INTERNATIONAL COMMISSION ON NON-IONIZING RADIATION PROTECTION

ICNIRP STATEMENT

GAPS IN KNOWLEDGE RELEVANT TO THE "ICNIRP GUIDELINES FOR LIMITING EXPOSURE TO TIME-VARYING ELECTRIC, MAGNETIC AND ELECTROMAGNETIC FIELDS (100 KHZ TO 300 GHZ)"

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Gaps in Knowledge Relevant to the "ICNIRP Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic and Electromagnetic Fields (100 kHz TO 300 GHz)"

International Commission on Non-Ionizing Radiation Protection (ICNIRP)

Abstract—**In the last 30 y, observational as well as experimental studies have addressed possible health effects of exposure to radiofrequency electromagnetic fields (EMF) and investigated potential interaction mechanisms. The main goal of ICNIRP is to protect people and the environment from detrimental exposure to all forms of non-ionizing radiation (NIR), providing advice and guidance by developing and disseminating exposure guidelines based on the available scientific research on specific parts of the electromagnetic spectrum. During the development of International Commission on Non-Ionizing Radiation Protection's (ICNIRP's) 2020 radiofrequency EMF guidelines some gaps in the available data were identified. To encourage further research into knowledge gaps in research that would, if addressed, assist ICNIRP in further developing guidelines and setting revised recommendations on limiting exposure, data gaps that were identified during the development of the 2020 radiofrequency EMF guidelines, in conjunction with subsequent consideration of the literature, are described in this Statement. Note that this process and resultant recommendations were not intended to duplicate more traditional research agendas, whose focus is on extending knowledge in this area more generally but was tightly focused on identifying the highest data gap priorities for guidelines development more specifically. The result of this distinction is that the present data gap recommendations do not include some gaps in the literature that in principle could be relevant to radiofrequency EMF health, but which were excluded because either the link between exposure and endpoint, or the link between endpoint and health, was not supported sufficiently by the literature. The evaluation of these research areas identified the following data gaps: (1) Issues concerning relations between radiofrequency EMF exposure and heat-induced pain; (2) Clarification of the relation between whole-body exposure and core temperature rise from 100 kHz to 300 GHz, as a function of exposure duration and combined EMF exposures; (3) Adverse effect thresholds and thermal dosimetry for a range of ocular structures; (4) Pain thresholds for contact currents under a range of exposure scenarios, including associated dosimetry; and (5) A range of additional dosimetry studies to both support future research, and also to improve the application of radiofrequency EMF exposure restrictions in future guidelines.**

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INTRODUCTION AND PURPOSE

THE MAIN goal of ICNIRP is to provide advice and guidance to protect people and the environment from unfavorable exposure to all forms of non-ionizing radiation (NIR). To this end, ICNIRP uses the scientific literature, including reviews of the scientific evidence and health risk assessments from other expert groups and international committees. ICNIRP's guidance thus incorporates the breadth of scientific outputs and consensus views regarding substantiated and potential health effects and ensures the robustness of its guidelines.

The guidelines for the protection of humans exposed to radiofrequency electromagnetic fields (EMF) in the range 100 kHz to 300 GHz have been published recently (hereafter "the Guidelines"; ICNIRP 2020a) and they primarily replace the 100 kHz to 300 GHz part of the ICNIRP (1998) radiofrequency EMF guidelines. The analysis of the scientific literature on the biological and health effects of exposure to radiofrequency EMFs, as well as the associated dosimetry, was updated in the Guidelines, taking in account that decades of research in the radiofrequency EMF range has subsequently been conducted. Appendix B of the Guidelines provides data regarding the biological and health effects extracted primarily from major international reviews of the scientific literature. This included an in-depth review from the World Health Organization on radiofrequency EMF exposure and health that was released as a draft Technical Document (WHO 2014), and reports by the Scientific Committee on Emerging and Newly Identified Health Risks (2015) and the Swedish Radiation Safety Authority (2015,

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2016, 2018). Appendix A of the Guidelines provides updated dosimetric information relevant to the Guidelines based on original research publications.

Although the Guidelines are based on the best science currently available, during the preparation process ICNIRP identified limitations in the data available from the international scientific literature that are likely to have a tangible impact on future guideline development (using the algorithm described in ICNIRP 2020b). This algorithm differs from methods used for more typical research agenda in that it only recommends data gaps "in so far as there is appropriate evidence that they are likely to help development needs," rather than merely being "possibly relevant." That is, it would not recommend research to determine whether radiofrequency EMF adversely affects an endpoint (e.g., depression) merely because it has not yet been studied but would require appropriate evidence and/or argument in support of its inclusion as a data gap. The principal goal of the present document is to invite the international scientific community to promote research in specific topics where gaps in knowledge were identified during the development of the radiofrequency EMF Guidelines and accordingly to benefit future guideline development.

METHOD

The method used to determine the data gaps is detailed in ICNIRP (2020b), where an algorithm was defined to identify the research needs objectively in terms of:

- Assessing the relevance of endpoints and mechanisms that are used as bases for the existing guidelines and whether more research is needed to determine their importance;
- Assessing whether there are other endpoints or mechanisms that research has shown may be important and whether more research is needed to determine their impact on the Guidelines; and
- Assessing whether there are data gaps related to thresholds for effects and dosimetry for endpoints that are relevant to the points above.

The primary input for this assessment came from the issues identified during the Guidelines development process, which was supplemented with additional literature where relevant.

RESULTS

Outcomes for which data gaps are identified

Pain threshold for radiofrequency EMF heating

Only one study has been identified that explored the relation between radiofrequency EMF skin exposure and threshold for pain perception. Walters et al. (2000) exposed an area (4-cm diameter) of the back of their participants to 94-GHz pulse-modulated exposure lasting 3 s. The average initial skin temperature was 34.0 °C. The threshold for a "pricking" pain was obtained with an average incident power density of 12.5 ± 0.5 kW m^{-2}, which resulted in a skin temperature of 43.9 °C. Studies that have used other sources to increase skin temperature show that the initial skin temperature appears to have little or no effect on the temperature threshold for pain (Green and Akirav 2010; Pertovaara et al. 1996), while the temperature threshold decreases both with increasing time at a given temperature and as (temporal) rate of temperature elevation increases (Stoll and Greene 1959, reported in Dewhirst et al. 2003; Pertovaara et al. 1996; Green and Akirav 2010). The threshold for pain also varies between different skin areas (Pertovaara et al. 1996) and is influenced by a mild heat injury (Torebjork et al. 1984). Knowledge from non-EMF heating studies about the influence of various factors on pain thresholds is useful also for determining thresholds for pain perception under radiofrequency EMF exposure. However, such studies that appear to include almost similar conditions (Green and Akirav 2010; Pertovaara et al. 1996) have reported thresholds that vary considerably (more than 10 °C), with reported thresholds ranging from about 38 to 55 °C (Stoll and Greene 1959, reported in Dewhirst et al. 2003; Pertovaara et al. 1996; Green and Akirav 2010; Torebjork et al. 1984).

Although the radiofrequency EMF exposure study by Walters et al. (2000) provided thresholds that are within the ranges of the above non-EMF studies with similar temperature elevation rates, further studies with radiofrequency EMF exposure are warranted, including those designed to determine the impact of rate of radiofrequency EMF-induced temperature rise on pain, and the effect of spatial extent and duration of exposure on pain. It is also important to note that radiofrequency EMF exposures differ from conventional thermal exposures that apply heat more superficially, particularly in that radiofrequency EMFs can cause a more-rapid temperature elevation at dermal and deeper epidermal layers where temperature sensitive nociceptors are located (e.g., Lawson et al. 2008). Since the penetration depth of radiofrequency EMF depends on the frequency, experimental studies with different frequencies would be useful in combination with simulation studies estimating temperature elevation as a function of tissue depth.

Core temperature rise and health effects

When the body is subject to excessive heating, core temperature can rise above the typical baseline level of 37 (±0.5) °C (Reilly et al. 2007). Where thermoregulatory functions (such as vasodilation and sweating) are not sufficient to restrict body core temperature rise to approximately 1 °C, adverse effects can occur for example, risk of accident increases (Ramsey et al. 1983), and at core temperatures >40 °C heat stroke can occur (Cheshire 2016). As radiofrequency EMF heats tissue, it is important to account for such

effects. Thresholds for adverse health effects due to core temperature rise have not been established for either radiofrequency EMF or non-EMF exposure sources. Conversely, because a 1 °C core temperature rise is typically used as a conservative threshold to avoid harm (ACGIH 2017), ICNIRP (2020) treated this as an adverse health effect, and additionally considered the radiofrequency EMF literature for evidence of harm associated with core temperature rise.

ICNIRP has set a conservative operational adverse health effect threshold for whole-body averaged SAR at 4–6 W kg^{-1}, corresponding to a core temperature rise of 1 °C. The upper frequency of the basic restriction for whole-body averaged SAR has been extended to 300 GHz, whereas it was 10 GHz in the previous ICNIRP guidelines (1998). The averaging time was also changed to 30 min based on knowledge gained through improvements in thermal dosimetry.

This revision has been made conservatively because only one research group (Adair et al. 2001, 2003, 2005) has conducted measurements above the occupational basic restriction for whole-body average SAR of 0.4 W kg^{-1} (with the research restricted to 100–220 MHz exposures). The above operational threshold in this frequency range is supported by computational studies (Bernardi et al. 2003; Foster and Adair 2004; Hirata et al. 2008), whilst relying on conservative exposure scenarios. ICNIRP also noticed that although there is very little associated research above 220 MHz, there is some evidence that far-infrared radiation may also importantly contribute to core temperature rise (Brockow et al. 2007), and so although conservatively extending the whole-body average limit to 300 GHz in ICNIRP (2020a), we here recommend further research to better characterize the radiofrequency EMF-whole body heating relation from 100 kHz to 300 GHz, including consideration of exposure duration and multi-frequency exposures. This would ideally utilize measurements, but as the number of exposure scenarios that can be experimentally tested is limited, computational studies are needed to extrapolate across the range of scenarios/frequencies. The computational models for thermoregulation are mainly derived for healthy adults (Stolwijk 1971; Fiala et al. 2001; Moore et al. 2015), and thus additional investigations with models of children and elderly are also needed, which may be useful to set or confirm reduction factors.

Ocular injury and function

The WHO Environmental Health Criteria from 1993 (WHO 1993) includes the assessment of some epidemiological studies: two reported on eye irritation among plastic sealers. Ten other occupational studies assessed effects on the lens, including cataracts. While most studies reported no effects, two studies observed an increased incidence of cataracts among those exposed. All cataract cases had been exposed to levels above 1 kW m^{-2}. A few newer epidemiological studies on vision and inflammation have been published with varying results and severe methodological limitations. Two human experimental studies (Irlenbusch et al. 2007; Schmid et al. 2005) on contrast sensitivity and discrimination thresholds reported no effects during exposures with SARs well below the ICNIRP (2020a) basic restriction values for the general public, and in animal studies effects on the lens, iris, cornea, retina, and the whole eye were investigated, with insufficient information provided about thresholds for adverse effects. Human data would be most useful, but experiments at high exposure levels are likely not feasible given ethical considerations. So, animal models analogous to humans with respect to morphology are here recommended. Computational dosimetric studies of temperature rise in the human eye are also recommended.

Pain from contact current

In the 2020 guidelines, the terminology of 'reference level' has been changed to 'guidance' for protection from contact current. The perception and pain thresholds for contact current are based on the only study in the kHz range (or higher), which is unlike the more-extensive literature on such effects at extremely low frequencies. Chatterjee et al. (1986) performed measurements of the threshold contact current for pain and perception in a large number of volunteers. From 100 kHz to 3 MHz the corresponding thresholds were, in general, constant at 35 mA and 42 mA, respectively. Particularly when one considers that there are many factors that determine the degree to which a radiofrequency field can generate a contact current and adversely affect a person (e.g., grounding conditions and contact area and location on the body), more research would be of great benefit. A particular issue concerns the transition frequency range over which the dominant interaction mechanism changes from nerve stimulation to heating. This would be important to further clarify as the upper frequency for nerve stimulation was conservatively set at 110 MHz in the 2020 guidelines due to lack of data.

Further clarifications are needed regarding the effect of grounding condition, contact area, and location on the body in terms of pain thresholds; computational and experimental dosimetry studies to clarify the influence of amplitude of contact current, contact area, exposure time, internal electric field, SAR, and temperature rise, as a function of field strength, are therefore recommended.

Comments on topical issues for which data gaps are not identified

Oxidative stress

Oxidative stress is known to be involved in many different processes resulting in the cell death and mediated by reactive oxygen species (ROS). Free radicals react with membrane lipids, enzymes, and other essential cell components with potential consequences for human health.

A number of experimental studies have investigated whether radiofrequency EMF can influence the radical

homeostasis of the cell, making different radical species, and thus act as an initiator of events that can lead to changes in the oxidative cell's status that in turn may be involved in development of disease processes (reviewed, e.g., by Consales et al. 2012). Most of the studies devoted to assessing the capability of radiofrequency exposure to modify the oxidation state of the cells have been carried out by measuring reactive oxygen species (ROS) formation, although in some cases other targets related to oxidative stress have been evaluated, such as antioxidant enzyme activity, glutathione (GSH) depletion, and mitochondrial RNA. In some cases, to address the influence of radiofrequency exposure, these measurements were performed with other cellular and molecular endpoints in both in vitro and in vivo models. Some cellular studies reported an increase of ROS levels (e.g., Liu et al. 2013, 2014; Sefidbakht et al. 2014; Marjanovic Cermak et al. 2018), while the majority obtained negative results (e.g., Luukkonen et al. 2009, 2010; Poulletier de Gannes et al. 2011). Furthermore, the data so far from the relatively few animal studies still showed ambiguous results when comparing results from different tissues, organs, and laboratories. For example, an increase of oxidative stress has been reported in the brain (Alkis et al. 2019), liver (Ismaiil et al. 2019), and in the testes (Jonwal et al. 2018), while a reduction of oxidative stress parameters has been reported by Okatan et al. (2018a) and Postaci et al. (2018) in the liver and by Okatan et al. (2018b) in the kidney. Additional research has not been able to reconcile these discrepancies. Accordingly, no data gaps have been specified.

Symptoms, well-being, and IEI-EMF

A large number of experimental studies have tested whether volunteers experience more non-specific symptoms when exposed to radiofrequency EMF. These experimental studies have been performed in healthy participants and in individuals who report experiencing symptoms that they attribute to exposure to radiofrequency EMF (idiopathic environmental intolerance attributed to EMF; IEI-EMF). Within the framework of the WHO radiofrequency EMF review project 40 human experimental studies with a total of 2,857 participants were reviewed (Bosch-Capblanch et al. 2024). No indications were found that acute radiofrequency EMF exposure below current guideline values triggers non-specific symptoms such as headaches or sleep disturbances in the general population or in IEI-EMF individuals. In addition, study participants could not perceive the radiofrequency EMF exposure status during experiments better than chance. Experimental studies applying open and double-blind exposure conditions have provided evidence of nocebo effects, since individuals reacted to open but not to blinded radiofrequency exposure conditions (Schmiedchen et al. 2019).

Regarding longer-term exposure, several epidemiological studies have investigated whether radiofrequency EMF exposure is associated with reports of non-specific symptoms in the general population. These studies have addressed both localized exposure to the brain from mobile device use, as well as whole-body exposure from far-field exposure from fixed site transmitters and other sources further away from the body. Prospective studies, like cohort studies, are most suited to address this question, although potential confounding and accurate exposure assessment remain challenging in this type of study design. For example, several studies reported associations of mobile phone use with symptoms such as headache, but further investigation indicated symptoms were related to phone use behaviors rather than to radiofrequency EMF exposure (Auvinen et al. 2019; Baliatsas et al. 2015; Schoeni et al. 2016; Traini et al. 2024). In line with this observation, a recent systematic review within the framework of the WHO radiofrequency EMF review project concluded, based on 13 longitudinal studies, that radiofrequency EMF exposure below guideline values does not underlie reports of non-specific symptoms such as headache or sleep disturbances or tinnitus or migraine (Roosli et al. 2024). Given the fast changes of wireless technology and associated changes of wireless device use and exposure patterns, follow-up research needs to develop new and innovative research methods in order to remain informative. However, it is currently unclear how further research would directly benefit future guidelines development. Accordingly, we have not specified this as a data gap.

Blood brain barrier (BBB) integrity and brain physiology and function

After the evidence reported in the group of papers by Salford and co-workers of radiofrequency-induced BBB permeability in the late 1990's, a number of scientists have failed to replicate the Salford reports, while other studies exploring the issue have not found effects. Poulletier de Gannes et al. (2017) presented the last important publication, exposing Wistar-Han rats to GSM 1800 or UMTS 1960 MHz signals at brain-averaged SARs of 0.026, 0.26, 2.6, or 13 W kg^{-1}, without showing any significant effect on degeneration or BBB permeability in the rat brain. The available evidence regarding effects of radiofrequency exposure on BBB and brain does not suggest that further research is likely to benefit the guidelines development process, and so no data gap has been specified.

Neurodegenerative disorders

Despite the increasing interest in this field of research, the epidemiological studies have rarely addressed this topic and experimental findings are still controversial.

The possibility that exposure to radiofrequency EMF could affect neuropathological conditions such as Alzheimer's disease (AD), Parkinson's disease (PD), and amyotrophic lateral sclerosis (ALS) has been analyzed in the past as well as quite recently using in vitro and in vivo methods. Since

2000 this research has increased, and many experimental studies were performed with animal models (adult and young). Of particular importance to this research is that most of these studies are not necessarily good analogues of the pathology and the biological assays described are heterogeneous. In general, after or during the exposure, animals were studied using a range of tests, including memory function (2), MRI (1), and blood flow (1), and then sacrificed and tissues and cell preparations analyzed. Some papers described histological and immunochemistry evaluation, looking at hormonal level plaque formation and protein aggregation, while others focused on gene expression and oxidative stress measurements.

Some consistent studies were published by Arendash and colleagues using mice transgenic for APPsw (amyloid precursor protein) and PS1 (presenilin), both resulting in increased amyloid beta (Aβ) deposition in brain tissue (a hallmark of AD development), and enhancement of neuronal activity; the findings after long-term radiofrequency exposure indicated a strong ability to reverse brain Aβ deposition, to induce changes in the regional cerebral blood flow, and to provide selective cognitive benefits, all without induction of brain hyperthermia and without an increase in brain oxidative stress (Arendash et al. 2010, 2012). However, dosimetry was not sufficient to provide confidence in these results.

Another very extensive group of studies analyzed the effect of chronic 1950 MHz exposure on an AD mouse model: they found significantly reduced Aβ accumulation in the hippocampus and cortex after 8 months radiofrequency EMF exposure, as well as reduced reactive parenchymal Aβ accumulation and active astrocytes in the brain (Jeong et al. 2015; Son et al. 2016, 2018). Similar results were reported for mice of different ages (Jeong et al. 2018, 2020) where the effect of radiofrequency EMF exposure was confirmed on relevant molecular tests, as well as their behavior and locomotor activity. Further data by Barthélémy et al. (2016) and Bouji et al. (2020) indicated that radiofrequency EMF-induced astrogliosis had functional consequences on memory but did not demonstrate that it has a secondary effect to neuronal damage in a rat model of AD: they showed higher hippocampal oxidative stress and reduced corticosterone with the higher SAR, suggesting more fragility related to neurodegenerative disease after exposures. There are not indications for further analysis.

Epidemiological research on radiofrequency EMF exposure and neurodegenerative disease is rare, possibly explained by the challenge of conducting retrospective exposure assessment for case-control studies, the absence of registry-based incidence data for these outcomes in many countries, and possible long latency times or general challenges of exposure assessment for longitudinal studies addressing this type of exposure over a longer period of time.

Two studies reported reduced risk for dementia or Alzheimer's disease with increased mobile phone use (Schüz et al. 2009; Zhao et al. 2023), but it is difficult to rule our reverse causation rather than it representing a causal protective effect: people with early signs of cognitive decline may not have started to use mobile phones or may have used them less frequently. Other neurodegenerative diseases such as ALS, Parkinson's, multiple sclerosis, and epilepsy were not found to be associated with mobile phone use in a large epidemiological study (Schüz et al. 2009). For these diseases the available data, which may suggest benefits rather than harm, do not provide sufficient evidence of harm to specify further research as a data gap for guideline development purposes.

Brain physiology and function

A substantial body of experimental human research has tested whether radiofrequency exposure affects sensory, cognitive and sleep processes, including measures of performance, brain electrical activity, and cerebral blood flow and metabolism. Some of this research has assessed endpoints that have clear relevance to health (e.g., memory performance), whereas other research has assessed underlying processes that could *potentially* affect health (e.g., cerebral blood flow and EEG related to memory processing). No substantiated adverse health effects have been found, and there have been no serious challenges to the integrity of the research itself (Pophof et al. 2024). In terms of the underlying physiology, increased EEG power in the alpha (while awake) and sleep spindle (while asleep) frequency bands have been substantiated. However, these effects are within normal physiological variation, and they have not been found to result in changes to health; for example, they are not sufficient to affect sensory or cognitive processes while awake, nor sufficient to affect sleep variables, such as sleep quality or duration, while asleep. Accordingly, no data gaps have been identified.

Some studies explored the capacity of radiofrequency EMF exposure to affect memory in normal animals with mixed results, for example an improvement in recognition memory in mice at high SARs was reported in one study (Wang et al. 2017), and poor memory performance in another (Sharma and Shukla 2020). Papers from a Korean group (Kim et al. 2016, 2017a and b, 2018, 2019) investigated the effect of chronic 835-MHz exposure on C57BL/6 mice and report that adaptation to stress and a further protective mechanism (autophagic accumulation in neurons in response to the stress) are induced by radiofrequency EMF exposure, which might be important in maintaining normal brain functions and maintaining normal behavior. However, overall, this research is not consistent within the literature more generally, and although some consistency has been observed within the above Korean group, there is no indication that their findings would be sufficient to adversely affect health. Accordingly, no data gaps have been specified.

Vestibular function

We have not identified informative epidemiological studies on effects of radiofrequency EMF exposure on vestibular functioning, and only one such human experimental study (Bamiou et al. 2008, 2015), which did not report any statistically significant effect of exposure. A literature search covering 1990–2022 did not find any animal studies dealing directly with effects of radiofrequency EMF exposure on vestibular function. Accordingly, as there is no indication of adverse health effects associated with the vestibular system, no data gaps have been specified.

Auditory function

Most of the studies on auditory effects are related to mobile communication devices. A literature search covering 1990–2022 found only 12 papers on animal studies that are related to the auditory system. Localized exposure of one of the animals' ears, found no influence on the inner ear function of radiofrequency EMF exposure alone or in combination with gentamicin (GM), an ototoxic agent (Aran et al. 2004; Galloni et al. 2005, 2009; Parazzini et al. 2007). Two studies on glycine receptor (GlyR) immunoreactivity by the neurotropic factors in the auditory brainstem region, and on auditory brain stem response in ICR mice reported a decrease in these factors; since they are considered protective against hearing damage, the authors suggest a detrimental effect of radiofrequency exposure on auditory function (Maskey et al. 2014; Maskey and Kim 2014). Other sporadic studies were performed without information of the effects on inner ear (Hidisoglu et al. 2018; Occelli et al. 2018; Kim et al. 2019; Er et al. 2020).

Several human experimental studies have explored auditory effects of radiofrequency EMF exposure, mostly from mobile phones. Eight studies (Janssen et al. 2005; Parazzini et al. 2007a, 2009, 2010; Paglialonga et al. 2007; Stefanics et al. 2008; Kwon et al. 2010; Bamiou et al. 2008) did not reveal any evidence for auditory effects via the use of either subjective or objective methods. Some of these results (Parazzini et al. 2007a, 2009, 2010) were from large multi-center studies. Therefore, no evidence for harmful acute auditory effects were identified and there is not sufficient evidence to specify further human experimental studies as a data gap.

Male fertility, reproduction, and embryo/fetus development

The epidemiological studies on these endpoints are mostly small, do not consider lifestyle factors, and are based on limited exposure assessments such as self-reported amount of mobile phone use. Two recent larger and population-based cross-sectional studies observed mostly absence of associations between various semen quality and radiofrequency EMF exposure indicators (Zhang et al. 2022; Rahban et al. 2023). The sporadically observed associations may represent chance findings or residual confounding. Any future study on this topic would need considerably improved design to be informative. Only one human experimental study is present in the literature and its results are not informative due to the low-quality (Davoudi et al. 2002).

A systematic review within the framework of the WHO radiofrequency EMF review project on the effects of exposure on pregnancy and birth outcomes in animals was published by Cordelli et al. (2023). It shows that radiofrequency EMF exposure does not affect fecundity and likely has only a small effect on fetal weight decrease. It should be considered that some studies retrieved by the literature search showed a detrimental effect on the incidence of dead or resorbed fetuses or the increase of malformations at high exposure levels, largely exceeding the current human exposure limits. These studies confirm what is known about the harmful effect of heating on fetuses, but they leave largely uncertain the possibility of radiofrequency EMF effects at lower exposure levels, closer to relevant human exposure limits.

Following conflicting results from experimental animal studies, another systematic review within the framework of the WHO radiofrequency EMF review project on the effects on male fertility on experimental mammals and human sperm exposed in vitro indicated a possible detrimental effect of radiofrequency EMF exposure on pregnancy rate, especially at high exposure levels that induced a substantive temperature increase, when the whole-body average SAR values in the included studies are well above the recommended human exposure limit values for the public set by international bodies (ICNIRP 2020a), and sperm count reduction, whereas the meta-analysis of data on litter size failed to identify an effect. Regarding the other endpoints analyzed, which relate to fertility, sperm quality, reproductive organ toxicity and hormonal effects, many of the studies examined suffered from severe methodological limitations that led to uncertainty of the results of the meta-analyses and did not allow firm conclusions to be drawn on most of these other endpoints (Cordelli et al. 2024). No data gaps have been identified as the research field does not provide sufficient evidence of effects of direct relevance to the guidelines.

Cancer

Tumors occurring in the head are among the most investigated outcome in this field of research. Numerous studies mostly found absence of associations between mobile phone use and tumors occurring in the head, such as glioma, meningioma, acoustic neuroma, pituitary and salivary gland tumors (US FDA 2020; Repacholi et al. 2012; Roosli et al. 2019). In a prospective cohort study of more than 700,000 women from the UK, followed for 14 y, brain cancer risk was not increased (relative risk: 0.97, 95% CI:0.90-1.04; Schüz et al. 2022). For children and young adults, the MOBIKIDS case-control study did not find any indication of an increased brain cancer risk (Castaño-Vinyals et al. 2022). A few case-control studies observed increased risk in

the highest exposure group (Interphone 2010, 2011; Coureau et al. 2014; Hardell et al. 2015). But given the retrospective exposure assessment, recall bias is a more likely explanation than causality since time trends of cancer incidence in many countries are not consistent with a noticeable risk from mobile phone use (Karipidis et al. 2018; Sato et al. 2019; Villeneuve et al. 2021; Deltour et al. 2022). This type of trend analysis is suitable for tumors with stable diagnostic practice and few external risk factors that can superimpose a time trend of interest following the uptake of mobile phone use in the population. Most reliable are prospective cohort studies that include objectively recorded operator data. A first analysis of the multicountry COSMOS study with participants recruited from Denmark, Finland, the Netherlands, Sweden, and the UK between 2007 and 2012 accrued 1,836,479 person-y and did not find any increased risk for glioma (relative risk: 1.00, 95 % CI 0.98–1.02 per 100 regression-calibrated cumulative hours of mobile phone call-time), meningioma (1.01, 95 % CI 0.96–1.06), and acoustic neuroma (1.02, 95 % CI 0.99–1.06) (Feychting et al. 2024). Additional research on this topic is unlikely to change the current picture. Except for prospective cohort studies with excellent exposure assessment, any epidemiological study will not be more informative than evaluating time trends of tumors. The IARC evaluation, published in 2011, concluded that there was weak evidence that radiofrequency EMF was genotoxic but that there was no evidence for mutagenicity (IARC 2013).

In the last 14 y, several endpoints have been investigated using cellular models and in most cases no effects of radiofrequency exposure were detected, although in a few cases slight variations were reported. In addition, some review papers have been published on genotoxicity (Vijayalaxmi and Prihoda 2019a). Some published studies have explored the extent of genetic damage in animal and human cells exposed in vitro to radiofrequency EMF. Overall, the data are inconsistent, and a mechanism for effects has not been identified: while some studies have suggested significantly increased genetic damage in cells exposed to radiofrequency EMF compared to unexposed and/or sham-exposed control cells, others have not. Several differences in exposure conditions and the variety of endpoints used in the experiments might have contributed to this. One very large study (Smith-Roe et al. 2020) that investigated the carcinogenic effects of the radiofrequency exposure (900 MHz, GSM or CDMA modulation) was performed in the United States in the framework of the National Toxicology Program (NTP) long-term carcinogenesis study. The whole-body exposure levels adopted were ≥ 1.5 W kg^{-1}. The results of the comet assay showed significant increases in DNA damage in the frontal cortex of male mice (both modulations), leukocytes of female mice (CDMA only), and hippocampus of male rats (CDMA only). Increases in DNA damage judged to be equivocal were observed in several other tissues of rats and mice. No significant increases in micronucleated red blood cells were observed in rats or mice. Therefore, the results from this large study add to the heterogeneity of the literature, rather than allowing a conclusion to be drawn.

Furthermore, experimental animal data for exposure to radiofrequency EMF have been published since the IARC Monographs evaluation, using both normal animal strains and those with a genetic predisposition to one or more types of cancer. Other studies have tested possible co-carcinogenicity with known chemical or physical carcinogens. These studies cover a wide range of experimental situations in terms of study design, exposure modality and biological endpoints. This variability doesn't help to make a univocal classification of the studies and, consequently, to compare the results. A systematic review, without year limitation, has been published very recently (Pinto et al. 2023) where data extracted from 27 eligible articles regarding the onset of neoplasms in laboratory rodents exposed to radiofrequency EMF have been analyzed; a quantitative analysis (meta-analysis) was conducted on 23 papers. A total of 25 organs/tumors were analyzed for malignant tumors and 16 for benign tumors to assess the confidence in the body of evidence of the carcinogenic effects. The large study of the NTP on carcinogenesis effects of radiofrequency exposure on rats and mice respectively, was included (even though not published but released only as a technical report in 2018).

These reports, although controversial, are considered among the most complete studies currently available on the impact of radiofrequency exposure on carcinogenesis (NTP 2018a and b). Almost all results obtained by Pinto et al. were non-significant, and they did not show an association between exposure to radiofrequency EMF and an increased risk of cancer in general except for: CNS/brain, male genital system and kidney for benign tumors, CNS/brain, heart and intestine for malignant tumors. The increased incidence of malignant heart tumors risk was an expected result, and it is due to the data on heart Schwannoma reported in NTP studies, without peer review publication, and in Falcioni et al. (2018) where only heart tumor was evaluated. Overall, these evaluations have determined a confidence rating from very low (heart sample for malignant tumors and CNS sample for benign ones) to moderate, resulting in inadequate or insufficient evidence for an association between radiofrequency EMF exposure and carcinogenesis in vivo. The heterogeneity of the literature, in terms of both methods and results, does not provide sufficient justification for recommending further research into genotoxicity or carcinogenic potential. Conversely, given the many strengths of the above NTP studies, particularly in terms of sample size and dosimetry, we consider the replication of that study to be important. We note though that there is currently an international consortium (Japan–South Korea) conducting such a replication, and so do not specify this as a data gap here.

A second systematic review, where the potential role of in vivo RF–EMF exposure combined with the well-known

carcinogens in tumor promotion/progression was published very recently (Pinto et al. 2024). A total of 25 papers were included in the review: a meta-analysis was conducted on 18 studies, while a narrative review was performed for the remaining seven eligible papers. In most cases, the results of the meta-analysis did not show a statistically significant difference in tumor onset between the sham and co-exposed samples. There was a numerically small increase in the risk of malignant tumors observed in the kidney and liver, as well as benign lung tumors. The confidence of evidence for health effects indicated "inadequate" evidence for an association between in vivo co-exposure to RF–EMF and known carcinogens and the onset of malignant or benign tumors in most of the analyzed tissues. Therefore, considering the limited number of eligible papers/studies for most of the analyzed tissues, these results cannot be considered conclusive (Pinto et al. 2024).

In conclusion, considering the number of well-performed studies that have been mostly negative in outcome, the insufficient evidence for an adverse health effect obtained with experimental as well as epidemiological approaches until now, and given that there is a high-quality NTP partial replication in progress, we do not specify further research in this area as a data gap.

Uncertainty in dosimetry

In the 2020 guidelines, there are several changes in the basic restrictions and reference levels compared to the 1998 guidelines, in addition to the increased upper frequency that a whole-body average restriction needs to be applied to account for core temperature rise:

1. The absorbed power density averaged over 4 cm^2 has been introduced as a basic restriction above 6 GHz for local exposures. Consequently, incident power density, which was a basic restriction in the ICNIRP guidelines (1998), was set as reference level. The reference level of the incident power density was revised, primarily because of the revision of the averaging area;
2. A reference level for local exposure has been introduced (in addition to that for whole-body exposures, which was already set in the 1998 ICNIRP guidelines);
3. The frequency range of the limb current restriction has been extended to be from 100 kHz to 110 MHz (which was 10 MHz to 110 MHz in the 1998 ICNIRP guidelines);
4. A limit for brief exposure was introduced.

When setting (1), the ICNIRP noticed that there are several recent reports on dosimetry above 6 GHz but only by a few groups (e.g., Foster et al. 2016; Hashimoto et al. 2017; He et al. 2017; Sasaki et al. 2017). As a result, human models and exposure scenarios reported were still limited and without experimental validation. Thus, the reference levels and basic restrictions were set in a conservative manner using computational modeling. A further weakness for computational dosimetry above 6 GHz is that the penetration depth of electromagnetic fields becomes more superficial and thus dosimetry with detailed modeling around the surface layers, where dielectric and thermal properties of tissue changes significantly (Sasaki et al. 2015), is an important part of validation (Haider et al. 2022). However, conventional anatomical models do not have sufficient resolution for such purposes; even the medical images used for the development of such models do not have the requisite resolution. Further modeling studies and associated experiments are needed to improve the quality and reliability of computational dosimetry, which may improve the relationship between external and internal physical quantities (and thus the derivation of reference levels).

Related to (2), the reference level for local exposure was introduced in the 2020 guidelines. Above 6 GHz, averaging area of the incident power density is defined as 4 cm^2, which approximately corresponds to the heat diffusion length, and is supported by analytical and computational studies (Foster et al. 2017; Hashimoto et al. 2017). However, the limit and averaging area (or volume below 6 GHz) has been specified as peak in ICNIRP 2020a, and the limit set in a conservative manner because only a few studies related to this topic are available. For example, Findlay and Dimbylow (2009) evaluated spatial averaged field strength and local SAR for specific exposure scenarios. Additional investigations are thus needed to set improved reference levels for local exposures. Above 30 GHz, an additional restriction for an averaging area of 1 cm^2, with a relaxation of the power density restriction by a factor of 2, was introduced. Note that the diameter of the aperture of the probe in the measurement of laser guidelines is 11 mm (ICNIRP 2013). This averaging area would also be worth revisiting especially at higher frequencies where smaller beams might be formed.

As for (3), the reference level for limb current has been set for compliance assessment purposes of protecting a grounded human. The human body model around the limb has only a few tissues and its reliability has not yet been discussed extensively. Also, local SAR for limb current may be influenced by the grounded condition of the foot (Taguchi et al. 2018), where its modeling accuracy is weak. Accordingly, additional studies are needed to better clarify the relation between local SAR and limb current, particularly as a function of grounding condition.

As for (4), the reference level for brief exposure (in particular, shorter than a few seconds) has been introduced to consider instantaneous temperature rise. However, as mentioned in the Pain section, only a few measurements have

been reported on this topic (Walters et al. 2000). Recent studies computed similar instantaneous temperature rise (Foster et al. 2020; Kodera et al. 2018). In addition to the pain threshold assessment, additional dosimetry studies are needed, including multiple and (realistic) non-stationary exposures to the reference level, especially intense brief exposures, including exposures above 300 GHz.

Related to all the dosimetry items listed above, present models and techniques mostly focus on healthy adults, although some dosimetry on children and pregnant women has been reported. Further exploration of the effects of age, sex, and other morphological differences on these models and their outcomes would be of great benefit for the derivation of reduction factors in future guidelines.

CONCLUSION

Literature available both in biology and dosimetry has been analyzed to set the guidelines for limiting exposure to radiofrequency EMF (100 kHz to 300 GHz) (ICNIRP 2020a). In terms of biology, although sufficient information was available as the basis for that guideline development, we have identified some gaps in knowledge that, if addressed with the above specified research, would greatly assist ICNIRP and others in the future development of radiofrequency EMF exposure guidelines: (1) Issues concerning relations between radiofrequency EMF exposure and heat-induced pain; (2) Clarification of the relation between whole-body exposure and core temperature rise from 100 kHz to 300 GHz, as a function of exposure duration and combined EMF exposures; (3) Adverse effect thresholds and thermal dosimetry for a range of ocular structures; and (4) Pain thresholds for contact currents under a range of exposure scenarios, including associated dosimetry. For biological outcomes where effects have not been substantiated, we did not find sufficient plausible evidence that radiofrequency EMF might cause harm below currently established thresholds. This does not imply that there are no open scientific questions. For instance, studies on oxidative balance and brain physiology repeatedly observed effects (although not consistently). Without knowledge of the underlying mechanism, this is unlikely to influence guidelines development. Similar considerations can be made for other outcomes discussed in this paper. For these reasons, further research is not specified as a data gap for the purposes of future guidelines development. Additionally, a range of dosimetry studies have been recommended to both support future research and to improve the application of radiofrequency EMF restrictions in future guidelines.

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