Drinking water meeting current standards and gastrointestinal illness:

A critique of the work of Pierre Payton, with discussion of its relevance to the UK and suggestions for a future study.
This document reports on the discussions and recommendations of the Epidemiology Survey Project Group appointed by the Department of the Environment, which met during June to August 1992.

The membership of the group consisted of:

Technical secretary: Dr Laura C Rodrigues
London School of Hygiene and Tropical Medicine, London

Chairman: Mr Tony Lloyd
Drinking Water Inspectorate, London

Members: Dr Ann Dawson
Dr John Dadswell
Mr Robert Lacey
Dr Paul West

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Executive summary

i. In 1991, Pierre Payment and co-workers reported on a randomized controlled trial conducted in Canada (the Montreal study). The paper claimed that the study had shown one third of the episodes of gastrointestinal infection in the population were caused by drinking tap water, even though the water met current microbiological standards. The Epidemiological Survey Project Group was asked to consider critically the methodology of the study, to re-evaluate its conclusions in the light of any weaknesses found, to assess the relevance of the study to the situation in England and Wales and, if appropriate, to suggest a specification for the design of any study which could be conducted here.

ii. The Group found some problems with the epidemiological design of the Montreal study, principally that participants were not blind to whether they were drinking tap or filtered water and thus the reporting of symptoms might have been biased. Against that possibility, a dose response relationship was reported between rates of gastrointestinal illnesses and variables participants were blind to i.e. quality of water in the distribution system, levels of contamination in the filters and quantity of tap water consumed. The study was therefore considered to be sound enough to be taken seriously in spite of methodological limitations.

iii. Other criticisms of the study included the use of reverse osmosis filters, because of the change in the chemical composition of the water and evidence of contamination by bacteria. This did not undermine the validity of the study, but raised questions about the interpretation of results. It was noted that no stool samples were collected; this might have helped to identify the types of organism associated with the gastrointestinal illnesses linked to drinking tap water.

iv. The study was considered relevant to England and Wales because the quality of the tap water appeared to be similar, although the quantity consumed might be lower in England and Wales. Very limited available data suggests the rate of gastrointestinal infections might also be lower than in Canada.

v. The Group supported the undertakings of a similar study in England and Wales and presented an outline design and costings for a study which would eliminate the methodological limitations of the Montreal study.
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCDC</td>
<td>Consultant in Communicable Disease Control</td>
</tr>
<tr>
<td>GI</td>
<td>Gastro Intestinal</td>
</tr>
<tr>
<td>GII</td>
<td>Gastro Intestinal Illness</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>HCGI</td>
<td>Highly Credible Gastro Intestinal Illness</td>
</tr>
<tr>
<td>RO</td>
<td>Reverse Osmosis Water Filter</td>
</tr>
<tr>
<td>UV</td>
<td>Ultra Violet</td>
</tr>
<tr>
<td>WQR</td>
<td>Water Quality Regulations</td>
</tr>
</tbody>
</table>
1. **Objectives and composition of the group**

1. The Department of the Environment appointed a group of experts to evaluate the methodology and findings of the report "A randomized trial to evaluate the risk of gastrointestinal disease due to consumption of drinking water meeting current microbiological standards". This study (the Montreal study) was conducted in Canada by a team headed by Pierre Paymet who claimed that a third of the rate of gastrointestinal illness in the population was attributable to drinking tap water even though the tap water met current microbiological standards.

2. The group was asked to assess critically the methodology of the study and re-evaluate its conclusions in the light of any deficiencies found; to assess the relevance of the study to the situation in England and Wales and, if appropriate, to suggest a specification for the design a similar study which could be conducted here. The objectives of the proposed study were to be determined by the group and the design was to take into account any weaknesses identified in the Montreal study.

3. The group was chaired by the Drinking Water Inspectorate (Mr Tony Lloyd) and included experts from the fields of public health (Dr Ann Dawson), epidemiology (Dr Laura Rodrigues), statistics (Mr Robert Lacey), microbiology (Dr John Dadswell) and water treatment (Dr Paul West). Dr Rodrigues was appointed as group technical secretary and made responsible for steering the work, drafting the final report and presenting the conclusions.
2. **Summary of the Montreal study**

1. Data presented in this section are abstracted from the main paper reporting the study unless otherwise indicated. Aspects of the study have been published in a number of other papers.

2. The study was carried out in Montreal to investigate whether there was an excess of gastrointestinal illness related to consumption of tap water prepared from sewage contaminated waters but which met accepted microbiological and physio-chemical water quality standards. The study was prompted by the finding of viruses in such water.

3. The study was carried out in a suburban population with socioeconomic and education levels typical of metropolitan Montreal. The area was served by a single water treatment plant drawing raw water from a river contaminated with human sewage discharges but with little contamination from chemical discharges. Treatment consisted of pre-ozoneation, flocculation by alum, rapid sand filtration, ozonation, and final disinfection by chloramine or chlorine dioxide. The final water met current Canadian microbiological and physicochemical water standards and was perceived by the population, 90% of which drinks unmodified tap water, to be of good to excellent quality.

4. The study sample consisted of 600 households. To recruit this sample 3741 households were selected at random from a directory of inhabited addresses in the area, contacted, screened and invited to participate in the study, until the desired 600 were obtained. All households in the study had to be owner occupied, French speaking, regular consumers of tap water, include at least one child aged 2 to 18 and willing to participate in the study.

5. The design was a randomized controlled trial, with about half of the households assigned to a no intervention group, which continued to drink unmodified tap water and the other half to the intervention group, which were supplied with a domestic, under the sink, reverse osmosis water filter (RO). The study was not blind, and so families knew whether they were drinking filtered or unmodified tap water.

6. The households were followed up from March 1988 to June 1989, with a break of two months during July and August 1988. Most of the analysis of data was done separately for the periods before and after the break. Baseline information was collected by home interviews and episodes of gastrointestinal illness (GII) were noted by a family member in a health diary maintained prospectively. A nurse from the study staff telephoned all families every two weeks and asked for the information in the health diary. In the study an episode of highly credible gastrointestinal illness (HCGI) was defined as either vomiting or liquid diarrhea, or nausea with soft diarrhea and abdominal cramps.

7. In addition to gastrointestinal (GI) and other symptoms, data were collected on water consumption, microbiological quality of water from the treatment plant (raw and treated), and from 25 sites in the distribution system and from the RO filtration units.

8. Sera were also collected and antibody levels measured for Hepatitis A virus, Coxsackievirus B2 to B5, Echoviruses 9, 11 and 30 and rotavirus. 617 individuals gave at least one blood sample, and 345 gave two, three or four samples. Samples were collected
in February, June, and September 1988 and in June 1989, irrespective of whether gastrointestinal symptoms were present. No stool samples were collected.

9. Analysis of the baseline interview revealed the two study groups (assigned to drinking filtered or tap water) were similar in sex distribution but marginally different in terms of age distribution. Data on socioeconomic characteristics were not presented. Over 95% of the families stayed in the study during the whole of period 1, and this was similar in the two groups. Over the two study periods, 14% of the families in the tap water group and 7% in the RO filtered water group left the study. The majority of these in the tap water group left because they wanted to start drinking filtered or bottled water (9 families), and in the RO filtered group because of problems with the filter (5 families).

10. Analysis of the quality of raw water showed high levels of pathogens and indicator organisms but treated water leaving the plant was free of indicator bacteria and human enteric viruses and in compliance with regulations. However opportunistic bacterial growth was observed in a number of the water filtration units.

11. The two study groups consumed similar volumes of water. Consumption at home was mostly of the type of water households had been assigned to. Outside the home both groups consumed mainly tap water, but this consisted of less that one sixth of total water consumption (Table 1).

Table 1: Mean number of glasses of filtered and tap water consumed weekly by study group, at home and away from home

<table>
<thead>
<tr>
<th>Study group</th>
<th>Filter</th>
<th>Tap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of water consumed at home</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Filtered water</td>
<td>37.4</td>
<td>0.0</td>
</tr>
<tr>
<td>Tap water</td>
<td>1.9</td>
<td>37.8</td>
</tr>
<tr>
<td>Away from home</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Filtered water</td>
<td>0.3</td>
<td>0.0</td>
</tr>
<tr>
<td>Tap water</td>
<td>7.7</td>
<td>8.7</td>
</tr>
</tbody>
</table>

From Payment et al, reference 1.

12. The incidence of GII was estimated in the two groups based on the number of episodes of HCGI by person years at risk. This was done separately for families, all adults, all children, and for the reporting adult. The incidence was higher in the first period, than in the second period. The overall incidence of HCGI was 0.76 per person per year in the tap water group, and 0.50 per person per year in the RO filtered water group. Therefore the preventable fraction (the proportion of illnesses in the tap water group that would be reduced by the use of filters and thus could be attributed to the quality of the tap water) was approximately 30% in all age groups. The incidence was higher in children but the preventable fraction was similar in adults and children. The difference in incidence between tap water and filtered water groups was statistically significant (p < 0.05) when children and informants were analyzed separately. When all participants were analyzed together, because of higher numbers the significance was more marked (p < 0.01). This is shown in Table 2.
Table 2:  Incidence of HCGI episodes per person per year by study group

<table>
<thead>
<tr>
<th></th>
<th>Period 1</th>
<th></th>
<th></th>
<th>Period 2</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Filter</td>
<td>Tap</td>
<td>Preventive</td>
<td>Filter</td>
<td>Tap</td>
<td>Preventive</td>
</tr>
<tr>
<td></td>
<td>n=298</td>
<td>n=304</td>
<td>fraction %</td>
<td>n=282</td>
<td>n=276</td>
<td>fraction %</td>
</tr>
<tr>
<td>Family</td>
<td>0.65</td>
<td>1.00</td>
<td>35.0</td>
<td>0.43</td>
<td>0.64</td>
<td>32.8</td>
</tr>
<tr>
<td>Informant</td>
<td>0.54</td>
<td>1.00</td>
<td>36.0</td>
<td>0.44</td>
<td>0.63</td>
<td>30.2</td>
</tr>
<tr>
<td>Youngest child</td>
<td>0.86</td>
<td>1.24</td>
<td>30.7</td>
<td>0.56</td>
<td>9.80</td>
<td>30.0</td>
</tr>
</tbody>
</table>

Controlled by age, sex and region. Differences in rates between the two groups are significant at p<0.05 for informant and youngest age group, and at p<0.001 for families, in each of the two periods.

13. The episodes of HCGI were mild, with a very small proportion in both groups reaching the health services. Absence from work or school, attributable to drinking tap water, was 30 days per 1000 persons per year.

14. There was a clear and statistically significant difference in the rate of episodes per person years in the two groups. The proportion of individuals who had reported at least one episode of illness was only marginally different in the filter and tap water groups with respectively 20% and 23% of informants having at least one episode, and 42% and 46% of children having at least one episode. The average number of episodes per person, however, varied markedly suggesting the effect of drinking tap water was not to increase the number of susceptibles, but rather to increase the number of episodes among the susceptibles (Table 3).

Table 3: Percent of study subjects reporting HCGI symptoms and mean number of episodes (among those reporting at least one episode) in both periods combined.

<table>
<thead>
<tr>
<th>Study group</th>
<th>Filtered water</th>
<th>Tap water</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% with episodes</td>
<td>Mean number episodes</td>
<td>% with episodes</td>
<td>Mean number episodes</td>
</tr>
<tr>
<td>Family</td>
<td>62.0</td>
<td>3.82</td>
<td>67.7</td>
<td>4.81</td>
</tr>
<tr>
<td>Informant</td>
<td>20.0</td>
<td>1.70</td>
<td>23.1</td>
<td>2.10</td>
</tr>
<tr>
<td>Youngest child</td>
<td>42.3</td>
<td>1.83</td>
<td>46.3</td>
<td>2.37</td>
</tr>
</tbody>
</table>


15. When the group drinking unfiltered tap water was analyzed to see whether increased water consumption was associated with increased rates of HCGI symptoms, results showed the incidence was lower in those drinking less than 25 glasses a week than among those drinking 26 glasses a week or more but this was not statistically significant. (Table 4). This was true both for the informants and for the children.
Table 4: Incidence of HCGI in period 2 by amount of unfiltered tap water consumed among unfiltered tap water drinkers.

<table>
<thead>
<tr>
<th>Number of Glasses per week</th>
<th>Episodes per Person per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informant</td>
<td></td>
</tr>
<tr>
<td>1-25</td>
<td>.42</td>
</tr>
<tr>
<td>26-45</td>
<td>.70</td>
</tr>
<tr>
<td>46+</td>
<td>.66</td>
</tr>
<tr>
<td>Children</td>
<td></td>
</tr>
<tr>
<td>1-25</td>
<td>.55</td>
</tr>
<tr>
<td>26-45</td>
<td>.89</td>
</tr>
<tr>
<td>46+</td>
<td>1.10</td>
</tr>
</tbody>
</table>

From Payment et al, reference 1.

16. Table 5 shows that an association was found, at a statistically significant level, between duration (but not incidence) of gastro-intestinal illness and HPC counts at 20°C in 5 areas in the distribution system.

Table 5: Relationship between number of days sick and number of episodes of HCGI and heterotrophic plate counts (HPC) at 35°C and at 20°C in water (for tap water drinkers) and in the reverse osmosis unit (for RO water drinkers).

<table>
<thead>
<tr>
<th>Tap water n=293</th>
<th>RO water n=113</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days sick per year</td>
<td>Number of Episodes per year</td>
</tr>
<tr>
<td>HPC 30°C</td>
<td>0.015</td>
</tr>
<tr>
<td>p 0.474</td>
<td>0.459</td>
</tr>
<tr>
<td>HPC 20°C</td>
<td>0.456</td>
</tr>
<tr>
<td>p 0.019</td>
<td>0.313</td>
</tr>
</tbody>
</table>

HCGI - Highly credible gastrointestinal symptoms
r = Pearson correlation coefficient
p = p value
From Payment (Reference 3).

17. When number of HCGI in the group drinking RO filtered water was compared with the level of bacteriological contamination in the RO unit, a statistically significant association (at the 5% level) was found between rate of HCGI and the heterotrophic plate (HPC) count from the RO units at 35 and 20 degrees Celsius. There was also an association between rate of illness and HPC at 35°C (Table 5). Table 6 shows the rate of HCGI in the tap water group and the quality of water in 5 areas and 25 collection sites in the distribution system.
18. Data on serology were analyzed for prevalence of antibodies in the population but not in connection with incidence of HCGI episodes. This was published in a separate paper⁷ in which the conclusion was that enteroviral infections were extremely prevalent in this population. No reference was made to illness in tap water drinkers versus RO filtered water drinkers.

19. The authors suggested the increase in illness associated with drinking tap water was caused by either low levels of virus and parasites resisting water treatment or regrowth of opportunistic low-grade pathogens within the distribution system.

20. The authors conclude there was a significant component (ie one third) in the rate of GII associated with drinking tap water that complied with currently accepted microbiological standards. The main methodological limitation of the study was that participants were not blind to whether they were drinking tap or RO filtered water and therefore the reporting of symptoms may have been biased by this knowledge. Against that possibility, the authors pointed out most highly credible GI symptoms are easy to recognize, that rates were similar to those previously reported in Canada, there was a dose response effect with increased amount of water drank and there was relative consistency of effect across age groups.

21. They concluded their study raised doubts about the adequacy of current standards of drinking water quality and for treatment and distribution of this water.
3. Critique of the Montreal study

1. In this section the study is reviewed in terms of its epidemiological design, the use of the RO filters and the monitoring of water quality and microbiology.

3.1 Epidemiological aspects

2. The study was considered to be basically sound epidemiologically, despite two weak points, the possibility of reporting bias and insufficient control of confounding factors. Absence of medical follow-up to confirm reported symptoms was not perceived as a limitation to the study.

a) Absence of blindness

3. Reporting bias is always a possibility when studies are not blind (i.e., participants are aware of whether they are in the intervention or control group); particularly if the outcome under study is subjective and depends on reporting by the subjects themselves.

4. The failure of the study to find much difference between the two groups in terms of the rate of hospitalisation or in the numbers of individuals reporting illness lends weight to this possibility. However, the presence of dose-response relationships in the reported levels of disease with variables that the participants would not have been aware of, does provide some reassurance that the results of the study are not wholly attributable to reporting bias.

b) Possibility of confounding

5. Less worrying is the possibility of confounding - i.e., that the difference in incidence of HCGI between the two groups was due not to the intervention but to underlying differences between the two groups. Randomization was used to make the intervention and control groups similar. It is however good practice to present information about the two groups or to provide baseline levels of disease in the two groups before the intervention, to establish whether they are in fact similar. This was not done.

6. Very little data were presented for comparison between the two groups - only age and sex distribution. This was particularly remarkable because data on socioeconomic variables is said to have been collected. There was a difference in the age distribution in the two groups, but this would not distort results as most analysis took age into account. No data was collected on baseline levels of disease prior to intervention. In spite of these limitations, randomization is a major strength of the study and so the possibility of confounding is low.

c) Self-reporting of symptoms

7. There was no medical or laboratory follow-up to check the subjective reporting of symptoms. It would have been reassuring if a more objective measure of GII was available. However, the type of GII episode associated with drinking tap water was apparently very mild, and was likely not have been detectable by a medical examination. In fact, in spite of the 30% reduction in incidence of HCGI episodes in the RO filter water group, the number of episodes severe enough to lead to medical consultation or hospitalization was similar in
the two groups. This suggests that the type of illness associated with drinking tap water is mild and can only be detected by self-reporting. Thus the absence of medical or laboratory follow up was not perceived as a limitation of the study. However, the sub-clinical nature of the episodes does modify the perspective in which the findings of the study should be viewed.

3.2 Use of reverse osmosis filters and monitoring of the quality of the water supply

8. Three problems were identified in the use of the RO filter units and the monitoring of water quality.

a) The use of RO domestic filters

9. Reverse osmosis filters modify chemical characteristics of water as well as filtering out microorganisms. Thus any reduction in the risk of gastrointestinal illness associated with use of RO filters could not be ascribed with certainty to the improvement in microbiological quality of water. It could equally have resulted from changes in the chemical quality of water. This did not invalidate the finding of reduced levels of disease, but sheds some doubt on the interpretation of its cause. Future studies may attempt to separate the microbiological and chemical aspects of the intervention by filters.

b) Deterioration of the microbiological quality of water in RO units

10. RO units were effective in removing pathogenic organisms but induced growth of bacteria in some of the treated water delivery systems. Although consumers of filtered water experienced 30% lower levels of GII, their level of disease was linked to the number of bacteria growing in samples collected from their RO filters. The bacteria found in the RO filters were Pseudomonas, Actinobacter, Flavobacterium, Chromobacterium, Alcaligenes and Moraxella. These were found in the population of colonies on medium R2A incubated at 35 degrees C and 20 degrees C. When both counts were considered in the same model, levels of GII were related only with organisms growing at 35 degrees C.

11. The fact that contamination of RO units increased the risk of disease did not contradict the observation that on average, consumers of RO filtered water had fewer HCGI episodes than consumers of tap water. It indicated the effect of tap water was likely to be larger than that detected, as some of it was counteracted by the increase in risk associated with contamination of the units.

12. The other issue raised by the finding that contamination of RO units increased the risk of HCGI episodes is ethical: should studies with some sort of intervention increase the risk of disease amongst participants?

13. Once again the consequences of this criticism were not to question the credibility of results but to indicate that future studies should try to identify filters which are less likely to become contaminated, thus allowing a more precise measurement of the risk associated with drinking tap water and thereby minimizing the ethical limitation.
c) Monitoring of water quality entering distribution of water

14. This was of concern because if the frequency and volume of sampling were not satisfactory then the assumption that the water quality satisfied current standards would have been violated.

15. Professor Payment in answer to enquiries from the group (summarized in documents 8 and 9), reported the water treatment company did not collaborate with the study and this limited access to information about water quality monitoring undertaken by the company, particularly on the quality of the source water. The limited data given on the quality of source water suggests that it was more contaminated than any UK river waters abstracted for potable use. The treatment process however included ozonisation in addition to chlorination, which should have been more effective against parasites and viruses than chlorine alone.

16. The main report on the study gave only a summary of water quality in the distribution system and at consumers taps, but an additional, unpublished paper gave more detailed information.

17. It should be noted that the Canadian guidelines for microbiological parameters were less strict than the standards in the UK Water Quality Regulations. It appeared that the Canadian standard required that no more than 10% of 100 ml samples could contain coliforms whereas the Water Quality Regulations required that no more than 5% of 100 ml samples contained coliforms. Data are presented on the quality of water on the distribution system in 5 zones and 25 collection sites. The number of samples collected, however, is not given. Also to increase sensitivity, larger, 1000 ml samples were collected, instead of the usual 100 ml samples. The Water Research Centre prepared a table (Table 6) overleaf, showing how the Canadian data would have appeared if 100 ml samples had been taken. The conversion equation used was:

\[ p = 1 - (1 - p_1)^{0.1} \]

where \( p_1 \) is the probability of failure for a 1 litre sample and \( p \) is the probability of failure for a 100ml sample. From the revised table, it is clear that in all points examined fewer than 5% samples contained coliforms, and thus the water complied with this aspect of the Water Quality Regulations (WQR). However, the WQR also require that no 100 ml sample contain faecal coliforms. According to Table 6, if 100 ml samples had been taken, in 7 of the 25 sites faecal coliforms would have been detected. In England and Wales 0.2% of samples taken in supply zones contain faecal coliforms with 11% of zones failing to comply with requirements in this aspect. We cannot calculate the overall percentage of samples in the study with faecal coliforms, as a total number of samples in each zone is not given. However, of the 25 sites, 21 sites had less than 0.2% samples with faecal coliforms; and 28% had some faecal coliforms.
Table 6: Results of analysis of water samples from the distribution system, and weekly GT rates per 100 persons per week in tap water and filter water drinkers in the 5 zones and 25 collection sites of the distribution system.

<table>
<thead>
<tr>
<th>Zone</th>
<th>Site</th>
<th>HC 20oC</th>
<th>total coliforms % pos/100ml samples</th>
<th>faecal coliforms % pos/samples</th>
<th>rate in filter water (B)</th>
<th>rate in tap water (A)</th>
<th>PV (A-B)/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1</td>
<td>973</td>
<td>1.3</td>
<td>0.0</td>
<td>1.04</td>
<td>1.44</td>
<td>28%</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>109</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>270</td>
<td>2.5</td>
<td>0.3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>4</td>
<td>203</td>
<td>0.2</td>
<td>0.2</td>
<td>0.96</td>
<td>1.21</td>
<td>27%</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>576</td>
<td>0.7</td>
<td>0.0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>926</td>
<td>3.8</td>
<td>1.8</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>7</td>
<td>54</td>
<td>0.0</td>
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<td></td>
<td>8</td>
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<tr>
<td></td>
<td>9</td>
<td>515</td>
<td>1.3</td>
<td>0.0</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>C</td>
<td>10</td>
<td>1233</td>
<td>1.0</td>
<td>0.4</td>
<td>0.83</td>
<td>0.85</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>189</td>
<td>0.0</td>
<td>0.0</td>
<td></td>
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Modified from Payment et al., reference 3; transformation to 100ml samples from the Water Research Centre. GM= geometric mean; PV=preventable fraction.

In summary, it appears that had 100 ml samples been taken, the water in the Canadian study would have complied with WQR in terms of coliforms, but not in terms of faecal coliforms. However, water in England and Wales also does not always comply with WQR and it is probably fair to say that the water in the Canadian study is not remarkably worse than that found in some regions, at some periods, in England and Wales.
18. The use of geometric means might have concealed some extreme coliform or E.Coli counts but it was noted that use of geometric means did not influence the percentage of samples recorded as having positive coliform counts.

19. Professor Payment responding to inquiries stated that the water supplier investigated each failure and in each case failures were attributed to dirty taps or defective plumbing. No evidence is given to support this statement. This was not seen as challenging the credibility of the study’s conclusions because the reasons given were not particularly convincing.

20. In summary, according to the revised table 6, the water sampled in the distribution points and in the taps in the study would have complied with the microbiological standards in the Water Quality Regulations.

3.3 Microbiological aspects

21. In this section the Group’s discussions about the usefulness of collection of serological and stool samples are presented.

a) Antibody levels

22. The serological specimens collected in the Montreal study were not analyzed in connection with incidence of gastrointestinal illness and thus were not useful in the interpretation of the study results. Seroprevalence results suggested a high level of endemic enterovirus in that population, and unusually Rotaviruses during the summer. However the anti-bodies detected were not necessarily responsible for GII or related to the drinking of tap or filtered water. In summary the serological investigation did not shed doubts on the study’s main conclusion that drinking tap water was associated with an increase in risk of HCGI. It did not help establish which organisms were likely to have been responsible for the increase.

b) Absence of stool examinations

23. The authors suggested the increase in illness was either a result of low levels of viruses or parasites resisting treatment or, of regrowth of opportunistic low-grade pathogens within the distribution system.

24. Unfortunately stool examinations were not done. Had they been, differences in distribution of agents in stools of cases arising among tap water drinkers and filtered water drinkers might have indicated which agents were more common among tap water drinkers and were thus responsible for the increased morbidity.

3.4 Conclusions on the Montreal study

25. The study did have weaknesses in the epidemiological design. The main one was that participants were aware of whether they were drinking tap or RO filtered water and this knowledge may have biased their reporting of symptoms. However, the fact that dose response relationships were found with levels of gastrointestinal illness and quantity and quality of tap water consumed, and with levels of contamination of RO units mitigates the criticism that reporting was biased because participants were not aware of these factors.
26. The possibility that the difference of levels of illness between the tap and RO filtered water group was caused by inherent differences in the two groups was not investigated extensively, but the fact that participants were randomized within the two groups suggests that this was unlikely.

27. In summary, although there were epidemiological weakness in the study, the results supported the hypothesis that drinking water of acceptable standards might be associated with an increase in mild gastrointestinal illness.

28. The use of RO units and the use of 1 litre samples instead of the usual 100ml samples did not challenge the main conclusions of the study. The serological study did not contribute to its conclusions, and it was regrettable that stool samples were not collected, as this would have helped to establish which organisms were associated with the increase in illness in the tap water group.
4. Are the findings of the Montreal study relevant to England and Wales?

1. As the credibility of the study was accepted by the group, it was important to see whether its conclusions were relevant for England and Wales. This was investigated at three levels: Firstly, was the water quality in the study as good as that in England and Wales; secondly, was water consumption comparable in the two countries and finally was the rate of increase associated with drinking tap water detected in the Canadian study compatible with levels of gastrointestinal infection in England and Wales?

4.1 Water quality in the study area and in England and Wales

2. The main report \(^1\) gave very little information about the quality of water in the study. A later, unpublished report \(^2\) gave more detailed information, but referred to 1 litre samples. When these were reworked into equivalent rates for 100 ml samples (Table 6), it became clear that microbiological quality in the distribution system during the study period complied with England and Wales standards being marginally worse than typical England and Wales water quality. This was described in detail in paragraph 3.2.17.

4.2 Consumption of drinking water in Canada and in England and Wales

3. The Water Research Centre presented a summary paper on consumption of drinking water in Canada and in Great Britain \(^12\), based on two studies reported in the early 1980s \(^13\)–\(^14\). Adult Canadians appeared to drink 40\% more tap water than the British. The difference is more marked in the consumption of cold water based drinks: adult Canadians appeared to consume 4 times, and their children twice the volume of cold drinks consumed in Great Britain. These data need to be interpreted carefully as they are derived from two separate studies, with no effort to standardize methodology. However, if these findings were true, and if there was a dose-response relationship between quantity of water consumed and illness, then the risk of gastrointestinal illness associated with drinking water would be smaller in the England and Wales than that found in Montreal.

4. A consequence of this was that a future England and Wales survey would need to be relatively larger in order to detect a statistically significant difference in gastrointestinal illness between the two groups.

4.3 Rates of GII in the study and in England and Wales

5. Very little is known about levels of gastrointestinal illness in the population of England and Wales. Preliminary data from the pilot study for a national study of gastrointestinal infection \(^15\) recommended by the Richmond Committee into Microbiological Safety of Food has indicated levels might be much lower than those found in the United States and Canada \(^1\), but similar to those found in the Netherlands \(^16\).

6. Conclusion: There are reasons to expect the additional burden of GII associated with drinking water in England and Wales to be smaller than found by Payment in his study. Firstly, the water quality in England and Wales might be marginally better; secondly, the volume of water consumed, particularly cold water, might be smaller; and thirdly, the baseline level of incidence of gastrointestinal illness might be lower. Only the undertaking of a similar study in England and Wales would confirm whether this is indeed the case.
7. In summary, the group supported the undertaking of a similar survey in England or Wales, but it recommended the final decision be taken by the Department of the Environment, after consideration of the costs involved.
5. Suggestion for a similar study to be conducted in England and Wales?

5.1 Objectives

1. The study should concentrate on the relationship between microbiological quality of water in distribution and rates of gastrointestinal infection. There is a need to ensure that chemical and microbiological standards were met in water leaving the treatment works but it was not practicable to monitor treated water for the whole range of pathogens likely to cause GII. The study should strive to identify organisms which are associated with any increase in gastroenteritis levels caused by drinking tap water.

2. The primary objective was defined as answering the following question:

   “Is their a contribution to the level of unattributable GI in the community from treated water”

The size of the excess, and the power and precision of the proposed study are detailed under section 5.4.

Two secondary objectives were defined:

* "To identify, through examination of stool samples, the microorganisms causing the excess GII associated with drinking tap water."

* "To identify the groups (by age, sex and socioeconomic status) which are more vulnerable to the excess GII."

3. The survey would not aim to identify predictive factors in water of excess risk nor try to establish whether the excess GII is caused by water quality at source or by regrowth phenomenon in the distribution system.

5.2 Features of the study area

4. The study area should be served by a water source classified A2 under the Surface Water Abstraction Directive (75/440/EEC) and receiving full conventional treatment (coagulation/sedimentation, filtration and chlorine disinfection). The distribution system should not be unduly complicated and should have a low number of service reservoirs. It would be necessary to secure the co-operation of the water company in maintaining a log of incidents or deviations from normal operating conditions in treatment and distribution. The type and age of property and area (new or old distribution system) could have a bearing on the project and should be considered in the more detailed planning of the project. One of the early priorities will be to secure the co-operation of the water company.

5.3. Overall study design

5. The basic design should be similar to that of the Montreal study in consisting of a community cohort study, with identification of households, randomization of the participants into the tap water and filtered water groups, collection of baseline information and then one year’s intensive follow-up with regular collection of data on incidence of gastrointestinal symptoms.
6. It should differ from the Montreal study in that it would be blind (i.e., participants would not be aware of whether they were drinking tap or filtered water), better data would be presented for comparison between the two groups, stool samples would be collected and examined for all cases of gastrointestinal illness and age-sex matched controls.

7. To minimise costs associated with installation of the filter, only households with at least three members will be included in the study. This could have the effect of reducing the average age of the study population by including more young children and fewer old people. This was not considered as a weakness of the study.

8. The possibility of a longer study period was discussed, as this would allow a reduction in the number of treatment units installed. It was rejected at this stage because it was considered it would be difficult to sustain the enthusiasm and co-operation of participants for two years. The final planning of study might still consider the study over two years, with the necessary adjustments for sample size, should it offer advantages which have not been identified at this stage.

9. Since permission will be needed for installation of the filter and dummy units it is likely that only owner occupied houses can be included. This will restrict the range of socio-economic groups represented in the study sample. This would not interfere in the testing of the main hypothesis, but may limit the generalization of results to other social groups. It is recommended that implications of this limitation be taken into account at the detailed planning of the study.

10. The health questionnaire would include socioeconomic data and weekly or fortnightly diaries. Data would be collected not only on GII symptoms but also on other illness. This would permit detection of bias or over-reporting of symptoms and non-gastrointestinal health effects of tap water consumption.

11. The recruitment process would be time consuming. It is recommended that General Practitioners (GP's) lists be used. From the Montreal study and the Richmond Committee pilot study it is estimated that between 15 and 50% take-up could be expected.

12. Each selected household would need to be visited to ensure that the plumbing arrangements were suitable, to explain the project in detail, obtain informed consent, collect baseline health information and provide training for taking stool samples and for completing the diaries. Visits might need to be made in the evenings or at weekends.

5.4 Sample size

13. A paper was prepared on sample size alternatives for this study. A sample size was chosen to enable the study to detect a twenty percent change in the rate of gastrointestinal illness between the two groups, with 90% power and 95% confidence. This assumed GII rates in the filter water group of 15% per person per year.

14. The other alternative sample sizes considered by the group were based on 95% power, and a range of preventable fractions from 10% to 35%.

15. The confidence level of 95% is conventional for these types of studies. The power of 90% was considered to be necessary if the study is to be convincing in the event of negative
result. Power of a study is the ability to find a difference if a difference exists; studies that find no difference between two study groups need a relatively high power to be credible.

16. The incidence of GII was taken from preliminary estimates in the pilot study for the Richmond Committee 15. The preventable fraction of 20% was selected taking into account the preventable fraction found in the Montreal study, the smaller volume of water consumed and the lower rates of GII in England and Wales 17.

17. These considerations dictated a minimum sample size of 2522 subjects in each group. To compensate for losses during the study, loss of power related to the need to control for age and sex in the analysis, as well as the lack of independence between cases (as episodes may tend to repeat in the same individual and family) and the tentative nature of the estimate of incidence, it was suggested that the total sample size be increased to 3000 in each group. As selected households will include at least 3 members, the suggested number of households would be 2000, with a 1000 in each of tap and filter groups.

18. Given the estimates of rates of GII and preventable fraction, it was estimated that between 850 - 1000 episodes of illness should be noticed in total in the two groups in the one year study period. If stool samples were to be collected from cases and controls, up to 2000 stool samples would be expected.

19. A sample size of 2000 households, with a follow-up period of one year would require the installation and maintenance of 1000 filters and 1000 dummy units for one year and the subsequent removal of this equipment.

5.5 Point-of-use devices and dummy units

20. The preferred intervention method would be a combination of cyst removal and disinfection. It would be essential to maintain blindness by installing dummy units in households consuming unmodified tap water. The use of bottled water was ruled out on the grounds that regular delivery on demand was impractical and might not produce results relevant to normal drinking water consumption patterns. The group agreed that the unit should consist of a filter and UV unit, with water supplied from the unit at sufficient pressure to supply the household drinking water in a way that blindness could be maintained. A third tap was not acceptable because of the need for installation and reinstatement and the lack of control over possible use of unmodified mains water.

21. The Inspectorate commissioned the Water Research Centre to produce a report titled "The estimation of costs associated with the installation of point of use water treatment devices in consumer’s premises" 18 which gave details of features and costs for installation maintenance and renewal of 5 types of point of use-of-devices and dummy units. These included a ceramic filter with UV disinfection and a single layer cartridge filter with UV disinfection. A carbon block filter unit with UV disinfection was chosen as the preferred system, being acceptable on cost grounds, not requiring a third tap and producing water at sufficient pressure. The manufacturers claimed that this only had a 98% efficiency for cyst removal, but this was considered acceptable.

22. A carbon filter would remove some organic compounds and residual chlorine, and might encourage considerable bacterial growth resulting in endotoxin production, but this was not considered an obstacle to the aims of the project, because of the use of an associated disinfection system.
23. To establish each UV unit was emitting disinfecting radiation in addition to visible light, it was recommended that all units are tested before installation and on maintenance visits. It was also recommended that the UV lamp be left on throughout the length of the experiment. The study should allow for payment for the electricity used, although the amount would be small. Similar arrangements would have to be made for the dummy units.

24. The installation and maintenance of the units should not be carried out by the manufacturers. This would prevent manufacturer’s engineers from influencing households and reduce the possibility of claims such as “installed with DWI approval” in advertising literature.

5.6. Water quality monitoring

25. The group discussed the need for chemical analysis in addition to microbiological analysis. The recommendation was that water analysis should be restricted to microbiology only as information on chemical analysis would be available from the water company’s public register.

26. It was hoped a water company would cooperate with the project and would be able to provide operational data throughout the study period including details of changes in quality of source water, changes in treatment and of any incidents affecting water quality. It was however agreed that it would be feasible to carry out the study without cooperation from the local water company.

27. Samples should be taken “as drunk” i.e. straight from the tap without flushing or flaming. Water samples should be examined for total coliforms, faecal coliforms, faecal streptococci, Clostridium perfringens and colony counts at 22°C and 37°C. Consideration should also be given to analysis for Aeromonas and Pseudomonas species. It might be necessary to analyze some samples for oocysts and viruses. Stool and water samples should be examined in single laboratories to ensure consistency of results.

5.7 Laboratory examinations

a) Serology and saliva

28. The possibility of using saliva or blood samples for serology was investigated. Saliva technology was considered to be not sufficiently advanced to provide the information the project would require on antibodies. It was also noted that ethical approval would not be given for the collection of blood samples from children.

29. Given these limitations and the questionable value of the serological results in the Montreal study, the group recommended serological samples should not be taken.

b) Stool samples

30. Stool samples should be collected and examined to help identify which organisms were associated with gastrointestinal infections associated with drinking tap water. This would be done by comparing the range of organisms present in stools of cases of GII among tap water and filter water drinkers. If stools were also collected from healthy controls, additional information would be collected on how tap and filtered water drinkers
controls, additional information would be collected on how tap and filtered water drinkers differed in the prevalence of microorganisms in the absence of illness. Requests for stool samples have almost no ethical implication, and are acceptable to a large number of subjects.

31. It is estimated about 2000 stool samples - 1000 from cases and 1000 from controls - would be collected during the study. These samples must be collected by the participants and submitted by post. Post Office approved packaging is available.

32. There was some discussion about which organisms should be examined in stool samples. The standard PHLS screen was for Salmonella, Shigella, Campylobacter, Giardia and Cryptosporidium species and other parasites. It was considered the study should also include enteroviruses, rotaviruses, Norwalk virus, specific E coli serotypes and possibly Aeromonas and Pseudomonas species.

5.8 Ethical approval, consent and liabilities

33. Ethical approval for the project must be sought from the Royal College. This would facilitate approval from the local ethical committee. Before the project started the local Consultant for Communicable Disease Control (CCDC), PHLS and the households' GPs should be informed.

34. It is unlikely that an ethical committee would allow participants to be paid for taking part in the project. However, some kind of incentive might be necessary and should be considered at the stage of detailed planning of the study. Payment of telephone line rental for the duration of the survey may be considered if, as in the Montreal study, telephone communication is an essential component of the study.

35. Contingency plans should be in place during the project to cover such events as a water quality incident necessitating the issue of advice to boil water and outbreaks of cryptosporidiosis or influenza in the local population. The question of liability insurance would also need to be investigated.

5.9 Pilot study

36. The group recommends the acceptance rate and the performance of the point-of-use device and dummy unit be tested in the field before the study is initiated. It is suggested the Drinking Water Inspectorate liaise with the Department of Health about the pilot study of gastrointestinal infections in England, as the two studies have several common features.

5.10 Tentative budget

37. Provisional costs for various parts of the study are detailed here. These are estimates which should be refined when more detailed planning of the study is undertaken.
38. An approximate total cost for a one year scheme.

Filter/UV units (Aqua-Nouveau B) (A) £500,000
Stool analysis (2000 @ £35 plus packaging and postage) (B) £80,000
Water analysis (sampling and basic parameters) (C) £110,000
Data coding, statistical analysis etc £70,000
Management costs (D) £250,000
Telephone compensation (2000 @ £50) £100,000
Recruiting participants and collecting health questionnaire (E) £350,000
10% contingency fund £100,000

**TOTAL** £1,560,000

(A) Includes carbon block filter, UV unit, “dummy unit”, installation and decommissioning and one maintenance visit after six months.

(B) The basic parameters would cost between £8.50 to £10 per sample. The cost above includes all the parameters listed. It is recommended negotiating a price with a specific laboratory when location had been decided.

(C) Price includes a sampler for 253 days at £121.48 per day, a van at £20.90 per week for 52 weeks, an estimate for fuel and 12 samples per day for 253 days for the basic parameters listed in 5.6 at £28.75 per sample. Not included are enterovirus analysis at £65 per sample or cryptosporidium / giardia analysts at £245 per sample.

(D) To include management of the project (£50,000) and pre-study screening visits to 2000 households at £100 per visit cv. Costs for a two year study would not be significantly different. A saving of approximately £100,000 on the filter units would be mostly offset by the additional costs for sampler and van and project management.

5.11 Summary of design of proposed study

39. The proposed study consists of a randomized controlled trial to test the hypothesis: consumption of tap water from a supply zone which only marginally complies with the total coliform standard prescribed in the Water Quality Regulations is responsible for a proportion of the GI symptoms in the general population. 2000 households with at least 3 members living in an owner occupied property in an appropriate area will be included in the study and allocated at random into a tap water or filtered water groups. Each household will have either a dummy unit or a carbon filter plus UV unit installed under the sink. Baseline data will be collected plus health data every one or two weeks. Cases of gastrointestinal illness and age-sex matched controls will have a stool sample analyzed. Water samples will be collected from the tap “as consumed” and analysed for microbiological parameters. Rates of disease, by age, sex and socioeconomic status will be compared in the groups. Ethical approval will be sought; informed consent obtained from all participants and care will be taken to consider the issue of liabilities.
References


