Tutorial exercise on Cohort & Expt studies; including Relative Risk and Confounding factors

Q Consider an industry based exposures to cement, construction material; possibility of long term exposure to cement leads to severe dermatitis (skin allergies) in hands leading them to leave job ; One such small scale industry was initiated in your city three years ago with 50 workers in a factory; about half of them worked in areas where they are exposed to cement and other half of them work in office building which is at a distance from the cement plant. All workers had undergone initial and yearly physical examination since the start of the factory and any skin problems were also noted. The government plans to initiate two large scale factories each with 500 workers; half of these working in cement plant areas and other half in the office areas. Company management will look after the health of its employees on a continuous basis and therefore asks you to initiate a study to evaluate the above stated hypothesis.

Q1. How will you design a cohort study to examine the above stated association?

Q2. Explain the design you will use in

        a) existing factory and the design for the
        b) new factories.

Q3. List and briefly describe the challenges that can be encountered in Cohort Studies.

Q4. How will you measure the exposure for the study you plan to design for new factories?

Q5. How will you measure the outcome ?

Q6. Suppose that you have initiated and conducted the study in the new factories. Following are the results of this cohort study. Over the period of one year 100 (50 from plant and 50 from office area of each factory) workers from each factory left the job. Of the 400 workers working in plant areas 210 had severe hand dermatitis and from 400 workers working in office areas 50 workers had hand dermatitis.

Q6.1 Construct a 2x2 table and label and fill the cells

Tutorial on Experimental Studies

The Diabetes Prevention Program Research Group conducted a large, randomized clinical trial involving adults in the United States who were at high risk for the development of type 2 diabetes (were not Diabetics; but pre-diabetics).

Research Question:

Does a lifestyle intervention or treatment with metformin, a biguanide antihyperglycemic agent, prevent or delay the onset of diabetes?

Study Participants:

Eligible: 25 years old or above; BMI of 24 kg/m^2 or higher; Fasting blood sugar conc. of 95 to 100 mg per deciliter (not diagnostic of Diabetes Mellitus). Eligible persons were excluded if they were taking medicines known to alter glucose tolerance or if they had illnesses that could seriously reduce their life expectancy or their ability to participate in the trial.

Intervention:

From 1996-1999; eligible participants were randomly assigned to one of three interventions: standard lifestyle recommendations plus metformin (Glucophage 850 mg twice/day), standard lifestyle recommendations plus placebo twice daily, or an intensive program of lifestyle modification. Mean duration of follow up was 3 years.

Outcome:

The primary outcome was diagnosis of diabetes mellitus measured six monthly; based on 1997 criteria of the American Diabetes Association. The diagnosis required confirmation by a second test, usually within six weeks, according to the same criteria

Result:

The cumulative incidence of diabetes was lower in the metformin and lifestyle-intervention groups than in the placebo group throughout the follow-up period (Cumulative Incidence of Diabetes According to Study Group.). The crude incidence was 11.0, 7.8, and 4.8 cases per 100 persons; for the placebo, metformin, and lifestyle-intervention groups, respectively (incidence of Diabetes.).

A   *B*

Q1. Calculate RR between Metformin & placebo; and lifestyle & placebo.

1·709   1,436

Q2. What other comparisons can be made between the groups?

A : 3.2

B - 6.2

Q3. Are there any confounders? How are they being addressed in this study?

age, BMI, habit, g...

Q4. What if there was a differential compliance in the two groups? Or they leave the study due to adverse effects or for any other reason?

Information Bias

Q7. Over all in both factories there were 300 men and 100 women working in cement plant areas; whereas 100 men and 300 women worked in office areas. 180 men and 30 women working in plant areas had severe hand dermatitis where as 20 men and 30 women working in office areas had hand dermatitis. Construct 2x2 tables and calculate the RR for men and women separately

Males

Females

Q8. Do the results differ by gender?