

5 Method

5.1 Study design

We performed two case-control studies, one with respect to the Bornem outbreak and one with respect to the outbreak in the 4 other schools, in order to test 2 epidemiological hypotheses:

1. Cases were more likely than control to consume Coca-Cola Company product
2. Cases were more likely than control to be susceptible to a MSI

We expected 2 controls for each case matched on class. In the school in Bornem, only one control for each case was selected.

The case control study was completed with an investigation of the outbreak-scenario of each school.

5.2 Population

Since the first outbreak occurred in a school and although there were many Coca-Cola-related illnesses reported outside of a school environment, it was more practical to ascertain cases and find suitable controls in a school setting. Thus, cases and controls were selected among students who were present during the days of the outbreak (reference day) occurred in each school of Bornem, Brugge, Harelbeke, Lochristi and Kortrijk.

5.3 Definition of the cases and the controls

A case was defined as a student, who reported on the reference day (the first day of the outbreak in the school involved) or the following day, at least one of the following complaints: nausea, vomiting, abdominal pain, diarrhoea, trembling, headache or dizziness.

Controls were students from the same class, next on the alphabetical list (descending order), present on the reference day and the following day and who were not sick in the two weeks preceding the reference day until the end of the following day.

5.4 Sample size

The calculation of sample size was guided by the current number of cases, the need for sufficient power and the practical feasibility to obtain information on all cases and control within a two-day period.

5.5 Case finding

Case finding was performed among students who complained to the directors of the schools.

5.6 Data collection

Following the initial request by the Ministry of Health on June 21st, the study was designed on June 22nd, while questionnaires were prepared and appointments were made with the school principals. The interviews with the students in the schools were conducted on the 23rd, 24th and 25th of June. All

data from those interviews were entered in a database on June 25th, and a preliminary analysis allowed a first report to be made by June 28th.

5.6.1 Interviews of the students

A standardised questionnaire was completed in schools during a face to face interview in the schools of Bornem, Brugge, Harelbeke and Kortrijk. The students were grouped and managed by an interviewer when completing the questionnaire in Lochristi. The interviews flowed in a set-up that allowed exposure information to be collected blinded regarding the case/control status.

The following data were collected:

- Demographic data (gender, age)
- Food consumption (place, time)
- Beverage consumption the day of the outbreak occurred (place, time, package, particular characteristic)
- Symptoms noted by the students (time, type)
- Having friend(s) who reported to be ill at the reference day
- Questions on mental health (SF36).

Thirteen trained interviewers collected information in the 5 schools on the 23, 24 and 25 of June.

5.6.2 Data collection from medical charts

An abstract form was developed to collect information from medical records of students who went to the emergency unit or were hospitalised.

5.7 *Information from the physicians*

Physicians who took care of the patients in the hospitals completed a qualitative and open questions of a standardised questionnaire. The collected information concerned the ambience and the behaviour of the students. Also their feeling about a possible organic cause responsible for the diseases was questioned.

5.8 *Information on the scenario in schools*

An interview by telephone with the directors of the five schools allowed having information concerning the scenario of the outbreak; i.e., how was the alert made? Who was contacted? How many students had health complaints? What was the process to identify students with health complaints? What were the criteria to refer student(s) to an emergency unit?

5.9 *Analysis*

The glass bottles of the Bornem school were provided by one Belgium plant and the plastic bottles and cans to the other schools were provided by other production plants. Therefore, it was decided to analyse separately the data from Bornem and those from the other schools. Descriptive analysis and

calculation of the Odds of the exposure among cases and controls were performed with EPI INFO version 6.04c and multivariate analyses with SPSS, version 8.0.

An analysis of the data collected by the poisoning call centre is not included in this report. Data of the media (written, TV, radio) were collected but have not yet been analysed.