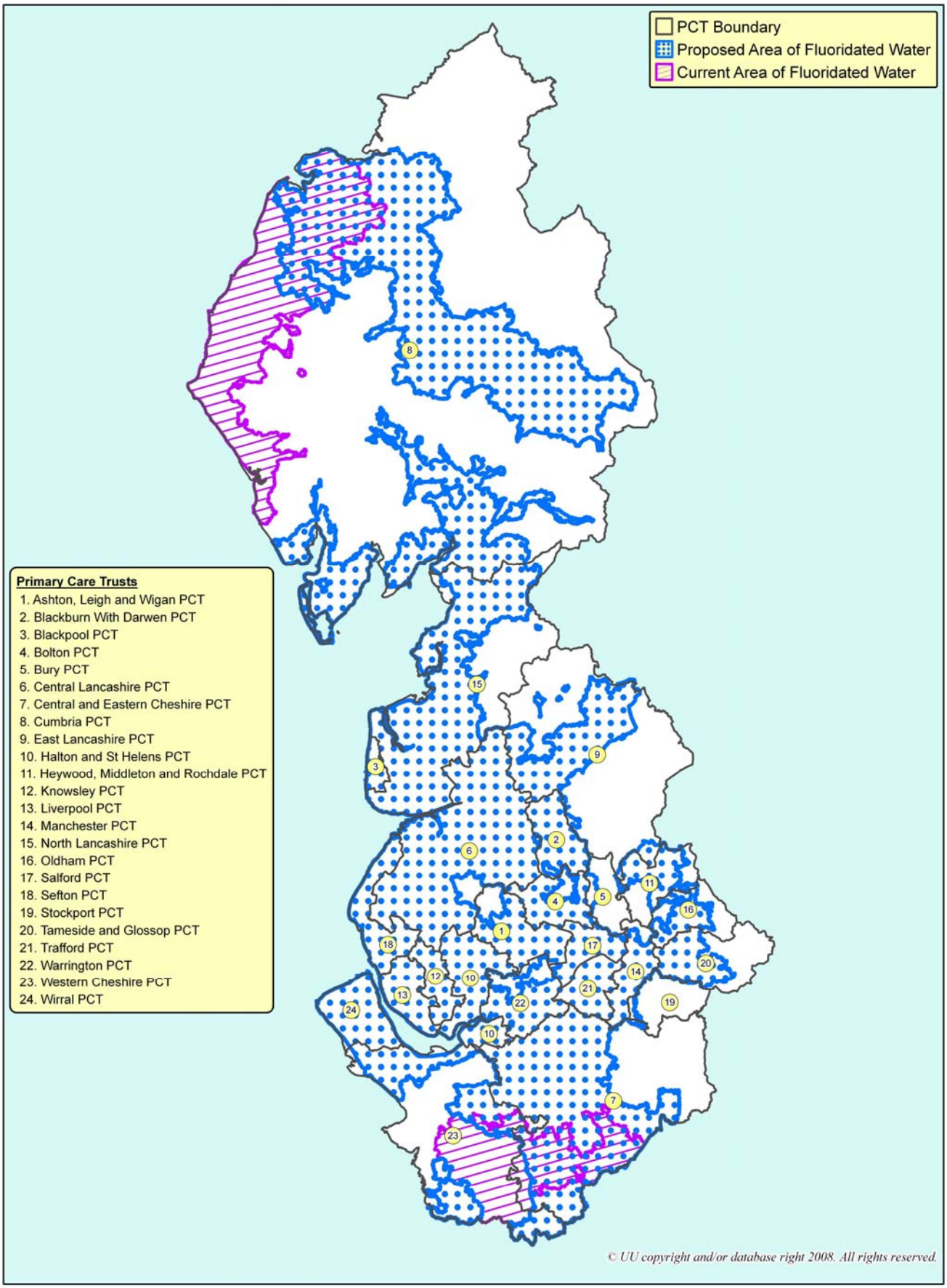
NHS North West Water Fluoridation Evaluation
Scheme 4a - Woodgate Hill

NATCANSAT
www.canceruk.net
0870 840 8033



NHS North West Water Fluoridation Evaluation
Scheme 4b - Watchgate

NATCANSAT
www.canceruk.net
0870 840 8033



3.3 Maps of Potential Schemes

NWFEG commissioned the National Cancer Services Analysis Team (NATCANSAT) to produce geographical representation of the possible fluoridation schemes in conjunction with the dental disease states, PCT and SHA boundaries and the road network. This will enable PCTs to consider the geographical spread of each scheme and the potential benefits to their population, as well as the implication of any decision they make on neighbouring PCTs and populations. The maps have been produced using data provided by United Utilities and the Dental Public Health Observatory. Every PCT has a set of maps relevant to that PCT only. They are also provided on disk. They consist of the following and are at **Appendix 5**:

- North West Overview using severity (dmft) data x 5 (one for each scheme)
- North West Overview using prevalence (%) data x 5 (one for each scheme)
- PCT detail severity (dmft) data x 5 (one for each scheme) by Census Ward
- PCT detail prevalence (%) data x 5 (one for each scheme) by Census Ward

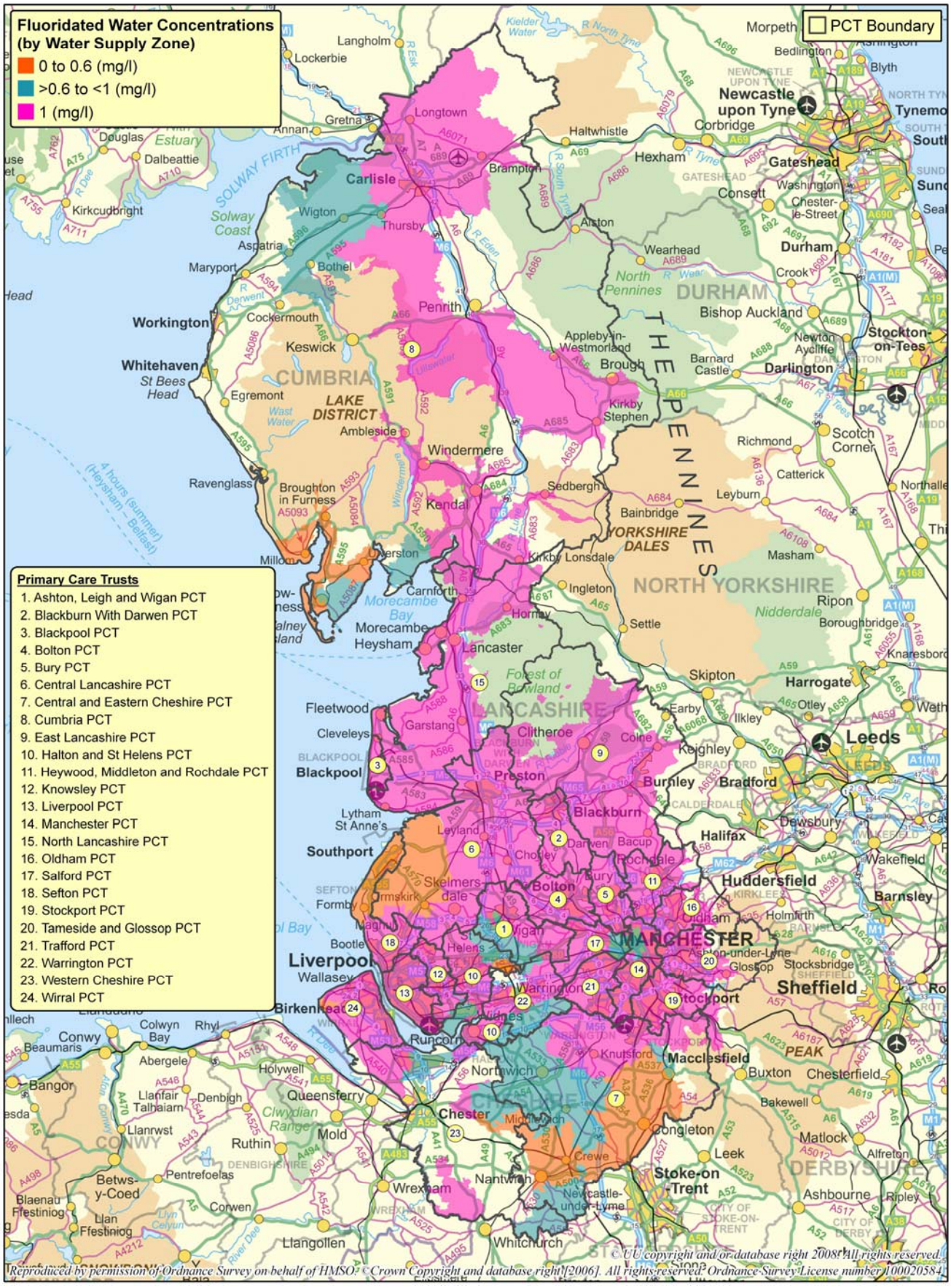
As explained in Paragraph 3.2, not all schemes deliver fluoridated water at 1 ppm across the North West. So NWFEG also asked NATCANSAT to produce maps showing the concentration rates for each scheme. These are as follows:

NHS North West Water Fluoridation Evaluation
Scheme 1 - Greater Manchester and Merseyside

NATCANSAT
www.canceruk.net
0870 840 8033

NHS North West Water Fluoridation Evaluation
Scheme 2 - Greater Manchester and Merseyside Plus

NATCANSAT
www.canceruk.net
0870 840 8033



NHS

North West Water Fluoridation Evaluation
Scheme 3 - Whole Region

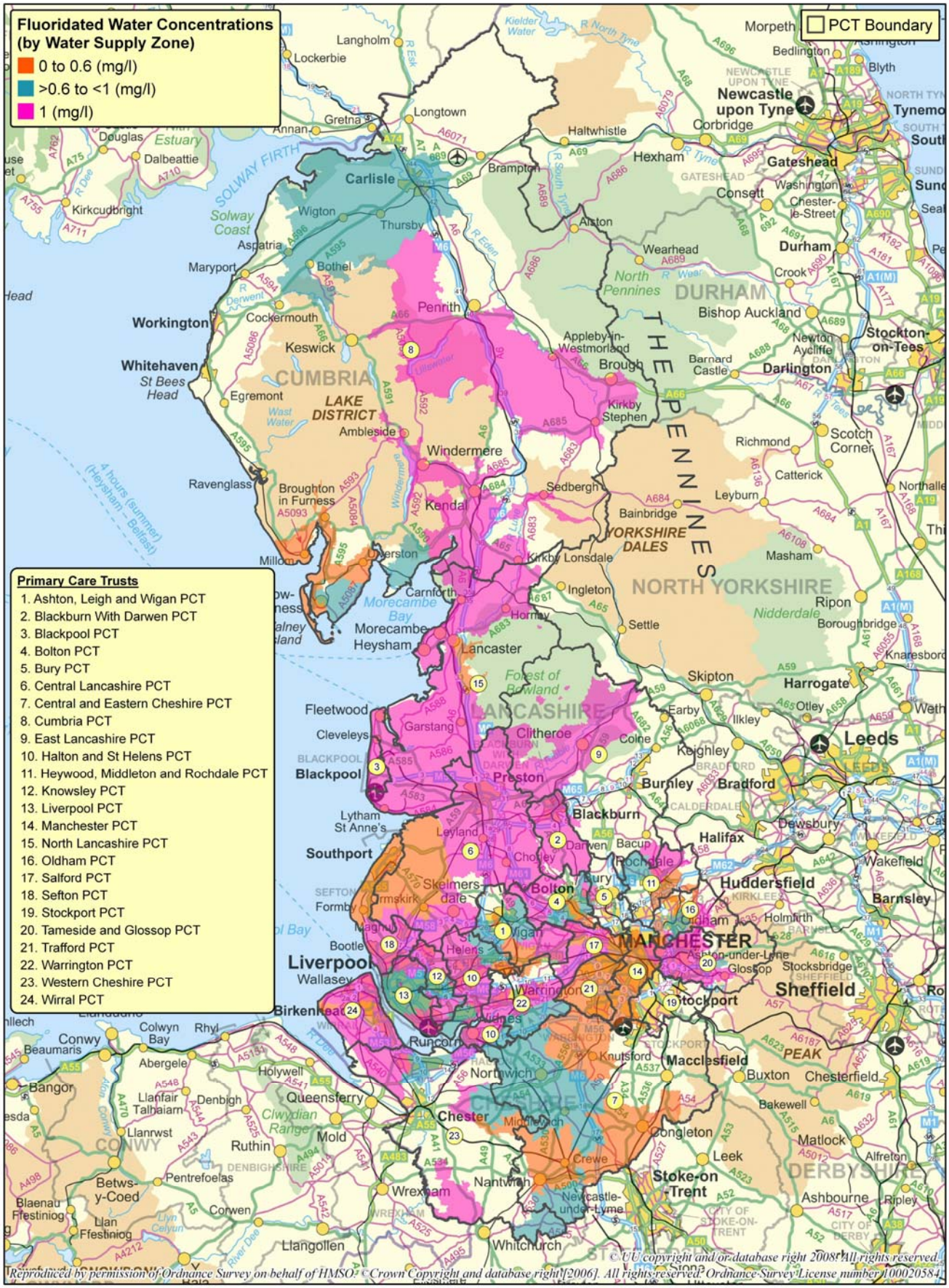
NATCANSAT
www.canceruk.net
0870 840 8033

NHS North West Water Fluoridation Evaluation
Scheme 4a - Woodgate Hill

NATCANSAT
www.canceruk.net
0870 840 8033

NHS North West Water Fluoridation Evaluation
Scheme 4b - Watchgate

NATCANSAT
www.canceruk.net
0870 840 8033



3.4 Potential Scheme indicative costs.

United Utilities have informed NWFEG that the technical solutions have been developed to comply with the Code of Practice on Technical Aspects of Fluoridation of Water Supplies 2005. In order to prepare the estimates at reasonable cost, some simplistic assumptions were necessary. Included in the cost estimates are those capital and operating costs associated with the modification of the existing treatment process as a result of the installation of fluoride dosing equipment, for example pH correction.

The costs are based on United Utilities internal model of 2007 and have a level of resolution of plus or minus 30% at quarter 1 prices 2007. The assumptions inherent in the estimates are detailed in the spreadsheets at **Appendix 4**.

Table 7 Indicative Costs for potential schemes

Potential Scheme	Total Capital Cost (indicative +/- 30% at 2007 prices)	Operating Costs per annum (indicative +/- 30% at 2007 prices)
1. Greater Manchester and Merseyside	£35,447,837	£1,966,605
2. Greater Manchester and Merseyside plus	£63,630,472	£3,613,038
3. Whole Region	£102,124,677	£6,473,163
4a. Woodgate Hill	£26,094,849	£1,808,284
4b. Watchgate	£27,013, 173	£2,031,772

United Utilities advise us that to provide more precise detailed estimates would require significant further work to be undertaken at greater cost, including site visits and design works, which were outside the original request. It is this more detailed work that the SHA would need to commission prior to identifying a final scheme upon which a public consultation would be based. NWFEG consider the variance of cost estimates sufficient to demonstrate the technical feasibility of a number of scheme options presented.

Further design works will incur significant costs and United Utilities advises that the SHA appoints a suitably technically qualified and experienced representative to coordinate the detailed design stage with them should the SHA wish to proceed.

United Utilities would foresee the development of an agreement for the reimbursement of the capital costs in addition to an agreement to define the operating and maintenance regime and reimburse the associated costs. This would be in addition to the draft model agreement covering the main terms to be included between a SHA and water undertaker, issued by the Department of Health. The progression of the necessary commercial agreements between United Utilities and the SHA would be subject to consensus on a sound indemnity from the Secretary of State for Health, in line with Section 58 of the Water Act 2003 (ref 3)

In addition, United Utilities advise that should the SHA decide to implement a scheme following a consultation, it will be necessary to agree how the project will be phased and a programme of implementation. This programme of implementation may take up to 5 years and would link to the capital development programme of United Utilities.

It is advised that, in addition to United Utilities costs, there is likely to be a small management cost shared between all PCTs involved to cover any monitoring arrangements that may need to be implemented by the SHA.

3.5 Technical Aspects of Water Fluoridation

The operational delivery of fluoridation to the water supply by water undertakers is regulated by the Drinking Water Inspectorate (ref 11.). This sets in place measures to prevent over-provision, and ensures that levels of 1.5mg fluoride per litre are not exceeded. The undertakers are required to have policies in place to cover the physical infrastructure necessary for safe unloading, storage and containment of potential spillage of the chemicals. Continuous fluoride monitoring linked to an appropriate alarm and automatic shut down, is required for all installations. In addition, manual tests must be carried out as a further safety check. Operating staff must be trained and component as described in the Code of Practice.

At the 3 plants in the North West where United Utilities have added fluoride, there has never been an exceedance of the permitted level of 1.5mgF/l.

3.6 Fluoride in Sewage Treatment Plant Effluent

United Utilities were asked to provide a commentary on the Fluoride in Sewage Treatment Plant Effluent and provided the following overview.

There are no data available on the levels of fluoride in wastewater effluent. However, in the UK there are strict operational criteria laid down in the Department of the Environment Code of Practice on Technical Aspects of Fluoridation of Water Supplies (DoE, 1987). This ensures that the mean fluoride concentration leaving the works in a calendar month is maintained between 0.9 and 1.1 mg/l, and is between 0.8 and 1.2 mg/l for at least 90% of the time when the fluoridation plant is in operation. It states that the fluoride content of the water leaving the works shall not exceed 1.5 mg/l at any time.

The lowest freshwater EQS is 1 mg/l (for calcium carbonate levels less than 50 mg/l, annual average; Dixon et al., 2000), which is the optimum level for drinking water fluoridation. Fluoride affects aquatic life at concentrations at 9-350 mg/l depending on the hardness of the water and the sensitivity of the species tested. Assuming a worst-case scenario (before dilution and where nothing is removed in treatment or in passage from the DWT plant to the STW effluent), theoretical maximum discharge concentration of fluoride into the environment could be 1 mg/l, which is in line with the lowest EQS for fresh water.

The British Fluoridation Society (BFS, 2001) looked at the environmental aspects of water fluoridation, reviewing literature and concluded that there appears to be no concern about the environmental aspects of water fluoridation among experts who have investigated the subject.

Defra (2003) investigated the effects of fluoridation and report that it will have minimal impact on the environment. Although the fluoridated water will be discharged into the environment through sewage, irrigation etc., there is no evidence of risks. This reflects the fact that fluoride is the thirteenth most common element in the Earth's crust and it is already present in all drinking water, sometimes at levels near or above the 1 mg/l concentration used in artificial fluoridation schemes.

In 2007, the Secretary of State for Environment, Food and Rural Affairs was asked in the Houses of Parliament "what assessment his Department has made of the environmental impact of the fluoridation of public water supplies" (Parliament, 2007). In answer Mr Woolas said that with regard to effects on the environment "Where public water supplies are fluoridated and the concentration of fluoride is maintained at 1.0 mg/l and any discharges of these supplies into the aquatic environment would be further diluted through the process of collection and treatment of waste water, the environmental impact would not be expected to be significant".

The effects of fluoride on sewage treatment processes are determined to be of low risk, with levels which cause microbial inhibition being much higher than the optimum drinking water fluoridation

level of 1 mg/l. Richardson (1985) report that fluoride concentrations of 135 and 1218 mg/l cause 10% and 50% inhibition of nitrification in a biological film reactor, respectively. Clarkson et al. (1989) report concentrations of fluoride up to 200 mg/l having no effect on the biological nitrification efficiency of 100 mg ammonia/l, although when increased to 500 mg/l this inhibition increased to approximately 80%. However, fluoride concentrations equal to or greater than 800 mg/l resulted in a total oxidation rate of only 30 to 60%. The authors also report that in the absence of fluoride, nitrification efficiency was near 100% for up to 500 mg/l ammonia. However, when fluoride was present at 2000 and 5000 mg/l, the nitrification efficiency for 500 mg/l ammonia was reduced to 11 and 16%, respectively.

For your enquiry no actual data for concentrations of fluoride in wastewater effluent and the effectiveness of fluoridation schemes at DWTWs were located. However, from the optimum level of 1 mg/l fluoride treatment for drinking water and DoE codes of practise to regulate fluoridation, this is not expected to inhibit biological treatment processes in STWs or cause environmental risk to the environment even assuming a worse case scenario with no dilution.

3.7 NWFEG Evaluation of Schemes

NWFEG is neutral on the issue of fluoridation, which is a matter for individual PCTs and the SHA. NWFEG has however reviewed the schemes indicated as technically feasible by the water undertaker and is of the view that of the schemes provided, scheme 4b (Watchgate) provides the best option in terms of balance between technical feasibility, cost and population covered. Compared with 4a, it includes a number of additional small water treatment works with the potential to deliver fluoridated water to populations suffering poor dental health. NWFEG is of the view that should PCTs request the SHA to undertake further work, scheme 4b would be a reasonable starting point to develop a technically viable scheme which may form the basis for any subsequent consultation.

3.8 Options for areas not covered by water fluoridation

Should water fluoridation schemes be introduced in the Northwest, some localities will not receive water containing fluoride at the optimum level of 1ppm including communities served by bore hole water supplies. PCTs may need to consider alternative fluoride vehicles for these communities, if they wish to avoid increasing oral health inequalities. The available options for PCTs have been reviewed within the OPM report. They include milk fluoridation, salt fluoridation, toothbrushing and toothpaste schemes, fluoride varnishes, fluoride supplements, and fissure sealants.

'Delivering Better Oral Health. An evidenced based toolkit for prevention' (Ref 10) summarises the strength of evidence for preventive interventions and gives guidance on the best options for different age cohorts. The report concludes that fluoride varnish applied professionally, represents an effective way of preventing dental decay and all children aged 3 year and above would be expected to benefit from this measure irrespective of the fluoride status of the water supply. The report also recommends that all families should use toothpaste that contains at least 1000 parts per million of fluoride.

Chapter 4 - Cost, Benefit and Financial Planning

4.1 Cost and benefit and risk analysis of fluoridation

NWFEG working on behalf of the 24 PCTs of the North West commissioned a cost and benefit analysis of the various interventions available to address dental health promotion, of which water fluoridation is one option. The detailed report is attached as **Appendix 2**. For the purposes of this chapter a part of the executive summary and table of findings about water fluoridation have been extracted and included here. The table is based on a much more detailed analysis and overview of the evidence available and it is recommended the full report is read.

Effectiveness & impact on inequality
The majority of preventive measures included in this review are measures that act as a vehicle for delivering fluoride. However, two measures do not deliver fluoride, namely fissure sealants (although some types can) and dental health education and promotion. These act as preventive measures by either protecting areas of the teeth susceptible to decay (as is the case with fissure sealants) or by increasing the knowledge of oral hygiene which is then intended to lead to improved long term dental hygiene related behaviour. The effectiveness of preventive measures can be measured in terms of their reducing the prevalence and/or the severity of dental caries. In addition, it is important to consider their effectiveness in reducing decay inequalities. Common issues identified for the majority of these interventions relate to a lack of confidence as to the precise reduction of caries that can be attributed to the intervention individually, the benefit for both low risk as well as high risk children and issues of compliance for all interventions except water fluoridation.

Water fluoridation
A systematic review of evidence pertaining to the effectiveness of fluoridated water (McDonagh et al, 2000) found that fluoridated water does reduce caries in both the primary and permanent dentitions when measured by its prevalence and its severity. However the degree to which caries is reduced is not definitive. The reduction in caries was found to be greater in areas which have higher levels of caries experience amongst the area population.

Fluoridated salt
The evidence on fluoridated salt suggests comparable benefits to water fluoridation when used but is unlikely to have an impact from a community perspective in terms of caries reduction.

Milk fluoridation schemes
The majority of the evidence finds that milk fluoridation schemes do reduce caries, but as with water fluoridation this reduction is not definitive. One study reported no significant benefits for primary dentition (Riley et al,, 2005). In addition the effectiveness of milk fluoridation schemes can be impeded by requiring parental consent, subsequent compliance and the sustainability of the schemes.

Fluoride toothpaste
Brushing with fluoride toothpaste reduces caries in both the primary and permanent dentitions and higher fluoride concentrations are more effective. However children from deprived backgrounds start toothbrushing later and use fluoride less frequently but issuing free toothpaste requires parental consent and does not guarantee compliance amongst those at most risk.

Fluoride varnish
A systematic review found that fluoride varnish is effective at substantially reducing caries in the primary and permanent dentitions as measured by severity (Marinho et al, 2002). The systematic review evidence finds that it is effective for both low and high risk children but that this supporting evidence was of poor quality. As fluoride varnishes are applied by a dental professional, they require regular attendance at dental services.

Fluoride supplements
Self-administered fluoride supplements are not recommended as a public measure because of the fluorosis risk if used by children under 6 years of age. There are also consent and compliance issues.

Fluoride mouthrinses
A systematic review concluded that fluoride mouthrinses are effective in preventing caries in the permanent dentition. They should not be used by children less than 6 years of age.

Fissure sealants
Systematic review evidence finds that resin based fissure sealants are effective in preventing caries on the occlusal surfaces of permanent molar teeth (Hiiri et al, 2006; Ahovuo-Saloranta et al, 2004). There is no available evidence however on whether the benefit of fissure sealants varies according to whether children were at high or low risk of caries. As fissure sealants are applied by a dental professional, they require regular attendance at dental services.

Other professionally applied topical fluoride interventions
Other professionally applied topical fluoride interventions include fluoride gels and slow release devices (SRGs) and are targeted at high risk individuals. Fluoride gels are effective at reducing caries and SRGs can be more effective than water fluoridation, although this is due to the fact that they are targeted at high risk individuals rather than the general population. As these interventions are applied by a dental professional, they require regular attendance at dental services.

Dental health education and promotion
There appears to be very little evidence on the effectiveness of dental health education and promotion in reducing caries severity. However systematic review evidence has found dental health education leads to improved knowledge levels and temporary improvements in dental hygiene (Kay & Locker, 1998; Watt et al, 2001; Sprod et al, 2003). In addition there are no health risks associated with dental health education.

Cost effectiveness
For all of the preventive interventions there is a lack of both reliable and recent evidence on costs and cost effectiveness from the UK. This makes it difficult to compare the cost effectiveness of the different interventions. However, for all interventions, cost effectiveness is related to whether it can effectively be targeted at high risk individuals as well as the costs of both the intervention itself and the costs need to implement and sustain its use for the required duration.

The cost effectiveness of fluoridating water supplies is affected by four variables; the size of the population served by the fluoridated water supply, the level of tooth decay in the population, the age and condition of the water works and the type of fluoride used. Fluoridating water supplies is more cost effective when there is a larger population with a higher level of caries and a low level of fluoride intake. The most recent data on actual costs is from 1998 (Sanderson, 1998). The evidence on salt fluoridation suggests that it is cost-effective as the costs are minimal. The most recent data is from 2005 (Gillespie & Marthaler, 2005).

Recent data from 2008 on the costs of milk fluoridation schemes in the UK report costs of £1 to £2 per child per year (Marino et al, 2007; Woodward, personal communication 2008) and as with other interventions it is more cost effective if run in a high caries area. Similarly there is consensus expressed in the evidence that fissure sealants are cost effective only when targeted at the highest risk children and applied to teeth that are at most risk of decay. Toothpaste and brushing schemes are not prioritised as the most cost-effective fluoride intervention although it is hypothesised that postal toothpaste schemes could be more cost effective if commenced following the eruption of primary molars (Davies et al, 2002). There is very little substantive evidence relating to fluoride varnish cost effectiveness but it can be maximised if fewer applications are given and if it is applied by dental nurses with appropriate training. There is insufficient evidence to be able to comment on the costs or cost-effectiveness of fluoride supplements, but where this is mentioned it is said to be

low. There is insufficient evidence of the cost effectiveness on both of the other professionally applied topical fluoride interventions. Similarly, there is little data available on dental health education and promotion but what there is suggests that dental health promotion is not very cost effective.

Limitations

In this case limitations refer to any potential health risks associated with the intervention and issues of compliance and sustainability that may impede upon an intervention's effectiveness identified in the evidence on each of the preventive interventions. The most frequently mentioned risk associated with the preventive interventions that deliver fluoride is fluorosis. This is caused by the excessive intake of fluoride by children aged between 0-6 years. The most "at risk" period for the aesthetically important upper anterior teeth is between 2-3 years of age. There are different levels of fluorosis which can range from being very mild to a level which is aesthetically severe. Fluorosis is a greater risk for individuals who already have a higher intake of fluoride, usually through exposure to a range of fluoride sources. Along with fluorosis, issues of compliance are a limitation for all other interventions that require behavioural changes.

The evidence on the associated risks of fluoridated water found that there is an increased risk of fluorosis. However there is no conclusive evidence on the relationship between fluoridated water and an increased risk of cancer, bone fractures or other effects (McDonagh et al, 2000). Systematic review evidence on milk fluoridation found one Chilean study that reported an increase in very mild dental fluorosis (Yeung et al, 2007). Ingesting fluoride toothpaste, especially in the first two years of life can increase risk fluorosis and this risk can increase in areas with fluoridated water supplies. The risk of ingestion applies mainly for very young children.

Compliance issues have been identified for fluoride supplements, which require daily compliance in order to be effective and are therefore not regarded as an effective public health measure. There is limited evidence on compliance issues relating to fissure sealants but there is a need for contact between the child and dental health services as is the case for fluoride varnish and other professionally applied topical fluoride interventions. In addition, systematic review evidence found that the effectiveness of fissure sealants reduced over time due to decreased retention rates and therefore require periodical reapplications (Hiiri et al, 2006). The risk associated specifically to salt fluoridation is that it is not a suitable fluoride intervention for people who need to reduce their salt intake. There is a lack of evidence on associated risks of the two other professionally applied topical fluoride interventions although it is noted that gels are less well tolerated than fluoride varnish and SRGs can become dislodged. There is little on the risks of fluoride varnish but the consensus expressed in the evidence is that it is safe.

Fluoridated water

Intervention	Overview	Evidence	Potential benefits and limitations				
			Cost	Compliance and sustainability	Risks	Impact on inequality	Other
Fluoridated water (FW)	**What is it?** Water fluoridation is a systemic fluoride intervention. Fluoride is added to water supplies so that the fluoride level of one part per million is reached within a geographically contained area. **Effectiveness** • Systematic review evidence found that FW reduces the prevalence and severity of caries. • The reduction in caries is greater in areas with higher levels of caries experience. However the degree to which caries is reduced is not definitive.	Two systematic reviews have been identified, one of which focuses wholly on the efficacy and possible health risks of FW (McDonagh et al 2000). The other reviews a range of fluoride interventions and uses McDonagh et al (2000) as its main evidence source for FW (NHMRC 2007). Both include international as well as national evidence. Three sources of evidence on cost effectiveness specifically were identified which include data from the UK and US. In addition three sources of evidence related specifically to effect on social equality were identified with some focus on North England. Three studies had as their focus possible associated risks	• Four key variables are identified to be important when evaluating the cost effectiveness of FW. These are the size of the population served by the water supplier, the level of tooth decay in the population, the age and condition of water works and the type of fluoride used • FW is more cost effective when there is a larger population with a high level of caries and low level of fluoride intake • Limited data – the most recent analysis is out of date (the most recent evidence is from1998)	**Compliance** • FW does not require changes to individual health-related behaviours and therefore non-compliance is not an associated risk. • FW does not require individuals to spend additional resources as costs are borne by the NHS. **Sustainability** • The sustainability of FW is dependent upon the maintenance of fluoridation schemes; e.g. if a FW scheme is discontinued the population will no longer have access to FW. • Systematic review evidence found the prevalence of caries rise if FW is withdrawn.	• Systematic review evidence found that there is an increased risk of fluorosis associated with FW. • Systematic review evidence finds no relationship between FW and other possible health risks such as cancer and bone fractures. • However the evidence included in the systematic review may not be informative abo the long term health risks associated with FW.	• Systematic review evidence suggests that inequalities in dental health across social classes in 5 and 12 year old children are reduced by FW when caries experience is measured by severity (dmft/DMFT). • However the systematic review evidence did not find that inequalities were reduced when FW effectiveness is measured by proportion of caries free children • Other sources of relevant evidence find that the benefits of FW for reducing caries in 5 year olds are greater for more deprived areas.	• There appears to be a lack of evidence on the effectiveness of FW for adults. One source of evidence, a meta-analysis of 9 studies, found that FW was effective in reducing preventing caries in adults.

4.2 NHS Financial Planning Guidance

The current guidance (1 – p 10 para 35) states that

> *'Subject to the availability of funding, the Department will pay the capital costs of new schemes or the replacement of plant required to maintain existing schemes. SHAs should note that the fluoridation plant becomes an asset of the water company and is therefore excluded from the NHS capital charges arrangements.'*

Therefore capital costs of any new scheme will not fall on SHA or PCT budgets. With regard to revenue costs for new schemes the guidance states that

> *'the PCTs will have to reimburse the SHA for the recurring costs of the fluoridation scheme. PCTs may use funds allocated to them for primary care dental services to meet these costs.*' (1 – p 11 para 36).

In principle, the allocation of costs to PCTs to reimburse the SHA for recurring costs would be calculated on a per capita receiving the benefit.

The revenue costs of potential water fluoridation schemes must be reviewed within the context of how much the NHS currently spends on dental services.

Dental services are principally provided by independent general dental practitioners. In the North West in 2008/9, the gross allocation for NHS contracts with independent general dental practitioners will be £415 million; this includes £90 million income from patient charges. A further £14 million is spent on PCT provided salaried community dental services and an additional estimated £15 million for hospital based (excluding foundation trusts) dental services. This makes a total estimated spend on NHS dental services in the North West of £444 million in 2008/9.

In addition a substantial amount of dental care is provided on a private basis. This is difficult to quantify as most private care is provided on a treatment by treatment basis through a confidential contract between the dentist and patient. The latest available information on private dental care in the UK comes from the 2004 report by the National Audit Office (13), which estimated that in 2003/4, £1.1-1.9 billion was spent on private dental care in England. By applying these figures to the population of the North West, plus a notional 2.5% uplift per annum, it is estimated that approximately £253 million pounds is spent on private dental treatment in the North West.

Chapter 5 - Recommendations and Next Steps

5.1 Next steps

a. Next Steps

This report from the NWFEG is presented to the North West PCT Chief Executives meeting for consideration.

PCT Boards will receive the report, with maps specific to their PCT area, containing information on the implication of each of the schemes presented. PCT Boards are asked to consider whether they wish to invite the Strategic Health Authority to undertake further work on this issue.

In considering the potential for fluoridation of the water supply, PCTs should take the opportunity to consider with all key stakeholders as they would for any significant service change or development. NWFEG would recommend the following are key stakeholders as a minimum:

- The local authority
- Local Overview and Scrutiny Committee
- Local dentists and GPs
- MPs
- Patient Forums

These stakeholders are listed as a minimum and PCTs are advised to follow their normal practice.

Because of the interdependency of the work between PCTs, it is requested that each PCT Board is in a position to consider its view of fluoridation by October 2008 (subject to agreement with the SHA)

The NWFEG has taken legal advice on two key issues in relation to the paper; firstly whether a PCT needs to consider the issue of fluoridation at all and secondly whether it is possible for a PCT to request the SHA to undertake further work on fluoridation without necessarily indicating PCT support or otherwise for fluoridation as an intervention.

On the first issue, NWFEG has been advised that PCTs have a statutory obligation to assess the oral health needs of their respective populations and to commission appropriate services to meet those needs. Exploring fluoridation of water supplies as an option amongst a range of possible interventions is a necessary and appropriate consideration for PCTs particularly in the light of the recent best practice guidance from the Chief Dental Officer of February 2008.

On the second issue, NWFEG has been advised that where a PCT requests the SHA to undertake further work on fluoridation without being able to demonstrate that the PCT has a position on the matter the PCT is at an increased risk of legal challenge. In this regard, a legitimate expectation is likely to have been created that the PCT would have reached a preliminary decision (subject to full public consultation and further appropriate SHA scoping) as to whether or not to make a request to the SHA given that the PCT would by then have had an opportunity to evaluate the findings of NWFEG and would also have completed the sounding exercises with local key stakeholders mentioned above.

b. Role of the NWFEG

Having delivered this report, the NWFEG according to the terms of reference is now substantially finished and the group will be disbanded.

c. North West Strategic Health Authority

NWFEG have advised the SHA Board that a paper was being collated and would be provided to PCTs and that it is possible some PCTs may wish to request that the SHA undertakes further work on the matter.

The next steps for the SHA will be determined by the outcome of discussion within individual PCTs, and there are at least 3 options:

1) that no PCT request further work by the SHA
2) that all PCTs request further work by the SHA
3) that some request further work by the SHA, and some do not

Depending on the outcome of the above, it will be a matter for the SHA to consider what steps, if any, should be undertaken regarding further scoping works with United Utilities and the remit of the public consultation, having regard to the following issues:

- The complexity of the water supply system
- The dental health of the populations affected

5.2 Recommendations

On the basis of the information provided, the North West Evaluation Group makes the following recommendations:

1) That the North West PCT Chief Executives meeting receive this report.
2) That the North West PCT Chief Executives meeting note the initial review of potential water fluoridation schemes.
3) That PCT boards consider whether they wish to request the SHA to explore the possibility of fluoridation of the public water supply
4) That in the event a PCT does request the SHA explore the possibility of fluoridation they express a view on the potential water fluoridation schemes presented in this report
5) That PCT boards frame a response to the SHA in accordance with the SHA guidance issued.
6) That following the production of this report, the NWFEG is disbanded.

References

(NB References contained within extracts from the OPM report can be found in that report in Appendix 2)

1. Department of Health, Fluoridation of Drinking Water, Gateway 9361, Chief Dental Officer February 2008

2. Choosing Better Oral Health; An Oral Health Plan for England; DH 2005

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8. Griffin SO, Regnier E, Griffin PM, Huntley V. Effectiveness of fluoride in preventing caries in adults. J Dent Res. 2007 May;86(5):410-5

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12. Water Fluoridation Review, Joint Report of the Adult Services and Health Scrutiny Panel and the Children and Young People's Services Scrutiny Panel, May 2007, Rotherham Metropolitan Borough Council

13. Kay E, Locker D. A systematic review of the effectiveness of health promotion aimed at improving oral health. Community Dental Health 1998; 15(3):132-144.

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16. The Nuffield Council on Bioethics, Public health: ethical issues 2007

17. Hardman MC et al 2007, A cluster randomised controlled trial to evaluate the effectiveness of fluoride varnish as a public health measure to reduce caries in children

Appendices

1 Terms of Reference of the North West Fluoridation Evaluation Group

2 Office for Public Management – Water Fluoridation in the North West Report March 2008

3 Review of Public Opinion on Water Fluoridation

4 United Utilities Detailed Information on potential schemes and costs

5 PCT specific detailed maps