The International EMF Project

Update on WHO EMF Activities

Dr E. van Deventer

Department of Public Health, Environmental and Social Determinants of Health
Geneva, Switzerland
WHO International EMF Project

- Established in 1996
- Coordinated by WHO HQ
- Objectives
  - Review the scientific literature on health effects of EMF exposure and formally assess health risks;
  - Promote a focused agenda of high quality EMF research;
  - Encourage internationally acceptable harmonized standards;
  - Provide information on risk perception, risk communication, risk management

The International EMF Project

investigates health effects of electromagnetic fields
advises national authorities on EMF radiation protection
WHO EMF Monographs

2002

2006

2007

2013

≠

2017
Health Risk Assessment

Problem Formulation

Hazard Identification
- Review key research to identify any potential health problems that an agent can cause

Exposure Assessment
- Determine the amount, duration and pattern of exposure to the agent

Exposure-Response Assessment
- Estimate how much of the agent it would take to cause varying degrees of health effects that could lead to illnesses

Risk Characterization
- Assess the risk for the agent to cause cancer or other illnesses in the general population
Health Risk Assessment

Problem Formulation

Hazard Identification
Review key research to identify any potential health problems that an agent can cause

Exposure Assessment
Determine the amount, duration and pattern of exposure to the agent

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Risk Characterization
Assess the risk for the agent to cause cancer or other illnesses in the general population

All studied outcomes
RF Environmental Health Criteria

Objectives

- Review the scientific literature regarding **adverse health effects** from exposure to radiofrequency fields
- Perform a **health risk assessment** of all studied health endpoints, as far as the evidence can offer
- Compile a **summary of national policies** around the world (based on a survey performed in Fall 2012 and update in 2017)
- Identify gaps in knowledge and highlight **research priorities** from a public health perspective
RF Environmental Health Criteria

Target audience

- Policy-makers in Ministries of Health, Ministries of Environment, Ministries of Telecommunications,
- Nongovernmental organizations
- Professional societies
- Academia
EMF EHC Monographs

• EHC 16 Radiofrequency and microwaves (1981)
• EHC 35 Extremely low frequency (ELF) fields (1984)
• EHC 69 Magnetic fields (1987)
• EHC 137 Electromagnetic fields (300 Hz-300 GHz) (1993)
RF Environmental Health Criteria

Scope

- Frequency range:
  - 100 kHz - 300 GHz
  - Include UWB, pulses, mm-waves

- Sources:
  - wireless networks, broadcasting, industrial RFID, EAS, radars,…

- Health benefits not included
  - Hyperthermia, MRI, medical treatments, diathermy, RF ablation surgery
RF Environmental Health Criteria
Contributors

- Review team (around 20 contributors)

- Task Group members
  - Individual scientists, not representatives of their organizations
  - Composition dictated by range of expertise and views, gender and geographical distribution
  - Membership approved by Assistant Director General
  - Role: assess risks to health, reach agreements by consensus, make final conclusions and recommendations that cannot be altered after the Task Group meeting

- Observers

- WHO Secretariat
Declaration of Interests

DECLARATION OF INTERESTS FOR WHO EXPERTS

WHO's work on global health issues requires the assistance of external experts who may have interests related to their expertise. To ensure the highest integrity and public confidence in its activities, WHO requires that experts serving in an advisory role disclose any circumstances that could give rise to a potential conflict of interest related to the subject of the activity in which they will be involved.

All experts serving in an advisory role must disclose any circumstances that could represent a potential conflict of interest (i.e., you must disclose all financial or personal involvements that could affect your work or judgment). The list of work being affected by interests and any potential conflicts of interest must be kept current. Your obligations as an expert may, depending on the circumstances, continue after you have completed your service for WHO.

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Code of Conduct for WHO Experts

Should be sent with the DOI form

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Should be sent with the invitation or appointment letter

1. The World Health Organization (WHO), acting through its Department of [ ], has access to certain information relating to [ ], which information WHO considers to be proprietary to itself or to parties collaborating with it (hereinafter referred to as "the Information").

2. The Undersigned, as a member of the [ ] advisory meeting, group or committee (collectively referred to as the "Advisory Process"), may have access to the Information in the course of his/her participation in the Advisory Process (whether
RF Environmental Health Criteria

Process

- Following WHO internal processes for scientific review and recommendations development
  - Systematic reviews
  - GRADE process
- Process
  - Set search criteria and quality criteria, include several languages
  - Published peer-reviewed literature since 1993 (> 1000 refs)
Relevant studies

- Development of an extensive database
  - Peer-reviewed scientific publications
  - Meta-analyses not included
    - May not have used the same inclusion and quality criteria as used in the EHC
    - Conclusions may partly be based on studies excluded from the EHC

- Search period: Jan 1992 – present

- Languages
Relevant studies (cont'd)

- Epidemiological studies
  - Diff. categories of study designs (no case-report or case-series)

- Human studies
  - Laboratory, intervention studies

- Animal studies
  - Laboratory (including ex vivo studies), observational studies (domestic animals)

- In vitro studies
  - Cell cultures, isolated tissue samples
Process

- Search strategy
  - Predefined and registered search criteria

- Screening
  - Predefined and registered selection criteria

- Analysis
Process

PubMed
ISI Web of Science
Embase
EMF Portal
ELMAR

Relevant papers identified from other sources (e.g., related papers, reference lists, searches for other topics, public consultation)

Papers identified from database(s)

Papers excluded upon screening (not relevant)

Papers removed (not compliant with quality criteria)

Papers included in the analysis

Selected papers

Inclusion criteria

Quality criteria

Health outcomes
Quality criteria

- Epidemiological studies
  - STROBE checklist, GRADE, Newcastle-Ottawa Scale

- Volunteer studies
  - CONSORT statement and checklist, Gold Standard Publication Checklist

- Animal studies
  - Gold Standard Publication Checklist

- In-vitro studies
  - Dosimetry, statistical analysis, T control,…
Quality criteria (cont'd)

- Statistical precision/statistical power (width of confidence intervals when provided, primarily study size)
- Potential biases
- Consistency and plausibility of results and, when relevant, exposure-response relationship
- Directness (validity in relation to, e.g. study population, exposure, time lag between exposure and outcome assessment, and endpoints)
Public consultation

- 686 comments
- 73 respondents through website + several by email
- 300 missing papers
WHO process to derive exposure limits

- Examples
  - WHO Air quality guidelines (indoor and outdoor)
  - WHO Nanotechnology guidelines
  - WHO Environmental noise guidelines

- Guideline exposure limits indicate a level of exposure beyond (below) which the TG is certain (reasonably confident) that there is a (no) risk

- The guideline exposure level will be based on a relevant risk increase of the most important adverse health outcomes for which there is evidence in the systematic reviews
Most important adverse health outcomes?

(Local increase in temperature)
- Cataracts
- Pain
- Burns
- Male fertility

(Core body temperature)
- Exhuastion
- Heat shock
- Dehydration

IEI-EMF
- Foetal development
- Cognition
- Blood-brain barrier

Environmental exposure
- Personal exposure
- Occupational exposure

Humans
- Animals
WHO process to derive exposure limits

- Take into account the quality of the evidence regarding the risks
- Evidence for an effect of exposure/intervention:
  - Effect size: relative risk, risk difference, mean difference
  - Precision of the effect: 95% confidence interval
  - Confidence in the underlying studies
GRADE (official) approach

1. Establish initial level of certainty

<table>
<thead>
<tr>
<th>Study design</th>
<th>Initial certainty in an estimate of effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized trials</td>
<td>High certainty</td>
</tr>
<tr>
<td>Observational studies</td>
<td>Low certainty</td>
</tr>
</tbody>
</table>

2. Consider lowering or raising level of certainty

<table>
<thead>
<tr>
<th>Reasons for considering lowering or raising certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>↓ Lower if</td>
</tr>
<tr>
<td>Risk of Bias</td>
</tr>
<tr>
<td>Inconsistency</td>
</tr>
<tr>
<td>Indirectness</td>
</tr>
<tr>
<td>Imprecision</td>
</tr>
<tr>
<td>Publication bias</td>
</tr>
<tr>
<td>↑ Higher if*</td>
</tr>
<tr>
<td>Large effect</td>
</tr>
<tr>
<td>Dose response</td>
</tr>
<tr>
<td>All plausible confounding &amp; bias</td>
</tr>
<tr>
<td>• would reduce a demonstrated effect</td>
</tr>
<tr>
<td>• would suggest a spurious effect if no effect was observed</td>
</tr>
</tbody>
</table>

3. Final level of certainty rating

<table>
<thead>
<tr>
<th>Certainty in an estimate of effect across those considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
</tr>
<tr>
<td>Moderate</td>
</tr>
<tr>
<td>Low</td>
</tr>
<tr>
<td>Very low</td>
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</tbody>
</table>

*upgrading criteria are usually applicable to observational studies only.

Adapted from “Methodological idiosyncracies, frameworks and challenges of non-pharmaceutical and non-technical treatment interventions” (Schünemann 2013)
How credible are the study results? Evaluating and applying internal validity tools to literature-based assessments of environmental health hazards

Andrew A. Rooney a, Glinda S. Cooper b, Gloria D. Jahnke c, Juleen Lam d, Rebecca L. Morgan e, Abee L. Boyles a, Jennifer M. Ratcliffe f, Andrew D. Kraft b, Holger J. Schünemann e, Pamela Schwingl f, Teneille D. Walker b, Kristina A. Thayer a, Ruth M. Lunn c,*
Assess individual study risk of bias

1) assess each study separately by outcome
2) use method specific to study type (i.e., different questions for animal or epidemiology studies)
3) Example: assess risk of bias for epidemiology studies by domains (e.g., exposure, outcome, selection, confounding, and other domains depending on approach used)

RESULTS for Paper A:
- Exposure: Low risk of bias
- Outcome: Low risk of bias
- Selection: Low risk of bias
- Confounding: Low risk of bias

RESULTS for Paper B:
- Exposure: HIGH risk of bias
- Outcome: Low risk of bias
- Selection: Low risk of bias
- Confounding: Low risk of bias

RESULTS for Paper C:
- Exposure: HIGH risk of bias
- Outcome: Low risk of bias
- Selection: HIGH risk of bias
- Confounding: HIGH risk of bias

RESULTS for Paper D:
- Exposure: Low risk of bias
- Outcome: Low risk of bias
- Selection: Low risk of bias
- Confounding: HIGH risk of bias

Fig. 1. Risk of bias of individual studies and its use in the evaluation of the body of evidence.
WHO process to derive exposure limits

- **Balance** these risks against the benefits and the effectiveness and costs of the interventions to remove the risks.

- Take into account the values and preferences of different sub-populations that are exposed to risk such as the general public and workers.

- Based on these arguments, determine the final level and strength of recommendation of a specific guideline exposure value.
RF Environmental Health Criteria

Summary

- Update following expert consultation (Fall 2014)
- Involvement of a guideline methodologist
- Monthly conference calls, face-to-face meetings (The Hague, Sept 2016)
- Prioritization of most relevant outcomes
- Perform full systematic reviews and GRADE-ing
- Update of the 2012 RF Policy survey (Spring 2017)
- Task Group meeting – Fall 2017
Thank you - ありがとう ございました

The International EMF Project
Radiation Programme
Public Health, Environmental and
Social Determinants of Health
World Health Organization
21 Avenue Appia
CH-1211 Geneva 27
Switzerland

email: emfproject@who.int
website: www.who.int/emf