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
- To develop a solid base of scientific evidence
- To facilitate dialogue between stakeholders
- To help countries set their national EMF regulations
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

Cancer
Health Risk Assessment

All studied outcomes

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
Environmental Health Criteria

- **Target audience**
  - National and international authorities

- **Reason for development**
  - To assist them in making risk assessment and subsequent risk management decisions
  - Mandate
  - Update
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)
EMF EHC Monographs

- Comprise:
  - Systematic and critical review of evidence for EMF effects on health
  - Health risk assessment
  - Risk management measures
  - Research recommendations
RF EHC: 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 EHC: Contributors

- Systematic review team (around 25 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
RF EHC Core Group

- Physics, dosimetry: Simon Mann, UK
- Epidemiological studies: Maria Feychting, Sweden
- Humans studies: Gunnhild Oftedal, Norway
- Animal studies: Eric van Rongen, Netherlands
- In vitro studies: Maria Rosaria Scarfi, Italy
- Public health: Denis Zmirou, France

- Monthly teleconferences
- Annual face-to-face meetings
Assistance

- Additional experts to help drafting sections
  Azadeh Peyman
  Olga Zeni
  Giorgio Aicardi
  Jukka Juutilainen
  Kerstin Hug
  Sarah Loughran
  Carmela Marino
  James McNamee
  Jonne Naarala
  Giuseppe Curcio
  Martin Röösli
  James Rubin
  Minouk Schoemaker
  Brahim Selmaoui
  René de Sèze
  Zenon Sienkiewicz
  Myrtill Simko
  Susanna Lagorio
  Vijaylaxmi
  Lawrie Challis (reviewer)
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 if you have any interest in the work that may be affected by the advisory role). (See definition of interests and administrative disqualification).

Code of Conduct for WHO Experts

Should be sent with the DOI form

WHO values and relies upon the normative and technical advice that is provided by leading subject matter experts in the context of similar processes. Such advice contributes that are promulgated by WHO for the benefit of public health.

CONFIDENTIALITY UNDERTAKING

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 "the Advisory Process"), may have access to the Information in the course of his/her participation in the Advisory Process (whether
<table>
<thead>
<tr>
<th>Preamble</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Summary and recommendations for further study</td>
</tr>
<tr>
<td>2. Sources, measurements and exposures</td>
</tr>
<tr>
<td>3. Electric and magnetic fields inside the body; SAR and heat</td>
</tr>
<tr>
<td>4. Biophysical mechanisms; tissue heating</td>
</tr>
<tr>
<td>5. Biochemical and biological effects</td>
</tr>
<tr>
<td>6. Brain physiology and function</td>
</tr>
<tr>
<td>7. Auditory, vestibular and ocular function</td>
</tr>
<tr>
<td>8. Neuroendocrine system</td>
</tr>
<tr>
<td>9. Neurodegenerative disorders</td>
</tr>
<tr>
<td>10. Cardiovascular system and thermoregulation</td>
</tr>
<tr>
<td>11. Immune system and haematology</td>
</tr>
<tr>
<td>12. Fertility, reproduction and development</td>
</tr>
<tr>
<td>13. Cancer</td>
</tr>
<tr>
<td>14. Health risk assessment</td>
</tr>
<tr>
<td>15. Protective measures</td>
</tr>
</tbody>
</table>

Annexes

By health endpoint
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

1. **PubMed**
2. **ISI Web of Science**
3. **Embase**
4. **EMF Portal**
5. **ELMAR**

... (other sources)

- Relevant papers identified from database(s)
- Relevant papers
- Papers included in the analysis
- Papers excluded upon screening (not relevant)
- Papers removed (not compliant with quality criteria)

Health outcomes
Inclusion criteria
Quality criteria
Selected papers
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

Radio Frequency fields: Environmental Health Criteria Monograph

Consultation on the scientific review for the upcoming WHO Environmental Health Criteria

The public consultation is now closed

The World Health Organization is undertaking a health risk assessment of radiofrequency electromagnetic fields, to be published as a monograph in the Environmental Health Criteria Series. This publication will complement the monographs on static fields (2006) and extremely low frequency fields (2007), and will update the monograph on radiofrequency fields (1993).

The draft chapters of this document which contain the scientific content are now open for technical consultation by RF experts. We are seeking comments on the accuracy and completeness of the information contained in these chapters. Please note that the literature searches have been done up to December 2012 (in a few instances to December 2013), so the more recent studies are currently not yet included. While the searches and chapters will be updated before finalization of the document, any suggestions for inclusion of peer reviewed studies are welcomed.

The process used in developing the chapters is described in Appendix X. Note that the chapters 1, 13 and 14 which will provide a summary, health risk assessment and protective measures are not available for this consultation. The drawing of conclusions from the literature and the drafting of these chapters is the remit of a formal Task Group that will be convened by WHO at a later stage in the process.

If you have questions, please contact us at: emfproject@who.int

October 1 to December 15, 2014

- 686 comments
- 73 respondents through website + several by email
- 300 missing papers
EHC PREPARATION FLOW CHART

Commitment to draft EHC

Document preparation initiated

Draft sent to IPCS Responsible Officer (RO)

Possible meeting of a few experts to resolve controversial issues

Revision as necessary

Responsible Officer, Editor check for coherence of text and readability (not language editing)

First Draft

International circulation to Contact Points (150+)

Comments to IPCS (RO)

Review of comments, reference cross-check; preparation of Task Group (TG) draft

Editor

Task Group meeting

Insertion of TG changes

Post-TG draft; detailed reference cross-check

Editoring

French/Spanish translations of Summary

Graphics

Word-processing

Camera-ready copy

Library for CIP data

Final editing

Approval by Director, IPCS

WHO Publication Office

WHO Publication Office

Printer

Proofs

Publication

--- Kick-off meeting

Jan 2012

First draft

Public consultation

Sept–Dec 2014

Second draft

Task Group meeting

Fall 2016

Monograph

publication

2017
Non-Ionizing Radiation

Basic Safety Standards
WHO's core functions

1. Articulate ethical and evidence-based policy positions
2. Setting norms and standards, and promoting and monitoring their implementation
3. Shaping the research agenda, and stimulating the generation, translation and dissemination of valuable knowledge
4. Providing technical support, catalysing change and developing sustainable institutional capacity
5. Monitoring the health situation and assessing health trends
6. Providing leadership on matters critical to health and engaging in partnerships where joint action is needed
WHO's core functions

1. Articulate ethical and evidence-based policy positions

2. Setting norms and standards, and promoting and monitoring their implementation

3. Shaping the research agenda, and stimulating the generation, translation and dissemination of valuable knowledge

4. Providing technical support, catalysing change and developing sustainable institutional capacity

5. Monitoring the health situation and assessing health trends

6. Providing leadership on matters critical to health and engaging in partnerships
Motivation for NIR standards

- Member states are increasingly interested in clear guidance based on harmonized standards and their application within an international framework of protection.

- Currently, a number of non-governmental organizations have developed guidelines or standards for limiting exposure to non-ionizing radiation (NIR).

- Gaps in and lack of consistency amongst guidelines in certain areas have proved to be challenging to regulators, policy-makers and their advisors in their efforts to develop national standards.
The IR Paradigm
Science, recommendations, standards

Scientific basis
Effects, risks, sources, levels, trends, ...

Recommendations
System of RP (philosophy, principles, dose criteria, ...)

Standards
(safety requirements, regulatory language, ..)

National regulations
Jointly sponsored by EC, FAO, IAEA, ILO, OECD/NEA, PAHO, UNEP, WHO

IAEA Safety Standards
for protecting people and the environment

Fundamental Safety Principles
Safety Fundamentals
No. SF-1

Protection Against Ionising Radiation

Radiation Protection Series P-3
The NIR landscape

Scientific basis
Effects, risks, sources, levels, trends, ...

Recommendations
System of RP (philosophy, principles, limits, ...)

Standards
Safety requirements, regulatory language,..

National regulations
The primary aim is to:

- provide an appropriate level of protection for people and the environment against the detrimental effects of radiation exposure

- without unduly limiting the benefits that may be associated with such exposure
The System of Radiological Protection

- Three exposure situations
  - Planned
  - Existing
  - Emergency

- Three categories of exposure
  - Public
  - Occupational
  - Medical

- Three principles
  - Justification
  - Optimization
  - Limitation
NIR Protection

- Three exposure situations
  - Planned
  - Existing
  - Emergency

- Three categories of exposure
  - Public
  - Occupational
  - Medical

- Three principles
  - Justification
  - Optimization
  - Limitation
ICNIRP Guidelines
EMF Radiation

- Guidelines for Limiting Exposure to Electric Fields Induced by Movement of the Human Body in a Static Magnetic Field and by Time-Varying Magnetic Fields below 1 Hz. 2014
- Guidelines for Limiting Exposure to Time-Varying Electric and Magnetic Fields (1 Hz - 100 kHz). 2010
- Guidelines on Limits of Exposure to Static Magnetic Fields. 2009
- Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic, and Electromagnetic Fields (up to 300 GHz). 1998
- Guidelines on Limits of Exposure to Static Magnetic Fields. 1994
ICNIRP Guidelines
Optical Radiation

- Guidelines on Limits of Exposure to **Laser Radiation** of Wavelengths between 180 nm and 1,000 μm. 2013
- Guidelines on Limits of Exposure to **Incoherent Visible and Infrared Radiation**. 2013
- Guidelines on Limits of Exposure to **Ultraviolet Radiation** of Wavelengths Between 180 nm and 400 nm (Incoherent Optical Radiation). 2004
- Revision of the Guidelines on Limits of Exposure to **Laser radiation** of wavelengths between 400 nm and 1.4 μm. 2000
- Guidelines on Limits of Exposure to **Broad-Band Incoherent Optical Radiation** (0.38 to 3 μm). 1997
- Guidelines on **UV Radiation** Exposure Limits. 1996
- Guidelines on Limits of Exposure to **Laser Radiation** of Wavelengths between 180 nm and 1 mm. 1996
Electromagnetic fields

- Current exposure limits based on mechanisms of interaction with threshold (deterministic effects)
- **Limitation** has been primarily applied
Optical radiation

• Known benefits as well as risks, therefore **optimization** principle applied

• For sources that present a risk of injury or ill health, justification and limitation also apply

---

**Risk vs Benefit**

- **Benefit**
- **Detriment**

"Dose"

Source: John O'Hagan, CIE
Ultrasound in medicine

Diagnostic
Therapeutic
Aesthetic medicine

Source: Jacques Abramowicz, WFUMB
Acoustic output over the years

• Before 1976: no limits to the permissible acoustic output from diagnostic ultrasound equipment.

• In 1976, the US Food and Drug Administration began regulating the output levels of machines to be no more than 94 mW/cm² spatial-peak temporal-average (SPTA) intensity for fetal use.

FDA mandated (together with AIUM, NEMA, public representatives): the Output Display Standard (ODS)

Manufacturers may increase maximal output (up to 720mw/cm² for fetal use) on the condition that two indices appear on-screen:

• Thermal index (TI) for thermal effects
• Mechanical index (MI) for non-thermal (a.k.a. mechanical) effects
• AND: a particular effort is to be made to educate the end-users about bioeffects, safety and TI and MI
“Although the ODS is sometimes referred to as a de facto international standard, it is only used for regulatory purposes in the USA. No international safety standard exists to guide the user in the safe and effective application of diagnostic ultrasound in medicine.”
Infrasound

• Also referred to as low-frequency sound, is sound with frequency <20 Hz
• National and international agencies: almost completely silent on standards or recommendations for protection from infrasound.
• Usually managed as a subset of considerations on protection from noise (Jakobsen, 2003; NOHSC, 2003).
• However, the relevant EU directive on noise protection (European Communities, 2003) omits specific reference to protection levels for infrasound.
A world standard

✓ Would improve knowledge of bioeffects and safety of various forms of ultrasound among end-users, given the blatant lack of education in this field;
✓ Would regulate modalities that are used all over the world, multiple times daily;

But more importantly
✓ Would protect the public and particularly millions of fetuses from potential harmful effects, if ultrasound is used indiscriminately

Source: J. Abramowicz, WFUMB
Developing NIR Standards
Vision

- A coherent set of *fundamental principles and basic requirements which shall*
  - Cover EMF, optical radiation, ultrasound and infrasound
  - Cover all exposure situations and exposed populations - but with clearly defined exceptions
  - Be based on existing scientific evidence – but consider uncertainties and lack of knowledge
  - Be justified and optimized by taking account risks-costs-benefits
  - Be realistic considering implementations
  - Be useful!
Developing NIR Standards

Challenges

- Diversity of spectrum, exposures, health effects
- Level of evidence - missing data, uncertainties
- Strong and rapid technological developments
- Philosophy, e.g. precaution, ethics
- Criteria for exceptions, or inclusions
- Risk-cost-benefit analysis
- Non-medical applications on humans
Developing NIR Standards
Opportunities

- Involvement
  - of developed and developing countries
  - endorsement by relevant UN organizations

- Translate criteria and principles into regulatory terms

- Support governments in
  - applying basic safety principles
  - implementing of guidelines

- Useful for
  - Health protection
  - risk communication
  - the international labor market
  - the global roll out of modern technology
  - international litigation
WHO “NIR BSS” Project

- 2012: Request from a Member State
- 2013: Discussion with the WHO IAC (June 2013, Paris)
- 2014: Consultancy meeting of experts and representatives of int. organizations and NGOs
- 2015: Core Group Meeting (27-28 April 2015)
Core Group Members

Dr Jacques S. ABRAMOWICZ
World Federation of Ultrasound in Medicine and Biology (WFUMB)
Professor and Director of Ultrasound Services
Department of Obstetrics and Gynecology
Wayne State University
Hutzel Women’s Hospital
UNITED STATES OF AMERICA

Dr Efthymios KARABETOS
Head of the Non-Ionizing Radiation Office
Greek Atomic Energy Commission
GREECE

Dr Mirjana MOSER
Independent expert in radiation protection
(now retired from the Radiation Protection Division, Swiss Federal Office of Public Health)
SWITZERLAND

Dr John O’HAGAN
International Commission on Illumination (CIE)
(Director, Division 6, Photobiology & Photochemistry)
Group Leader, Laser and Optical Radiation Dosimetry Group
Public Health England
UNITED KINGDOM

Dr Rick TINKER
Director Radiation Health Services
Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)
AUSTRALIA

Dr Sigurdur MAGNUSSON
Director
Icelandic Radiation Safety Authority
ICELAND

Dr Shengli NIU
International Labour Organization
Geneva
SWITZERLAND
NIR Regulatory Framework
"Fundamental Safety Principles"

- Develop a draft "Fundamental Safety Principles for Non-Ionizing Radiation" (April 2015 - May 2016)

- Circulate for consultation (Spring-Summer 2016)
  - Member States
  - International organizations, professional bodies, and other relevant NGOs
"Basic Safety Standards"

- Setting responsibilities for Requirements
  - Government
  - Regulatory body
  - Responsible persons or organizations
  - Registrants and licensees
  - Relevant parties

- Establishing a legal framework and defining responsibilities

- Notification, authorization, licensing, exemptions and clearance

- Justification, optimization and dose limits

- Information, protection, training
Discussion

Basic Safety Standards for Non-Ionizing Radiation