EPIDEMIOLOGICAL RESULTS AND POLICY IMPLICATIONS

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THE INTERNATIONAL COMMISSION ON NON-IONIZING RADIATION PROTECTION

ICNIRP is an independent scientific organization that:

• provides guidance and advice on the health hazards of non-ionizing radiation

• develops international guidelines on limiting exposure to non-ionizing radiation that are independent and science based

• provides science based guidance and recommendations on protection from non-ionizing radiation exposure
STANDING COMMITTEES

- SC I – Epidemiology  
  Chair: Anders Ahlbom (Sweden)
- SC II – Biology and Medicine  
  Chair: Richard Saunders (UK)
- SC III – Physics and Engineering  
  Chair: Rüdiger Matthes (Germany)
- SC IV – Optical radiation  
  Chair: Bruce Stuck (USA)
SC I (EPIDEMIOLOGY) 2004 - 2008

A. Ahlbom  Sweden  Chairman

• A. Green  Australia
• L. Kheifets  USA
• D. Savitz  USA
• A. Swerdlow  UK
ICNIRP:

• is the recognized non-governmental organization in non-ionizing radiation for WHO and ILO

• maintains close liaison and working relationship with all international bodies engaged in the field of non-ionizing radiation protection
ACTIVITIES OF ICNIRP

ICNIRP:

• Revises and evaluates the scientific literature
• Develops protection criteria and standards
• Organizes or co-organizes workshops
The IARC Monograph Program on the Evaluation of Carcinogenic Risks to Humans was established in 1969 and modified in 1987 to include agents other than chemicals.
Each IARC monograph, on a specific agent or condition of human exposure, consists of two elements:

- A critical review of the scientific literature relevant to carcinogenesis
- An evaluation of the strength of the total evidence for carcinogenicity to humans
IARC CLASSIFICATION

- **Group 1:** The agent is *carcinogenic to humans*
- **Group 2A:** The agent is *probably carcinogenic to humans*
- **Group 2B:** The agent is *possibly carcinogenic to humans*
- **Group 3:** The agent is *not classifiable as to its carcinogenicity to humans*
- **Group 4:** The agent is *probably not carcinogenic to humans*
WHO

The International EMF Project was established in 1996 to:

- Review the scientific literature on biological and health effects of EMF
- Identify gaps in knowledge requiring research that will improve health risk assessments
- Formally assess health risks of EMF exposure after the required research is completed
- Provide information on risk perception, risk communication, and risk management
THE CRITERIA OF WHO

- Identification of biological and health effects
- Recommendation for science-based standards
- Recognition of public concerns and social aspects
- Some consideration for preliminary results, case reports, etc.
Evaluations of possible health hazards of exposure to EMF were carried out in the past by WHO in cooperation with IRPA/INIRC and UNEP and published as EHC Documents.

Updated evaluations have been carried out or are in progress, in collaboration between WHO, ICNIRP, and IARC.

Tasks and responsibilities have been assigned in order to avoid redundancies and maximize synergies.

However, extensive, critical reviews and analysis of the published scientific literature are independently performed by each partner.
SEQUENCE OF ACTIONS

- Identification of gaps and research agenda (WHO)
- Synthesis of overall knowledge (ICNIRP)
- Evaluation of carcinogenicity (IARC)
- Overall evaluation of health hazard (WHO)
- Revision of standards (ICNIRP)
STATIC MAGNETIC FIELDS

- Environmental Health Criteria 1987
- ICNIRP Review 2003
- WHO Review December 2004
- Revised EHC Expected 2005
STATIC MAGNETIC FIELDS

- No acute effect below 4 T
- No relevant acute effect expected below 8 T, but possible discomfort (vomiting, vertigo)
- No evidence of long-term effects. No epidemiology
- Attention justified by new MR devices and techniques
• Environmental Health Criteria 1984
• IARC Evaluation 2002
• ICNIRP Review 2003
• WHO Review October 2005
• Revised EHC Published 2007
Electromagnetic Fields and Epidemiology
Erice, March 26 - April 2, 2008

- Dosimetry
- Biology
- Epidemiology
FUNDAMENTALS OF ICNIRP GUIDELINES

- Procedures and criteria are defined *a priori*
- Restrictions are based on science.
- No consideration for economic or social issues
- Only established effects are considered
STEPS IN THE DEVELOPMENT OF GUIDELINES

- Critical review of the literature
- Identification of health effects and biological effects relevant for health
- Identification of the critical effect
- Establishment of basic restrictions
- Derivation of reference levels
Any single observation or study may indicate the possibility of a health risk related to a specific exposure.

However, risk assessment requires information:

• From studies that meet quality criteria
• From the totality of science
The review performed by ICNIRP is at the same time:

- **Comprehensive**
  No one single study can prove a health effect

- **Selective**
  Studies are critically evaluated based on
  - **Quality**
  - **Replicability**
  - **Consistency**
A decision must be made whether the available evidence allows the identification of an exposure hazard, i.e. an adverse health effect that is caused by an NIR exposure.

By this identification, the effect becomes “established”.

Science-based exposure limits are set with regard to established effects.
Effects are considered as established based on:

- Quality of the studies (peer review)
- Consistency
- Replicability
- Cause-effect relationship
THE CRITICAL EFFECT

If several effects occur, it may be possible to rank them according to the exposure level at which each effect becomes relevant.

The critical effect is the established adverse health effect that is relevant at the lowest level of exposure.
ESTABLISHED EFFECTS OF EMF

All effects of EMF that have been established so far are acute in nature

ELF
Stimulation of electrically excitable tissues

RF
Increase of body temperature (general or local)

Such acute effects occur above given exposure thresholds
WHICH ROLE FOR EPIDEMIOLOGY?

- “Early warnings” (clusters, analyses of trends etc.)
- Provide input for the development of optimization systems
- Provide data for precautionary measures
SYSTEMS OF PROTECTION

• Health threshold based systems
  Adequate for well established, threshold effects

• Optimization systems
  Adequate for no-threshold known hazards

• Precautionary measures
  Adequate for suspected, not established hazards
RANKING OF EVIDENCE

EVIDENCE ≠ PROOF
humans
animals
cells

ASSOCIATION ≠ CAUSALITY

BIOLOGICAL EFFECT ≠ HEALTH EFFECT

Biological models
Dosimetry

Electromagnetic Fields and Epidemiology
Erice, March 26 - April 2, 2008
IARC has classified ELF magnetic fields as possibly carcinogenic to humans, based on childhood leukaemia.
The NIEHS Task Group concluded that ELF magnetic fields are possibly carcinogenic for humans (Group 2B)

- Group 2B  19 votes
- Group 3   8 votes
- Group 4   1 vote
WHERE ARE WE?

The cumulative support from studies may be reflecting an underlying causal process that is diluted through exposure measurement error or is truly weak. Alternatively, control selection bias, selective emphasis of findings, and random error may have created the appearance of a pattern of association. The failure of methodologic improvements to yield clearer results suggests either that there is no causal linkage to identify or the refinements are not as significant as we believe.

(David Savitz. Twenty years of epidemiological evidence on electromagnetic fields and cancer, 1999)
LIMITS OF EPIDEMIOLOGY

- The epidemiological studies conducted on possible health effects of EMF have improved over time in sophistication of exposure assessment and in methodology.

- Several of the recent studies on childhood leukaemia and on occupational exposures in relation to adult cancer are close to the limit of what can realistically be achieved by epidemiology, in terms of size of study and methodological rigour, using presently available measurement methods.

ICNIRP 2003
• Especially for childhood leukaemia, there is little to be gained from further repetition of investigation of risks at moderate and low exposure levels, unless such studies can be designed to test specific hypotheses, such as selection bias or aspects of exposure not previously captured.

• In addition there is a need for studies in humans of possible physiological effects of EMF that might relate to risks of chronic disease

ICNIRP 2003
WHICH SUPPORT TO EPIDEMIOLOGY?

The results of numerous animal experiments and laboratory studies examining biological effects of magnetic fields have produced no evidence to support an aetiologic role of magnetic fields in leukaemogenesis.

Four lifetime exposure experiments have produced no evidence that magnetic fields, even at exposure levels as high as 2000 µT, are involved in the development of lymphopoietic malignancies.

Ahlbom et al. 2000
Several rodents experiments designed to detect promotional effects of magnetic fields on the incidence of leukaemia or lymphoma have also been uniformly negative.

There are no reproducible laboratory findings demonstrating biological effects of magnetic fields below 100 \( \mu T \).

Ahlbom et al. 2000
From the current scientific literature, there is no convincing evidence that exposure to RF shortens the life span of humans, induces or promotes cancer (WHO, 1998).

Available epidemiological studies on broadcast antennas inconsistent and non informative (poor exposure assessment).

Epidemiological studies on mobile phones mostly negative.

INTERPHONE study in progress.
WHICH IARC GROUPS CORRESPOND TO ESTABLISHED CARCINOGENICITY?

Group 1: The agent is carcinogenic to humans

Condition:

Sufficient evidence in humans

Sufficient evidence:
A causal relationship has been established

An agent in Group 1 is an established carcinogen
 WHICH IARC GROUPS CORRESPOND TO ESTABLISHED CARCINOGENICITY?

Group 2A: The agent is probably carcinogenic to humans

Condition:
Limited evidence in humans
Sufficient evidence in experimental animals
Limited evidence:
A positive association has been observed; a causal interpretation is considered credible, but chance, bias or confounding cannot be ruled out

Carcinogenicity has been established in animals, though not in humans
The agent may be (conservatively) considered an established carcinogen
WHICH IARC GROUPS CORRESPOND TO ESTABLISHED CARCINOGENICITY?

Group 2B: The agent is possibly carcinogenic to humans

Condition:

Limited evidence of carcinogenicity in humans

Less than sufficient evidence of carcinogenicity in experimental animals

Less than sufficient evidence:

At most, a positive association has been observed; a causal interpretation is considered credible, but chance, bias or confounding cannot be ruled out

The agent cannot be considered as an established carcinogen
ICNIRP ON LONG-TERM EFFECTS

ELF

In the absence of support from laboratory studies, the epidemiological studies are insufficient to allow an exposure guideline to be established.

RF

Although there are deficiencies in the epidemiological work, [...] the studies have yielded no convincing evidence that typical exposure levels lead to adverse reproductive outcomes or an increased cancer risk in exposed individuals.

ICNIRP Guidelines, 1988
EU Recommendation
“Only established effects have been used as the basis for the recommended limitation of exposure”

EU Directive
“The long-term effects, including possible carcinogenic effects […] for which there is no conclusive scientific evidence establishing a causal relationship, are not addressed in this Directive”


ICNIRP STATEMENT ON MOBILE PHONES

CONCLUSIONS

Following a critical review of the scientific literature ICNIRP has reached the following conclusions:

1. The results of published epidemiological studies do not form a basis for health hazard assessments of exposure to RF fields, and neither can they be used for setting quantitative restrictions on human exposure. They do not provide a basis for hazard assessments in relation to the use of hand-held radiotelephones and base transmitters.

2. Data from laboratory studies relevant to cancer do not provide a basis for limiting exposure to the fields associated with the use of hand-held radiotelephones and base transmitters.

3. Limits for human exposure to the fields associated with the use of hand-held radiotelephones and base transmitters should be those of the INIRC (IRPA/INIRC 1988) for whole body average SAR and those of ICNIRP for localized SAR set out in this document.

4. There is no substantive evidence that adverse health effects, including cancer, can occur in people exposed to levels at or below the limits on whole body average SAR recommended by INIRC (IRPA/INIRC 1988) or at or below the ICNIRP limits for localized SAR set out in this document.

5. At the frequencies and power levels involved in the use of hand-held radiotelephones there will be no concern about shocks and burns.

6. The localized SARs in the head associated with the use of hand-held radiotelephones must be assessed for each frequency and configuration used.

7. For hand-held radiotelephones used in occupational situations, ICNIRP recommends that the localized SAR in the head be limited to 10 W kg\(^{-1}\) averaged over any 10 g mass of tissue in the head (0.1 W absorbed in any 10 g mass of tissue in the head).

8. For hand-held radiotelephones used by the general public, ICNIRP recommends that the localized SAR in the head be limited to 2 W kg\(^{-1}\) averaged over any 10 g mass of tissue in the head (0.02 W absorbed in any 10 g mass of tissue in the head).
WHAT TO DO IF INTERPHONE WILL COME OUT POSITIVE?

- Modify ICNIRP’s WB limits and reference levels?
- Modify local SAR limits?
  Down to what?
- Recommend limited use?
  Still as precautionary measure?
- Recommend technical solutions to reduce actual exposure?
  Why not now?

Who is responsible for each of these actions?
### WHY IS THE PRECAUTIONARY PRINCIPLE INVOKED?

**Public health impact and public perception of selected environmental health risks in Italy**

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Disease</th>
<th>Expected cases/year</th>
<th>Public health relevance</th>
<th>Public perception of risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radon</td>
<td>Lung cancer*</td>
<td>2.200-5.100(1)</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Benzene</td>
<td>Leukaemia**</td>
<td>16-275(2)</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>EMF</td>
<td>Leukaemia**</td>
<td>3(3)</td>
<td>+</td>
<td>+++</td>
</tr>
</tbody>
</table>

* Estimated total lung cancer cases per year @ 32,000
** Estimated total leukaemia cases per year @ 5,000
(1) Estimates based on published literature
(2) Italian National Toxicological Committee estimates
(3) WHO, 1997

**WHO European Centre for Environment and Health, Rome Division**
## Conclusion of the study

<table>
<thead>
<tr>
<th></th>
<th>Scientists</th>
<th>Public</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is an effect when none exists (false positive)</td>
<td>As low as possible</td>
<td></td>
</tr>
<tr>
<td>There is no effect when one exists (false negative)</td>
<td></td>
<td>As low as possible</td>
</tr>
</tbody>
</table>

Type I Error

After Kheifets, 2002
In statistics, a null hypothesis \( (H_0) \) is a hypothesis set up to be nullified or refuted in order to support an alternative.

When used, the null hypothesis is presumed true until statistical evidence indicates otherwise.

From Wikipedia
WHICH IS THE NULL HYPOTHESIS?

EMF are carcinogenic

or

EMF are not carcinogenic

If you are unable to prove/disprove either,
your conclusion depends on the initial hypothesis
WHO RECOMMENDATIONS

Public protection against EMF

*Recommendations to Member States*

Facing Health issues
- Compulsory standards
- Science-based measures

Facing public concern
- Separate voluntary standards
- Precautionary measures
WHAT IS THE PRECAUTIONARY PRINCIPLE?

The precautionary principle is an approach to risk management that is applied in circumstances of scientific uncertainty, reflecting the need to take action in the face of a potentially serious risk without awaiting the results of scientific research.

EC - DG XXIV, 1998
SOURCES OF UNCERTAINTY

- Existence of an adverse effect
- Extrapolation to environmental doses
- Extrapolation to different frequencies
- Extrapolation from animal data
- Dose
- Exposure measurements

Uncertainty  →  Reduction factors
WHEN IS THE PP APPLIED?

Recourse to the precautionary principle presupposes:

- **Identification of potentially negative effects resulting from a phenomenon, product or procedure**
- **A scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question**
EVALUATION OF RISK

Suppose that, out of 10 studies of equal quality, 1 is positive and 9 are negative.

- The role of scientific bodies (e.g. ICNIRP) is to present the balance of evidence, and the studies should have the same weight.
- The role of health authorities is to take decisions, and negative findings generally weigh more than positive ones.
Measures adopted should be:

- Proportional to the desired level of protection
- Not discriminatory in their application
- Consistent with others adopted in similar circumstances
- Based on cost/benefit analysis
- Provisional
- Able to assign responsibility for providing the scientific evidence for a comprehensive risk evaluation
POPULATION EXPOSED TO MAGNETIC FIELDS FROM POWER LINES IN ITALY

Exposed population

Attributable risk of childhood leukemia

B(μT)
BACKGROUND MAGNETIC FIELDS IN HOUSES

### EXTRA CASES OF LEUKAEMIA ATTRIBUTABLE TO MAGNETIC FIELDS IN ITALY

<table>
<thead>
<tr>
<th>Exposure level</th>
<th>Population</th>
<th>Excess cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>B &lt; 0.1 μT (*)</td>
<td>5.67x10^7</td>
<td>11.68</td>
</tr>
<tr>
<td>B &gt; 0.1 μT</td>
<td>299,400</td>
<td>0.84</td>
</tr>
<tr>
<td>B &gt; 0.2 μT</td>
<td>213,100</td>
<td>0.78</td>
</tr>
<tr>
<td>B &gt; 0.3 μT</td>
<td>148,600</td>
<td>0.70</td>
</tr>
<tr>
<td>B &gt; 0.4 μT</td>
<td>111,900</td>
<td>0.64</td>
</tr>
<tr>
<td>B &gt; 0.5 μT</td>
<td>95,300</td>
<td>0.62</td>
</tr>
<tr>
<td>B &gt; 0.6 μT</td>
<td>62,500</td>
<td>0.52</td>
</tr>
<tr>
<td>B &gt; 0.7 μT</td>
<td>58,900</td>
<td>0.50</td>
</tr>
<tr>
<td>B &gt; 0.8 μT</td>
<td>50,900</td>
<td>0.48</td>
</tr>
<tr>
<td>B &gt; 0.9 μT</td>
<td>46,000</td>
<td>0.46</td>
</tr>
<tr>
<td>B &gt; 1.0 μT</td>
<td>37,400</td>
<td>0.40</td>
</tr>
<tr>
<td>B &gt; 1.5 μT</td>
<td>15,000</td>
<td>0.26</td>
</tr>
<tr>
<td>B &gt; 2.0 μT</td>
<td>8,900</td>
<td>0.20</td>
</tr>
</tbody>
</table>

(*) Reference level, corresponding to background exposure (B = 0.05 μT)
ARE MEASURES PROPORTIONAL TO THE RISK?

Italy

In the case ELF magnetic fields are carcinogenic, exposure above 0.5 \( \mu \text{T} \) could be responsible for 1 incident case of leukaemia (out of about 500) per year.

Actions to reduce exposure from power lines below 0.5 \( \mu \text{T} \) are estimated to cost around 25,000 million USD.
WHAT DOES “CARCINOGENIC” MEAN?

Question:
Cigarette smoke is carcinogenic. What does it mean?

Lay people’s answer:
If I smoke cigarettes, then I may get cancer
WHAT DOES “POSSIBLY CARCINOGENIC” MEAN?

Question:
EMF are possibly carcinogenic. What does it mean?

Lay people’s answer:
If I am exposed to EMF, then I may get cancer

Correct answer:
If EMF are really a cause of cancer and I am exposed to EMF, then I may get cancer
WHAT IS THE RISK?

P₁ = probability that EMF are carcinogenic
P₂ = probability of getting cancer due to the exposure

Total probability of getting cancer:

\[ P = P₁ \cdot P₂ \]

Can P₁ be quantified?
On a scale 0 to 100, how do you estimate ELF magnetic fields to be a cause of cancer?

**Probably carcinogenic**

- 0
- 50
- 100

**Possibly carcinogenic**

- 0
- 50
- 100
A cautionary policy for EMF should be adopted only with great care and deliberation. The requirements for such a policy as outlined by the European Commission do not appear to be met in the case of either power or radio frequency EMF; however other related policies, such as Prudent Avoidance, may be justified.

*WHO, Backgrounder on Cautionary Policies, March 2000*
WHO’S RECOMMENDATIONS (ELF)

Provided that these benefits are not compromised, implementing precautionary procedures to reduce exposures is reasonable and warranted [...].

Given the weakness of the evidence for a link between exposure to ELF magnetic fields and childhood leukaemia and the limited potential impact on public health, the benefits of exposure reduction on health are unclear and thus the cost of reducing exposure should be very low.

EHC 238, 2007
Susceptibility towards EMF is very high because alleged risks concern:

- A pathology particularly dread such as cancer
- A category particularly protected such as children

What is the relevance of EMF in the general context of cancer and in the general context of children’s health?
Electromagnetic fields

Some studies have shown a risk of childhood leukaemia with exposure to high level residential extremely low frequency electromagnetic fields, but causality has not been established

(p. 243)

2003, 351 pages
Early warning:
Wertheimer and Leeper 1979

Almost 30 years passed

• Has the warning been disregarded?
• What is the lesson learnt?
• Can we expect a different lesson in the future?
Electromagnetic fields

Assuming that the association is causal, the number of cases in excess would be in the order of 1%. [...] 

Whether or not this is to be considered acceptable (keeping in mind that the association is not proven) is an ethical matter, requiring a thorough and transparent discussion among different stakeholders.

(p. 89)
THE OPTIMIZATION PRINCIPLE (ALARA)

Cost

Total Cost

Cost of Health Detriment

Cost of Protection

Exposure Level

Electromagnetic Fields and Epidemiology
Erice, March 26 - April 2, 2008
Actions on limiting the exposure of the general public to electromagnetic fields should be balanced with the other health, safety and security benefits that devices emitting electromagnetic fields bring to the quality of life, in such areas as telecommunications, energy and public security.

*EU Recommendation, 1999*
Actions on limiting the exposure of the general public to electromagnetic fields should be balanced with the other health, safety and security benefits that devices emitting electromagnetic fields bring to the quality of life, in such areas as telecommunications, energy and public security.

*EU Recommendation, 1999*
ALARA FOR EMF?

Cost

Total Cost

Cost of Health Detriment

Social Cost

Exposure Level

UNKNOWN

COUNTRY-DEPENDENT

Total Cost

Cost

Exposure Level
CONCLUSIONS

- Epidemiology is crucial for any EMF protection policy
- Epidemiology is (probably) more subject to interpretation than other research lines
- The dividing line between science-driven policy and policy-driven science is thin and fragile