ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD

The second study of infectious intestinal disease (IID) in the community - determining disease burden and calibrating national surveillance systems in the UK

The Issue

1. To brief the Committee on the FSA commissioned second study of infectious intestinal disease in the community and provide an update on the progress of the study to date.

Background

2. The public health impact of gastrointestinal infection was underlined by the publication of the Department of Health funded IID Study in England by the FSA in 2000. As well as defining disease burden, a major component of the IID study was calibration of national surveillance systems, i.e. estimation of the factor by which the number of cases of infection with specified pathogens needed to be multiplied to establish the actual number of infections in the community.

3. The FSA's target to reduce foodborne disease by 20% over a five-year period between 2001 and 2006 was a major Government public health initiative. Progress was measured using laboratory-report based surveillance data for five key pathogens: salmonellas, campylobacters, *Clostridium perfringens*, *Escherichia coli* O157 and *Listeria monocytogenes* and a reduction of 19.2% was achieved. However, to reflect on recent figures and to measure future progress the FSA will need to know whether or not the relationship between disease burden in the community and official statistics is similar to the situation over a decade ago. Since the original IID Study was undertaken in the mid 1990s several structural changes have occurred in national surveillance and these might have altered that relationship to a greater or lesser degree. Therefore contemporary information on the relationships in the reporting pyramid is required.

4. To gather the contemporary information required a second IID study has been commissioned by the FSA. The study will run for 50 months (from April 2006 until May 2010) and is being undertaken by the University of Manchester in collaboration with the Health Protection Agency (the Centre for Infections and the Regional Microbiology Network), Medical Research Council General Practice Research Framework, London School of Hygiene and Tropical Medicine, University of East Anglia, University of Nottingham, Communicable Disease Surveillance Centre Northern Ireland, National Public Health Service for Wales, Health Protection Scotland and NHS Direct. The project has a total budget of nearly £5.6 million. The principal

Investigator for the study is Professor Sarah O'Brien from the University of Manchester.

5. The main aims of this study are:
    - to estimate prospectively the burden and causes of IID in the population and presenting to General Practitioners in the UK
        - to compare these results with national surveillance data
    - to estimate the burden of self-reported IID in each UK nation via a telephone survey
        - to compare these results with the prospective estimate.

6. Two studies will be conducted in parallel:
    - a **prospective study** involving 84 GP practices across the UK using "future-proof" microbiological techniques and comprising
        - a population cohort study (8400 person-years of follow-up)
        - a study of cases of IID presenting to GPs
        - a study of routine clinical practice in primary care
        - a study to estimate the completeness of reporting to the four national surveillance centres
    - a **telephone survey** (sample size 3600 per country).

7. The study has been designed to be able to detect a 20% decline in severe disease and data will be used to re-calibrate national surveillance data, defining the relationship between disease in the community and official statistics. The overall project design is illustrated in Figure 1 and the way the data gathered will be used to generate a reporting pyramid is illustrated in Figure 2.

8. With such a large, complex project a considerable lead-in time was required prior to the commencement of the data gathering to allow underpinning organisational work to take place. This commenced in May 2006 and by September 2007 the following actions had been undertaken:

    - recruitment and training of staff
        - statisticians, project managers, laboratory staff
    - preparation and submission of documentation required for ethical approval of the study
    - preparation of questionnaires, training manuals and other supporting materials
    - development of a web-based data collection system, logging database and telephone survey database
    - formulation of algorithms for microbiological testing of specimens
    - development of a study website (www.iid2.org.uk)

9. The active phase of the project commenced on 3rd September 2007 with a 3 month pilot study.
   - Six GP practices were recruited for the prospective study pilot. This allowed key issues such as recruitment, questionnaire design and systems testing to be carried out.
   - A pilot of the telephone survey methodology was carried out in October and November 2007.

10. Overall the pilot study was successful and showed that the systems in place for conducting the study worked well. Some issues, such as lower than expected recruitment to the cohort, were highlighted and changes have been instituted to ensure these issues do not impact on the main study.

11. The main phase of the study commenced in April 2008 and will continue until July 2009. Following data analysis the final report is expected to be submitted in May 2010.

ACMSF Action

12. The Committee is asked to note the progress of this project so far and invited to comment upon it.

Microbiological Safety Division
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Figure 1: The second study of infectious intestinal disease in the community (IID2)

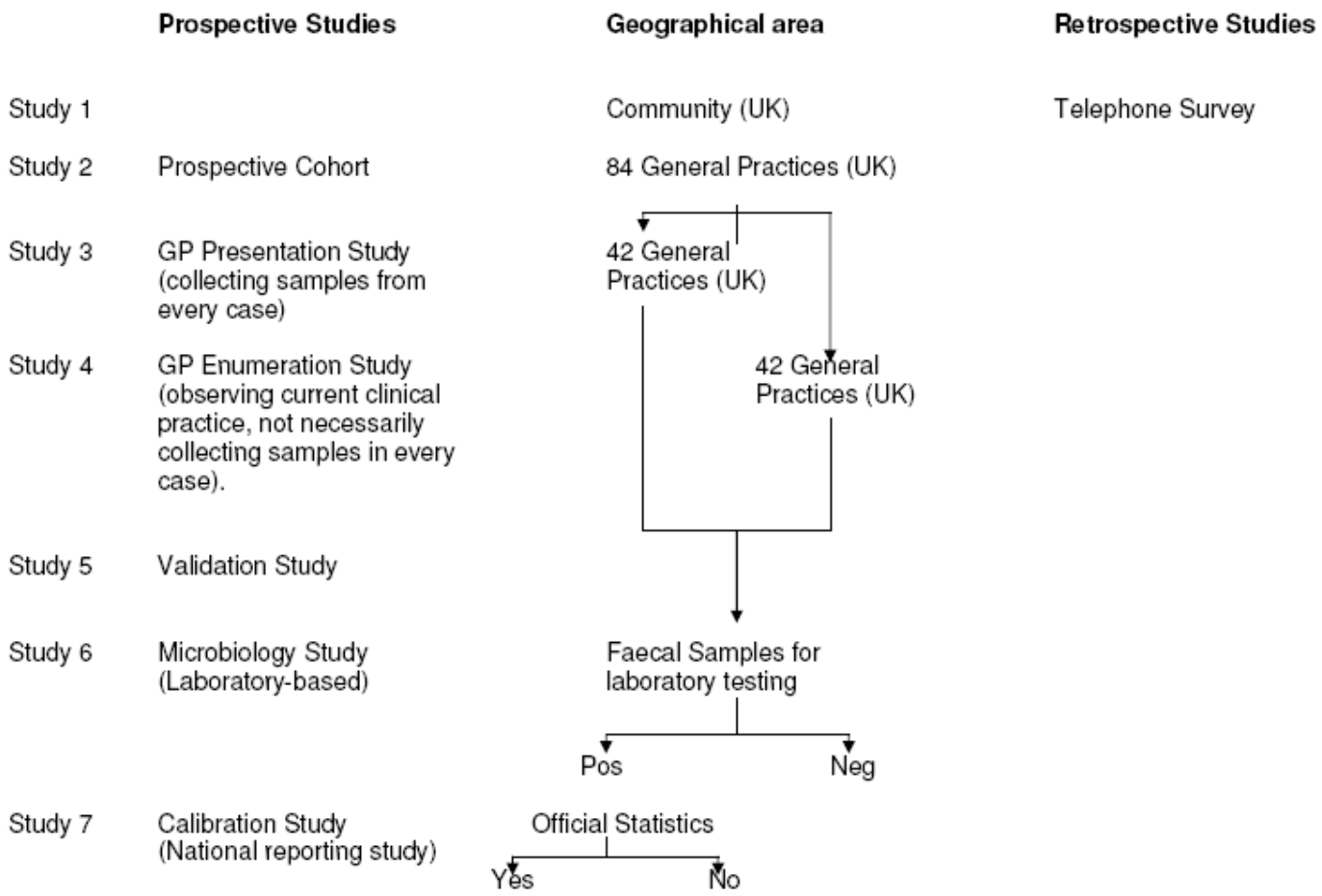

Figure 2: The second study of infectious intestinal disease in the community - determining disease burden and calibrating national surveillance systems in the United Kingdom