Understanding of health effects on decision making concerning waste management: from evidence to action.

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... what’s the point of this talk?

- An important aspect of today’s society is the current dilemma of the role of science and technology in conjunction with the profound crisis of the political representation.

- What can be the relation between recognizing a causal association and the process of decision-making or attribution of moral responsibility?
... science, ethics, decisions

- According to Simon Weil, as a result of the dominating assumption of utilitarianism, that is strength of quantity, modern science cannot embrace the truth.

- What ethical values can knowledge be based on?
  - Equilibrium
  - Respect (an equal exchange between man and things)
  - Basic needs

All of this however is in view of action; knowledge is not formed from an abstract logic, but develops in an individual that works in the real world and actively participates in society
Decisions with health implications that aim at attaining the goals of interventions (actions) on the basis of knowledge (evidence) have to consider:

- What needs to be known,
- What can be known,
- What has to be done
Early recognition of risk

… depends on the economic-organizational investment:

- the desire to know and face actual and current problems…
- the economic and political activities that have determined the risk.
Key elements in identifying and preventing risks

- Who must provide evidence?
- What type of evidence is necessary?
- How will this evidence be produced?
- What quality of evidence is necessary?
- How strong must the association be in order to declare a substance “toxic” (e.g. carcinogenic teratogenic) and reduce exposure?
- Values attributed to the Precautionary Principle
Who must produce evidence?

- Governmental organization researchers?
- Researchers financed by interest groups? (e.g. Asbestos industry, telephone companies, …tobacco)?
- Academy authorities or local area officials (e.g. Local health authorities)?
- Ordinary people and workers?
Value of Lay and Local knowledge… of the homogeneous group

- Early warning from victims (be careful of distorting selections: “pensioner party fallacy”, “healthy worker effects”)
- Knowledge of real conditions (life/work)
- Knowledge of exposure and how to reduce it
- Knowledge of alternatives (… in the field)
What type of evidence?

Affected? Damaged? Dying? or Dead

- Cellular?
- Animal?
- Man?
# ON BEING WRONG: ENVIRONMENTAL AND HEALTH SCIENCES AND THEIR DIRECTIONS OF ERROR

<table>
<thead>
<tr>
<th>SCIENTIFIC STUDIES</th>
<th>SOME METHODOLOGICAL FEATURES</th>
<th>MAIN DIRECTIONS OF ERROR-INCREASES CHANCES OF DETECTING A:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental Studies</td>
<td>High doses</td>
<td>False positive</td>
</tr>
<tr>
<td></td>
<td>Short (in biological terms)</td>
<td>False negative</td>
</tr>
<tr>
<td></td>
<td>range of doses</td>
<td>False negative</td>
</tr>
<tr>
<td>(Animal Laboratory)</td>
<td>Low genetic variability</td>
<td>False negative</td>
</tr>
<tr>
<td></td>
<td>Few exposures to mixtures</td>
<td>False negative</td>
</tr>
<tr>
<td></td>
<td>Few Foetal-lifetime exposures</td>
<td>False negative</td>
</tr>
<tr>
<td></td>
<td>High fertility strains</td>
<td>False negative (Developmental/reproductive endpoints)</td>
</tr>
</tbody>
</table>

1 Some features can go either way (e.g. inappropriate controls) but most of the features mainly err in the direction shown in the table.
<table>
<thead>
<tr>
<th>Observed</th>
<th>Confounders</th>
<th>False positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Studies</td>
<td>Inappropriate controls</td>
<td>False positive/negative</td>
</tr>
<tr>
<td>(Wildlife &amp;</td>
<td>Non-differential exposure misclassification</td>
<td>False negative</td>
</tr>
<tr>
<td>Humans)</td>
<td>Inadequate follow-up</td>
<td>False negative</td>
</tr>
<tr>
<td></td>
<td>Lost cases</td>
<td>False negative</td>
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<td></td>
<td>Simple models that do not reflect complexity</td>
<td>False negative</td>
</tr>
<tr>
<td>Both Experimental And Observational Studies</td>
<td>Publication bias towards positives</td>
<td>False positive</td>
</tr>
<tr>
<td></td>
<td>Scientific cultural pressure to avoid false positives</td>
<td>False negative</td>
</tr>
<tr>
<td></td>
<td>Low statistical power (e.g. From small studies)</td>
<td>False negative</td>
</tr>
<tr>
<td></td>
<td>Use of 5% probability level to minimise chances of false positives</td>
<td>False negative</td>
</tr>
</tbody>
</table>
How should Evidence be produced?

In a context of complexity, multicausality, uncertainty and... ignorance
Public health protection

1. Traditionally based on the association pattern of exposure and illness

2. Risk evaluation
   - Risk identification: Is the agent dangerous for man?
   - Exposure profile: How much and how long is the population exposed?
   - Profile of the relation dose-response
   - Quantitative estimate of risk: what is the added risk to man as a result of exposure to the substance?

3. Risk management (Hazard Analysis and Critical Control Points, HACCP)
Some conclusions about epidemiologic evidence

- in science (…to build a career) you try to reach clear significantly relevant statistics, (false positives $p<0.5$, before crying “wolf”…) whereas in prevention it is much more serious “to miss” the false negatives (type $\beta$ error)

- The hierarchical organization (EBM/EBP) of evidence from observation studies is extremely low. Such studies have however allowed us to set air quality limits and to face, for example, the issue of nanoparticles

- What value should be given to different studies? In their disclosure it is necessary the establish limits and determine comparability.
How does understanding uncertainty help us?

- The level of uncertainty gives us an indication of what we know and what we don’t know. Science uses uncertainty to design better experiments/studies to probe the unknown.
- The explanation of the uncertainty helps to understand the health benefit and to make better informed decisions.
- Uncertainties encountered tell us how much confidence to put in future studies.
- Quantifying the uncertainty helps to reveal the limits of our knowledge and its usefulness in making decisions.

Some consequences of multi-causality and complexity

1. Some combinations can be co-causal
2. Results coherence (Consistency/coherence) is not always achieved
3. “Small” environmental risk factors can be important:
   - As a link in a casual chain
   - As a trigger for disease
   - To obtain large secondary benefits
4. Difficulty in the evaluation of benefits of interventions for public health
5. Wider and better use of the Precautionary Principle
What type of evidence?
Bradford Hill. 1965, Environment and Disease: Association or Causation(*)

Some “criteria” to define a cause-effect relation

- Association strength
- Consistency: observation repeatability in different time – space setting
- Temporal relationship
- Specificity
- Dose-response relationship
- Biologic plausibility
- Coherence with general knowledge
- Analogy: analogous effect with those of other factors in known risks.
- Experimental approach, in remedial medicine Randomized Clinical Trial (RCT), or more acceptable if the prevention worked (!!)

Bradford Hill criteria are asymmetrical

- The presence of the “criteria” provides good evidence for causation; their absence may not provide good evidence against a real association.

- Such asymmetry is even stronger when one considers the multi-causality and the complexity of the cause-effect relation.
Standards of evidence depend on context

- Determination of “sufficient evidence” for preventive action depends on context
  - whether safer alternatives exist
  - weighing risks of acting when no hazard versus not acting on a true hazard
Precautionary Principle (PP)

- In 1992 at Rio: “In order to protect the environment, wide measures of precaution must be applied by all nations according to their ability. In the face of risk and serious or irreversible damage, the absence of scientific certainty should not be a pretense to put off the adoption of efficient measures directed at preventing the degradation of the environment”

- “A risk management approach in a scientifically uncertain situation, which calls for action in the face of a proportionally serious risk without waiting for the conclusive findings of scientific research”
Two aspects not always applied by PP

- Do not use only “diagnostic” force, but use above all look for solutions. This means that PP does not mean “blocking the activities”, but on the contrary it is the responsibility to further develop knowledge and offer alternative proposals.

- PP together with procedures, such as Health Impact Assessment (HIA, that is evaluation – also through simulations – of the health effects), that in uncertain situations, leads to decisions that take into account freedom of initiative, propriety, equality, and dignity.
EU policy: The waste hierarchy

- Changes in package design
- Changes in purchasing habits
- Changes in industrial practices
- Source reduction
- Waste reduction
- Generation of waste for management
- Recovery for recycling (including composting)
- Combustion disposal

- Backyard composting
- Increased reuse
- Other changes in use patterns
- Landfill disposal
Conclusion

- The laudable desire for good evidence to support public health policy must be balanced against the necessity of acting to prevent illness and injury, in the face of substantial uncertainties

  - The precautionary principle is useful in focusing attention on the need for this balance