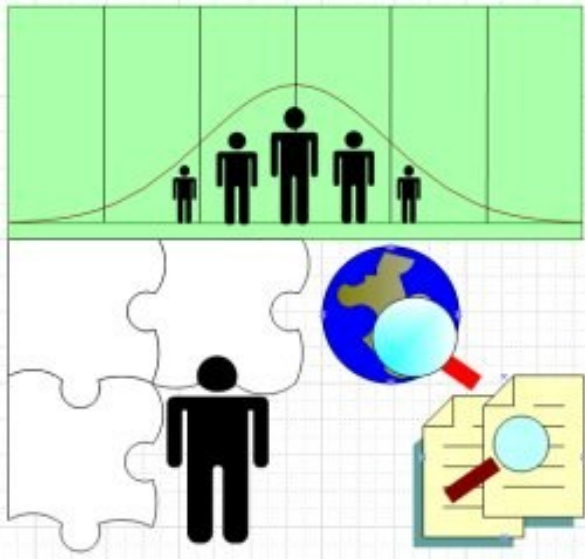


Qualche riflessione sull'epidemiologia in ambito giudiziario:

1.causalita'

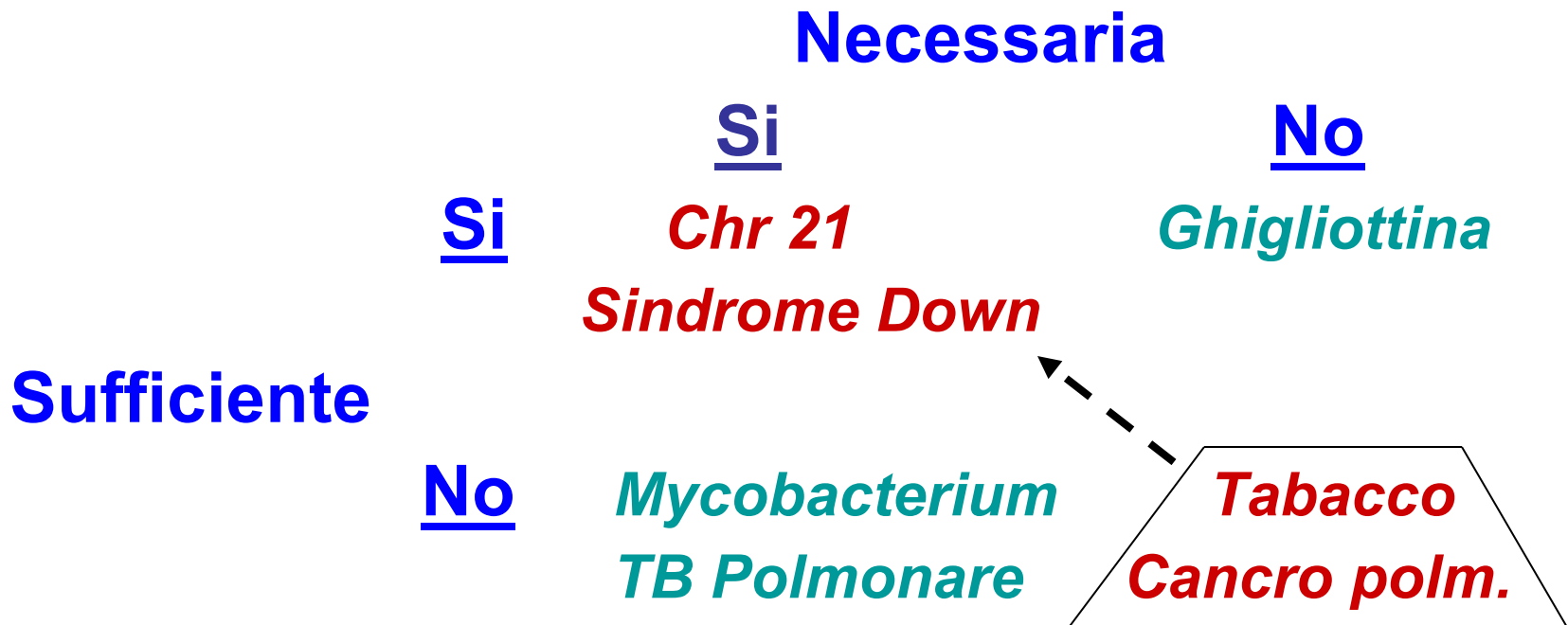
2.responsabilita' e ruolo dell'epidemilogo/a

Rodolfo Saracci



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 (born 1972):
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-etero : 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 :

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

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”

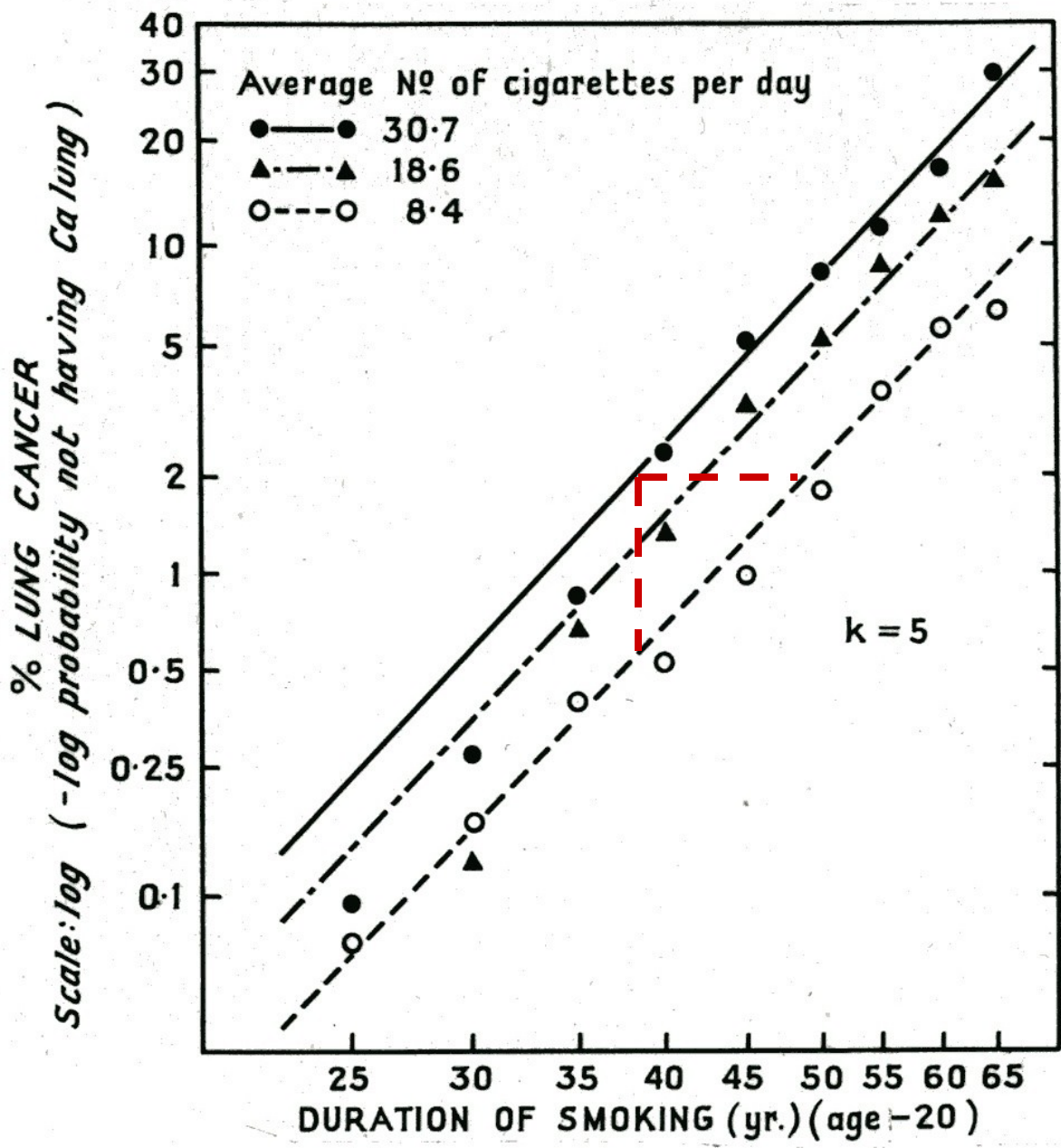
(Greenland S, Robins JM. Epidemiology, justice and the probability of causation. Jurimetrics 2000 ; 40 : 321-340)

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'



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 verità in ambito giudiziario emerge attraverso un processo contraddittorio di punti di vista contrastanti
- -**Vincolo professionale** dell'avvocato :
i diritti di una persona
- -**Vincolo professionale** dell'epidemiologo/a:
(a) l'imparzialità 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) ?**

