



The Interdepartmental Group on Health Risks from Chemicals

# Understanding Epidemiology for Chemical Risk Assessment

Introduction - a brief overview of epidemiological methods and some statistical topics



#### Course aims

- To provide an introduction to epidemiological methods
- To facilitate critical evaluation of published material in which these methods are used
- To give sufficient background to assist in decision and policy making processes

# Cranfield

## Introduction to epidemiology

#### Epidemiology

- is the study of the distribution of disease in human populations
- and of factors that determine the distribution

#### Objectives

- to understand the aetiology (causes) of disease
- to identify preventive measures
- to evaluate preventive measures and therapeutic interventions



# Introduction to epidemiology (cont)

- Descriptive studies
  - summarise distributions of disease incidence, mortality, survival, etc
- Intervention (experimental) studies
  - investigate relationships between disease distribution and other factors in controlled conditions



## Introduction to epidemiology (cont)

- Analytical (observational) studies
  - investigate associations between disease distribution and factors that might be involved in aetiology of the disease
  - include
    - cross-sectional (snap-shot) studies
    - cohort (prospective) studies
    - case-control (retrospective) studies



# Introduction to epidemiology (cont)

- Issues to consider
  - study objectives
  - target and study populations
  - sample size and sampling method
  - existence of and adherence to a written protocol
  - training of study staff
  - piloting of study methods
  - response rate
  - verification of data



- Target population
  - a group of individuals about whom we seek information
  - eg children in Hammersmith
- Population mean
  - the average value of some characteristic in the population
  - eg the average birth weight of children in Hammersmith
- Population standard deviation
  - a measure of the spread of values (variability) of some characteristic in the population eg the mean



#### Sample

- a subset of the target population which is used to estimate population parameters
- eg 2000 children born in Hammersmith in a specified period

#### Sample mean

- mean calculated from the sample and used as estimate of the population mean
- eg mean birth weight of 2858 g

#### Standard error of the mean

- a measure of the spread of values (variability) of the sample mean that would be obtained if we were to draw samples of the same size repeatedly
  - (the sample standard deviation divided by the square root of the sample size)



#### Confidence interval for the mean

- a range of values within which the population mean is expected to lie with a certain confidence
- the general formula is sample mean critical value standard error of the mean
- the critical value depends on the statistical distribution that the sample mean is assumed to follow
- and the degree of confidence required (typically 95%)
- eg a 95% confidence interval for the mean birth weight of 2837–2879 g



- Interpretation
  - 95% of samples selected in the same way as our particular sample would produce a 95% confidence interval that would contain the population mean
  - ie we are using a method that works 95% of the time (and fails 5% of the time)



- Hypothesis testing
  - a framework for drawing conclusions about a target population from a sample
- Null hypothesis (H<sub>0</sub>)
  - the hypothesis to be tested
  - typically the negation of the hypothesis that really interests us
  - eg the mean birth weight of children in Hammersmith is 2850 g
- Alternative hypothesis (H<sub>1</sub>)
  - summarises departures from the null that interest us
  - eg the mean birth weight of children in Hammersmith is not 2850 g



#### Test statistic

- a measure of the strength of departure from the null hypothesis
- eg a statistic based on the difference between the sample mean and the mean under the null hypothesis

#### Probability (p value)

- calculate the probability of obtaining a test statistic as extreme or more extreme than the one for our sample if the null hypothesis is true
- eg p=0.59 in the test for comparing the sample mean birth weight of 2858 g with the hypothesised mean of 2850 g



- Use the probability to decide whether or not to reject the null hypothesis
- Large probability = event occurred which is not uncommon ⇒ no reasons to reject H<sub>o</sub>
- Small probability
  - either  $H_o$  true and improbable event occurred or  $H_o$  is false  $\Rightarrow$  reject  $H_o$
- Significance level is the value of the probability at which it is decided that the event is sufficiently improbable to reject H<sub>o</sub>



#### Interpretation

- traditionally, significance levels less than 0.05 are regarded as statistically significant and in such cases the null hypothesis is rejected in favour of the alternative hypothesis (at the 5% level)
- but with p=0.59 we cannot reject the null hypothesis that the mean birth weight of children in Hammersmith is 2850 g



- Confidence intervals revisited
  - a 95% confidence interval that excludes the mean value of the test statistic under the null hypothesis represents a difference that is significant at the 5% level
  - but with a 95% confidence interval of 2837– 2879 g, which includes the value 2850 g, we cannot reject the null hypothesis that the mean birth weight of children in Hammersmith is 2850 g



- Power of a study
  - The probability of detecting a real difference between groups i.e. the probability of rejecting the null hypothesis when the alternative hypothesis is true
  - depends on various factors, including the sample size (bigger studies generally have greater power)