Chapter 1
Executive Summary

1.1 BACKGROUND

In 1989, in response to national epidemics of foodborne infection with *Salmonella enteritidis* phage type 4 and *Listeria monocytogenes*, the Secretary of State for Health and Minister of Agriculture, Fisheries and Food set up the Committee on the Microbiological Safety of Food, under the chairmanship of Professor Mark Richmond. This Committee recommended

> 'a study of the incidence of infectious intestinal disease based on GP consultations in which microbiological confirmation of the clinical diagnosis is carried out'

and that:

> 'the true incidence of infectious intestinal disease in the community needs to be ascertained. Thus we also recommend that a study including microbiological screening should be set up to provide information of the incidence of gastrointestinal illness in the community that can be linked to a microbiological cause. This should take place, if possible, in the same areas as the GP-based study'

In addition to these recommendations, the successors to the Richmond Committee decided that the value of the study would be enhanced by the collection of information on people without infectious intestinal disease, so that differences between the ill and the well could be identified. It was also decided that the clinical course of the disease, its long-term sequelae and socio-economic costs should be addressed.

1.2 AIMS AND OBJECTIVES

The principal aim of the study was to estimate the number of cases of gastroenteritis, or intestinal infectious diseases (IID), occurring in the population of England, and find out how many people with IID consulted their general practitioners (GPs).

We sought to identify as many as possible of the disease-causing organisms, or pathogens, responsible for IID. We then compared our estimate of the actual number of cases of IID in the population of England and presenting to their GPs, and the pathogens responsible for illness, with the routine national surveillance data from laboratory reports to the Public Health Laboratory Service (PHLS) Communicable Disease Surveillance Centre (CDSC). We also set out to identify the factors which might lead to IID, and the costs which might result.

Because it is impossible to separate out with any precision or reliability those cases of IID which result from food poisoning and those cases resulting from other causes, our study necessarily addressed all cases of IID and not merely the cases caused by eating contaminated food. We therefore included in our study cases infected with pathogens known to be spread predominantly from person to person, and cases with pathogens usually held responsible for food poisoning, as well as those cases who, although suffering from IID according to our definition, had no pathogen found in their stools. Our definition of IID was: any person with loose stools or significant vomiting

lasting less than two weeks, in the absence of a known non-infectious cause and preceded by a symptom-free period of three weeks. Vomiting was considered significant if it occurred more than once in a 24-hour period and if it incapacitated the case or was accompanied by other symptoms such as cramps or fever.

The study attempted to estimate the accuracy of laboratory reporting to the PHLS and CDSC; it did not attempt to determine the accuracy of national food poisoning statistics, which depend upon statutory notifications by doctors on the basis of clinical suspicion.

The specific objectives of the study were:

- To estimate the number and aetiology of cases of IID in the population, presenting to GPs, and having stool specimens sent routinely for laboratory examination.

- To compare these numbers and the aetiologies with those recorded by the national laboratory reporting surveillance system.

- To estimate the prevalence of asymptomatic infection with agents associated with IID.

- To document differences between cases of IID (in the population and presenting to GPs) and similar but well people (controls).

- To estimate the socio-economic burden of IID and its distribution.

1.3 METHODS

The study design was necessarily complex. It was based on an extensive review of previous studies, and on our own experience gained in carrying out a pilot study in 1992. Information from subjects was gathered between August 1993 and January 1996.

Seventy general practices in England were recruited from the Medical Research Council General Practice Research Framework. The practices were representative of all practices in England in terms of their geographical spread, urban or rural location, number of doctors and social deprivation. Groups of people representative of each practice population were invited to take part in a study. On average four out of ten did. For six months these people were asked to report every week whether or not they had suffered gastrointestinal disease. This was equivalent to following up 4,888 people for a full year. Cases who developed IID and matched controls (people similar but well) within these cohorts provided stool specimens for extensive laboratory investigation. In addition information was collected by questionnaire about their personal characteristics and things they may have done which could have had a bearing on whether or not they suffered illness, i.e., increased or decreased their risk of developing IID.

A further questionnaire was also sent out to cases some weeks after their illness. This included questions about how much their illness cost them, as well as questions about how much they would be prepared to pay for safer food and whom they saw as responsible for food safety. Some cases from the community presented themselves to their GPs and when this occurred, it was recorded. These parts of the study were the ‘population cohort component’ and ‘nested case-control’ components. The main results from these parts of the study were the rates of IID in the population.

As well as these cohorts from the 70 general practices, all cases who presented with IID to their GPs in 34 of the general practices over a 12-month period — and age and

sex matched controls — were asked to provide stool specimens for laboratory investigation. Information was obtained from them on personal characteristics, risk factors, and for cases, the same questions about costs and attitudes as in the population cohort component. This was the 'GP' component, and its main important results were the rates of cases of IID presenting to GPs and risk factors for acquiring IID.

In the remaining 36 similar practices, cases presenting with IID during the same 12-month period were identified. When cases presented themselves to these practices, the GPs' routine procedure for sending stool specimens was observed and recorded. Again, the personal characteristics of the cases were documented, and it was noted whether a stool specimen was obtained or not, and if so what the results were. Also, the same questions about costs and attitudes were asked as in the population cohort component and GP components. No controls were used for comparison in this part of the study. This was the 'enumeration' component and its most important result was an estimation of the rate of submission of stool specimens by GPs from cases of IID.

Two methods were then used to estimate the proportion of cases occurring in the population which are recorded in the national surveillance system. In the first — a direct method — the names of those cases for whom positive stools were obtained from the enumeration component were sought in the national database and the degree of under-reporting calculated.

In the second — an indirect method — we compared the rates of IID we estimated to occur in the whole population of England with the rates appearing in national surveillance, and the degree of under-reporting was calculated.

In total, we collected data and stools from over 6,000 cases of IID as well as from controls.

1.4 RESULTS

We estimated that 20% of the population of England suffered IID in a year, and 3% of the population presented themselves to their GP.

This means that nine and a half million cases of IID occur annually, of which one and a half million present to their GPs. Half a million have stools sent for microbiological examination. In our study, despite using extensive microbiological testing, no target organism was found in about two thirds of cases in the community, and nearly half those presenting to the GP. In normal practice, a much greater proportion of 'negative stools' is reported: over three-quarters of the stools submitted in the enumeration component of this study, which observed normal practice, were negative. This may be due to a number of factors: the diarrhoea may be non-infectious, or due to a pathogen which cannot be identified, or which is no longer present in sufficient numbers to be detectable, or whose identification is difficult, or not attempted.

Viruses, almost half of which are SRSV (Small Round Structured Viruses), account for about 16% of cases of IID in the community. *Yersinia* and *Aeromonas* are almost as common, or more common, in controls as cases, and their clinical significance is therefore unclear. If these are excluded from calculations, viruses are as common as bacteria in association with IID in the community in cases where a target organism was identified. In cases presenting to GPs, viruses were detected in over 20%, with rotavirus accounting for one third of these. Bacteria are, however, much commoner: excluding *Yersinia* and *Aeromonas*, nearly 40% of cases presenting to GPs have a bacterial pathogen identified.

We estimated by our direct method that for every 136 cases of IID in the community, 23 presented to a GP, 6.2 had a stool sent routinely for microbiological examination; 1.4 had a positive result; and one was reported to the PHLS' CDSC.

The ratio varies according to the organism. Approximately three cases of salmonellosis, a predominantly foodborne disease, occur in the community for every one reported to PHLS CDSC, whereas as many as 1,500 or more cases of SRSV infection, which is often spread from person to person, may occur for every one reported to the PHLS CDSC.

Put in another way: for every 1,000 cases of IID in the community, 160 presented to their GP, 45 had a stool sent routinely for microbiological examination, 10 had a positive result, and 7 were reported to PHLS, CDSC.

We estimated by our indirect method the ratio to be 88 cases in the community to every one reported to PHLS CDSC.

This ratio is lower than the ratio of 1:136 calculated by our direct method and this suggests that the indirect method may underestimate the community rate in relation to cases reported in the national data. This would occur if, as we suspect, national surveillance tends to over-represent the proportion of cases which are part of outbreaks. In other words, in estimating the ratio by this method, the national surveillance system's limitations in identifying apparently sporadic cases are partially offset by its greater efficiency in identifying cases which are part of outbreaks.

We found many differences between cases and controls.

When analysed by each of the enteropathogenic organisms, social factors and crowding, travel abroad, and bottle-feeding of infants were associated with an increased risk of IID. We also found that cases of infection with almost all organisms are consistently less likely than controls to have consumed certain foods (pulses, salads and rice prepared at home, fruit, pasteurised dairy products and fish) in the previous ten days. This may have arisen from the study design but we can find no evidence for this. It may therefore be a true association. We believe further research is warranted to confirm or refute this observation, as, if it is a true association, it may have implications for the prevention of IID.

We found the consumption of very few specific foods to be associated with an increased risk of suffering from IID.

There are a number of possible reasons for this, including the fact that most of our cases suffered from infection with organisms spread predominantly from person to person. A second explanation is that the time period we asked about — ten days prior to the onset of illness in cases — was too long to allow us to discriminate sufficiently between cases and controls, i.e., over that time period so many controls would also have eaten common foods that there was no difference between them and cases. If these explanations do not fully explain the lack of positive associations, a third explanation is that current understanding, based as it is almost completely on either the investigation of outbreaks or cases sufficiently ill to present to their GP, is not applicable to sporadic cases. The absence of an association between IID and, for example, the consumption of chicken in the home, in our study is indeed true of the mild, sporadic cases which constitute most of the burden of illness which occurs. This may be because such cases are linked to lightly contaminated foods, possibly as a result of cross-contamination from more heavily contaminated products.

We estimated the average cost of a case of IID, whatever its cause, in England to have been £79 at 1993–1995 prices.

About 36% of this cost falls to the NHS, 8% is a direct cost to the case and 55% is the cost to employers in lost production by the case or a carer. The average cost of a case presenting to a GP is £250; the average cost of a case presenting to a GP with *Salmonella*, a predominantly foodborne organism, is £606, and the average cost of a case presenting to a GP with SRSV, which is often spread from person to person, is £176. We estimated that IID in England cost at least three-quarters of a billion pounds a year. Cases presenting to their GP account for over half of this total. We found that cases presenting to the GP are ill for an average of 8.6 days. A quarter of these cases had symptoms persisting three weeks after illness.

1.5 CONCLUSIONS

The true burden of IID in England has been estimated: the number of cases, the associated microorganisms, and the costs. The identification of characteristics associated with the presence or absence of disease has raised questions to be answered by future studies, and which, if confirmed, have implications for reducing the burden of IID, whether foodborne or not.