Qualche riflessione sull'epidemiologia in ambito giudiziario: 1.causalita' 2.responsabilita' e ruolo dell'epidemilogo/a

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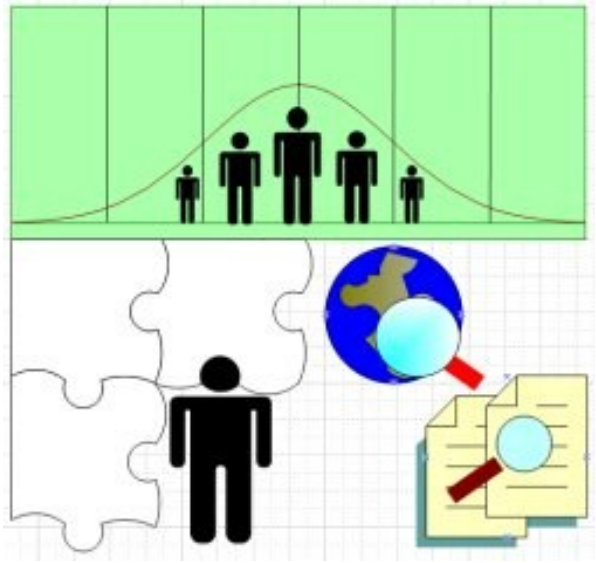
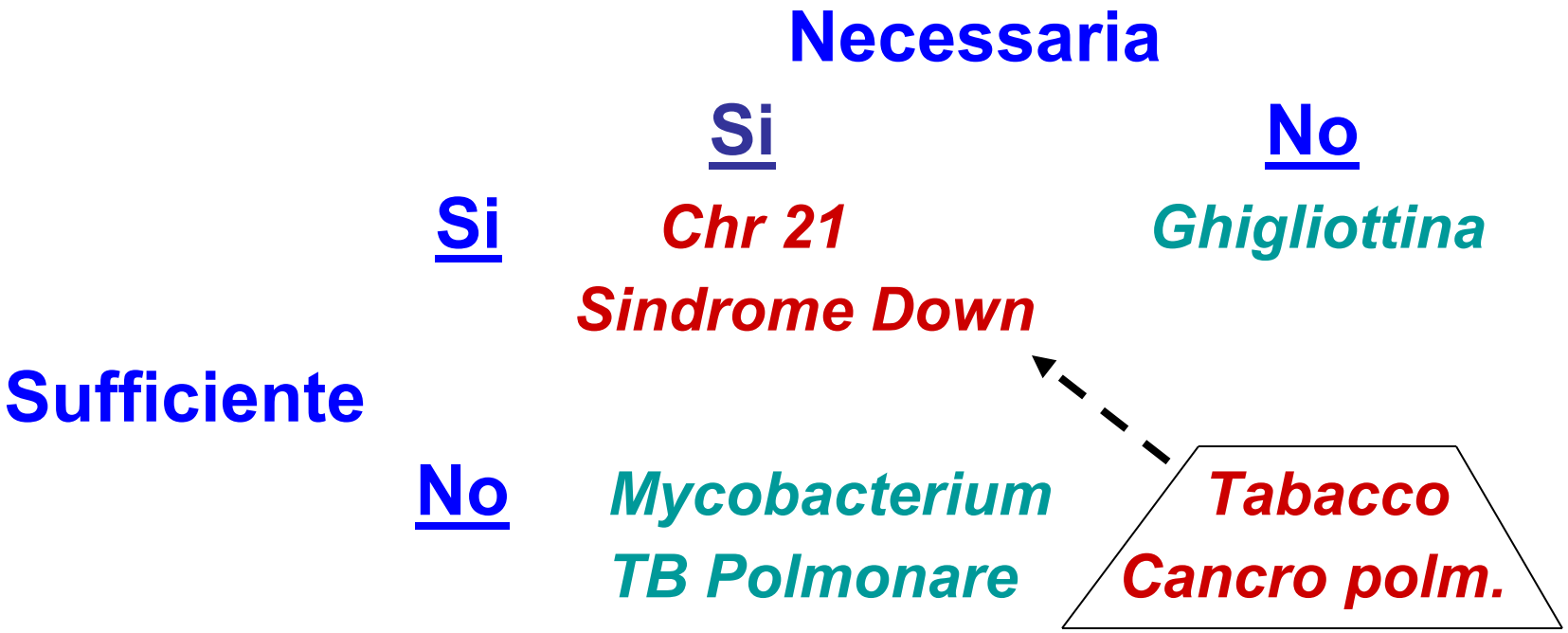


Causalita’

Cause necessarie e sufficienti



1
Il rapporto causale generale : stabilire una regola scientifica valida

- **Stabilire che un fattore X (es. esposizione a benzene) e' una causa di leucemia :**

  (a) richiede l'osservazione di un *gruppo N* di soggetti in cui l'effetto di interesse e' stato osservato (salvo casi eccezionali : N>1) ;

  (b) non esiste nessun principio necessario/ tassativo - salvo la sequenza 'esposizione prima dell'effetto- su *quanti* soggetti debbono essere osservati, e *come*, per poter affermare la validita' scientifica del rapporto.

Some circumstantial evidence is very strong, as when you find a trout in the milk

(Henry David Thoreau, 1854)

An evidence-based system (born1972): IARC categories of evidence of carcinogenicity in humans : 1

- ***Sufficient*** **: a causal relationship has been established between exposure to the agent, mixture or exposure circumstance and human cancer. That is, a positive relationship has been established between the exposure and cancer in studies in which *chance, bias and confounding* could be ruled out with reasonable confidence**

IARC categories of evidence of carcinogenicity in humans : 2

- ***Limited*** **: a positive association has been observed between exposure to the agent , mixture or exposure circumstance and cancer for which a causal interpretation is considered by the Working Group to be credible, but *chance, bias or confounding* could not be ruled out with reasonable confidence**

IARC categories of evidence of carcinogenicity in humans : 3

- ***Inadequate*** **: the available studies are of insufficient quality , consistency or statistical power to permit a conclusion regarding the presence or absence of a causal association between exposure and cancer , or no data in humans are available**

IARC categories of evidence of carcinogenicity in humans : 4

- ***Suggesting lack of carcinogenicity*** **: there are several studies covering the full range of levels of exposure that human beings are known to encounter, which are mutually consistent in not showing a positive association between exposure to the agent , mixture or exposure circumstance and any studies cancer at any observed level of exposure. A conclusion of "evidence suggesting lack of carcinogenicity" is inevitably limited to the cancer sites , conditions and levels of exposure and length of observation covered by the available studies. In addition, the possibility of a very small risk at the levels of exposure studies can never be excluded**

Guides to causality of observed associations

- Strength of association
- Consistency
- Dose-response relationship
- Temporal relationship
- Biological plausibility
- Specificity
- Coherence of evidence
- Experiment
- Analogy

(Doll R, Proof of causality : deduction from epidemiological observation, 2002 ; after Hill ,1965)

Esempi di evidenza 'convincente'

(cat. IARC 'sufficiente + ~ probabile')

- **HRT e CHD : trial randomizzato**
- **Fumo di tabacco : studi osservazionali di tipo diverso, replicati, concordanti**
- **Dietilstilbestrolo : mini-studio caso controllo**
- **Bis-clorometil-etere : serie di casi**
- **Benzene : serie di casi**
- **Onda di calore : studio ecologico**
- **……**

Il rapporto causale : dal generale all'individuale

Il grado di certezza concernente il

rapporto causale generale

richiesto come supporto di un

rapporto causale individuale

e' uguale o superiore a quello richiesto per iniziare un intervento preventivo

2
Il rapporto causale individuale: attribuire *una* causa a un caso

La soluzione attraente e generale :

$$AF_{esposti} = \frac{R-1}{R}$$

Se (solo se) AF > 0.50 (quindi R >2) la causalita' dell'esposizione nel caso in esame e' considerata "more likely than not" (e il soggetto e' compensato)

2
Il rapporto causale individuale
attribuire *una* causa a un caso

La soluzione attraente e generale :

- **Postula implicitamente un meccanismo *in generale* indimostrabile IOB (independence-of-background)**
- **Anche laddove questo fosse valido non tiene conto di possibili rischi competitivi legati all'esposizione**

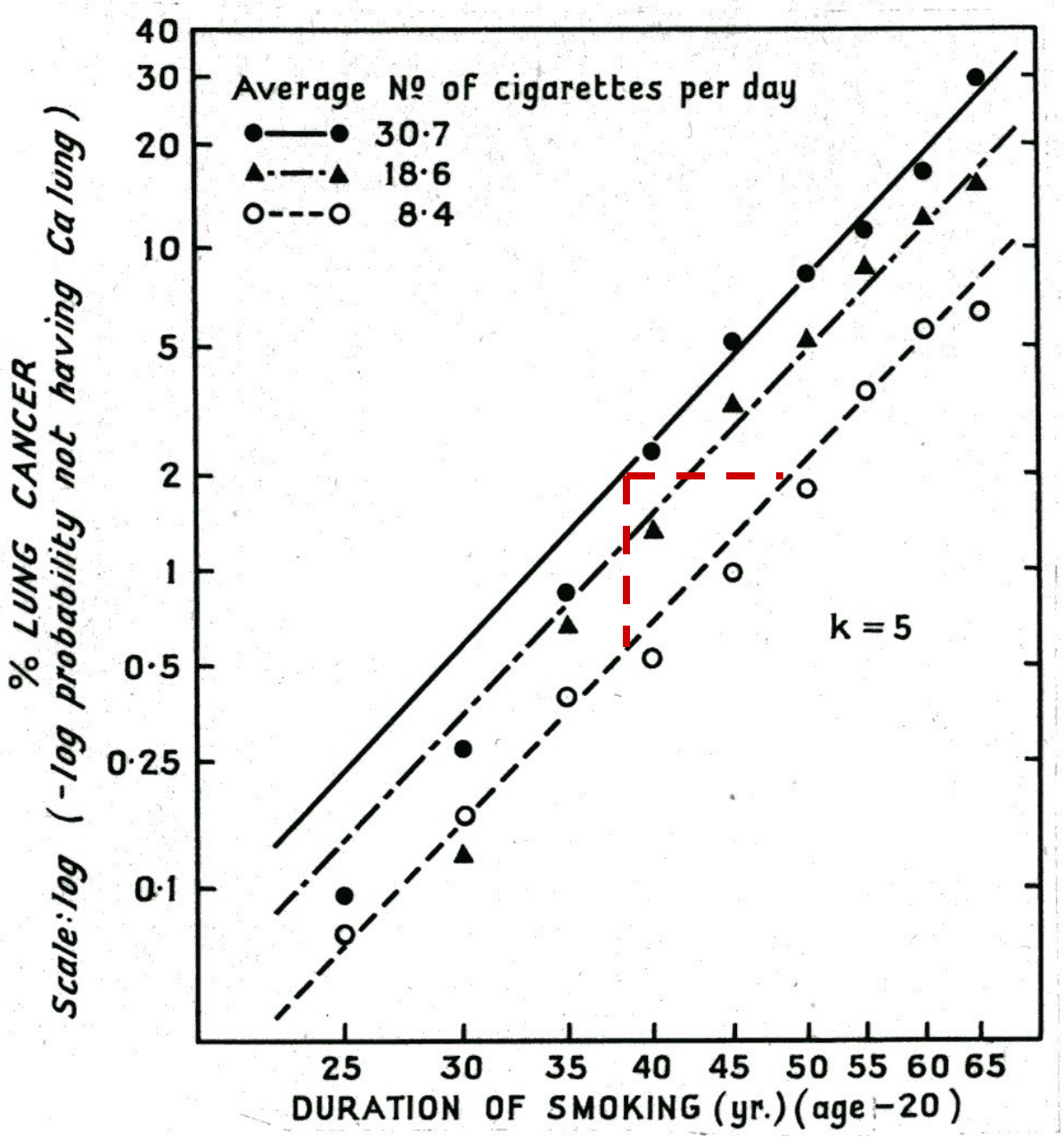
"Thus, when an exposure is known to be harmful in some cases, available data from epidemiology and biology are simply incapable of telling us whether *a given case* was "more probably than not" harmed by exposure"

(Greenland S, Robins JM. Epidemiology, justice and the probability of causation. Jurimetrics 2000 ; 40 : 321-340)

2
Il rapporto causale individuale
attribuire *una* causa a un caso

La soluzione attraente e generale …..

..in generale **si puo' considerare che fornisca un limite inferiore (= AF) alla probabilita' che l'esposizione sia causale nel caso in esame, ma non un limite superiore, che e' 100% se tutti i casi osservati tra gli esposti sono stati ad es. 'accelerati'**


% LUNG CANCER
Scale: log (-log probability not having Ca lung)
40
30
20
10
5
2
1
0·5
0·25
0·1
Average № of cigarettes per day
30·7
18·6
8·4
k = 5
25
30
35
40
45
50
55
60
65
DURATION OF SMOKING (yr.) (age −20)

Responsabilita’e ruolo dell’epidemiologo/a

3. Epidemiologists' education is casual concerning transition from evidence to actions

- There is no unique theoretical position to which to refer
- Time for and emphasis on decision/policy issues are scarce
- Issues may be dealt with as essentially technical
- Even elementary distinctions may be blurred

- **How scientific (epidemiological) evidence leads to public health decisions and actions should be an *integral part* of the education and training of epidemiologists , and not just left as an optional 'add on'**
- **This should form the support of an explicit recognition of the roles and responsibilities of epidemiologists in society**

“THE ROLE OF THE ACADEMIC EXPERT IS TO TELL THE TRUTH”

(Yale’s T.R. Marmor ,quoted by L. Maggi , Journal of Public Health Policy, 2000, 21:296-302)

Scientists are not individually
"truth tellers"!

They are collectively
"truth explorers → objective knowledge"
by striving to be maximally impartial
as individuals

Four distinct but perpetually confused concepts

- **Objectivity** = ***inter-subjective validity. Basis of scientific knowledge ; never attainable individually [→ "truth"]***
- **Impartiality** = ***taking into account all available relevant evidence. A must for the individual scientist***
- **Neutrality** = ***equipoise in respect to value-loaded alternatives***
- **Independence** = **from what/whom ?**

Three different roles for the epidemiologist :

- 1.**SCIENTIST** :

  1A. an *epidemiologist/methodologist* evaluating the validity of exposure-disease associations

  1B. a *biomedical scientist* evaluating the causal nature of associations

Three different roles for the epidemiologist :

- **2.’PUBLIC/COMMON GOOD’ ORIENTED SCIENTIST:**

  a *public health oriented scientist* granting the benefit of scientific doubts first to the exposed people

Three different roles for the epidemiologist :

- **3.DECISION MAKER:**

  a *public or private agent* taking into account scientific evidence + economic, ethical, social, political aspects to decide actions

Posizione personale sul ruolo dell'epidemiologo/a in ambito giudiziario.1

Due premesse :

- **Vincolo civile del cittadino sottoposto alla legge :**
  la verita' in ambito giudiziario emerge attraverso un processo contradditorio di punti di vista contrastanti

- **-Vincolo professionale dell'avvocato :**
  i diritti di una persona
  -Vincolo professionale dell'epidemiologo/a:
  (a) l'imparzialita' scientifica (b) la salute

Posizione personale sul ruolo dell'epidemiologo/a in ambito giudiziario.2

- L'avvocato puo' in linea di principio "sostenere la causa di chiunque"

- L'epidemiologo/a puo' avere :

  *1. il ruolo di perito del giudice. Q.: garanzia della obbiettivita' della perizia ?

  *2. il ruolo di perito della parte lesa nella salute.
  Q.: rinuncia al vincolo (a) ?

  *3.il ruolo di perito della controparte :
  Q.: rinuncia ai vincoli (a) e (b) ?