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Prioritizing health outcomes when assessing the effects of exposure to radiofrequency electromagnetic fields: A survey among experts

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ABSTRACT

Exposure to radiofrequency (RF) electromagnetic fields (EMF) (frequencies of 100 kHz to 300 GHz) has been steadily increasing. In addition to heat-related effects of RF EMF, other yet-unspecified biological effects, might exist which could possibly lead to health effects. Given the large number of health endpoints that have been studied, we wanted to prioritize those that would merit systematic reviews.

We developed a survey listing of all health endpoints reported in the literature and we asked 300 RF EMF experts and researchers to prioritize these health effects for systematic review as critical, important or unimportant. We also asked the experts to provide the rationale for their prioritization.

Of the 300 RF EMF experts queried, 164 (54%) responded. They rated cancer, heat-related effects, adverse birth outcomes, electromagnetic hypersensitivity, cognitive impairment, adverse pregnancy outcomes and oxidative stress as outcomes most critical regarding RF EMF exposure. For these outcomes, systematic reviews are needed. For heat-related outcomes, the experts based their ranking of the critical outcomes on what is known from human or animal studies, and for cancer and other outcomes, they based their rating also on public concern.

To assess health risks of an exposure in a robust manner, it is important to prioritize the health outcomes that should be systematically reviewed. Here we have shown that it feasible to do so in an inclusive and transparent way.

1. Introduction

Exposure to radiofrequency (RF) electromagnetic fields (EMF) (frequencies of 100 kHz to 300 GHz) has been steadily increasing due to developments of radio and television in the 1950s, and more recently wireless telecommunications, including mobile telephony, as well as a number of industrial and medical applications. The characteristics of the exposure have been changing over time and are expected to change further in the near future with the deployment of 5G mobile network technology and increasing wireless connectivity of devices via the internet (Internet of things). These developments mean that a growing portion of the global human population is now exposed to RF EMF. Since mobile phone technologies became widespread in the general population in the late 1990 s and early 2000 s, and with new technological developments and applications, some citizens, governments and experts have raised concern of potential public health consequences (Health Council of the Netherlands 2020; IARC 2013; Independent Expert Group on Mobile Phones, 2000).

Established health effects from exposure to RF EMF are up until now limited to those that may result from increased tissue temperature and, for frequencies in the lower RF range, from excitation of sensory cells or other nerve cells. Current exposure limits are set so that exposure will not lead to such effects, by for example ensuring that any rise in the core body temperature by RF EMF will not exceed one degree Celsius

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(D'Andrea et al. 2007). At present, evidence for biophysical mechanisms that may result in health hazards other than the thermal effect (Foster et al. 2018) and the excitation of nerve cells (Reilly 2002; Saunders and Jefferys 2007) is lacking. However, it cannot be excluded that other biophysical mechanisms may exist and some have been suggested e.g. (Sheppard et al., 2008), and such mechanisms could possibly lead to health effects. Given that virtually everyone is exposed to RF EMF, it is important to review the evidence for health outcomes that can possibly result from RF EMF exposure.

The World Health Organization (WHO) has a long-standing history in reviewing the findings of research on the health effects of exposure to electromagnetic fields (World Health Organization 1993; 2006; 2007). In parallel with this work, WHO adopted internationally recognized methods and standards for guideline development to ensure that its guidelines are of the highest quality. The WHO Handbook for Guideline Development (World Health Organization 2014) states that all WHO health recommendations should be based on systematic review of the literature. Such reviews of intervention questions start with framing a clearly stated research question, often formulated as a PICO (Population, Intervention, Comparator and Outcome) question. The PICO question can include up to seven important outcomes (Guyatt et al. 2013). It is proposed that only the health outcomes that are most critical for decision making should be evaluated (Guyatt et al. 2011).

In the case of environmental health, a systematic review starts with a clearly formulated PECO question that defines the Population, Exposure, Comparator and Outcomes of interest (Morgan et al. 2018). In this context, the health outcomes of interest are the potential adverse health effects stemming from exposure to biological, chemical or physical agents. Often, exposure to a specific agent leads to numerous adverse health effects. For example, it has been shown that exposure to lead can cause damage to the brain, the nervous system, anaemia, hypertension, renal impairment, immunotoxicity and toxicity to the reproductive organs. Thus, for the evaluation of potential adverse health effects of environmental exposures, several different health outcomes may be important. However, not all adverse health effects are equally important. For example, reversible irritation of the skin is of a different magnitude and impact than cancer or permanent brain damage. When developing guidelines or standards for environmental exposures, there is a need to prioritize adverse health outcomes as it is impractical and unnecessary to evaluate all possible health outcomes in detail. However, as opposed to clinical medicine, there are no good examples of how to undertake such a prioritization of environmental health outcomes. Even though there are many studies on prioritizing interventions (Woods et al. 2016) or stakeholder involvement in environmental health (Haddaway et al. 2017), these studies do not describe how to rank the outcomes using a formal process.

As part of the WHO review of the effects of RF EMF exposure, it was decided to conduct formal systematic reviews of the health outcomes that are most important for RF EMF exposure (World Health Organization 2014). Many potential health and biological effects of RF EMF exposure have been mentioned in the literature, from brain cancer to changes in oxidative stress biomarkers (IARC 2013; Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), 2015). Since it is not feasible to review all the possible biological and health effects systematically, a prioritization exercise was undertaken. To that end, a survey was developed and shared with a large and varied group of RF experts. They were asked to prioritize potential health outcomes or biological effects from exposure to RF EMF and to provide a rationale for their choices. Here we report the findings of that survey.

2. Methods

Working from the findings of the WHO RF EMF review, a list of possible health effects that have been studied was constructed (World Health Organization 2018), including 34 outcomes under the following eight broad categories:

- Health effects due to temperature increase
- Cancer
- Fertility and birth outcomes
- Symptoms affecting health
- Neurological impairments and disorders
- Neuroendocrine effects
- Immunological effects
- Haematological effects

Additionally, an open-ended answer was provided where the respondent could list other outcomes not in the list.

Based on the methodology proposed in the WHO Handbook for Guideline Development (World Health Organization 2014) and proposed by the GRADE working group (Guyatt et al. 2011), the respondents were asked to rate the importance of each health outcome numerically using a scale from 1 to 9, where 1–3 meant unimportant, 4–6 meant important but not critical for decision-making and 7–9 meant critical for decision-making. For ratings above 3, the respondents were asked to provide a rationale for their rating based on one or more of the following 5 categories: (1) evidence from human studies, (2) evidence from animal studies, (3) evidence from *in to vitro* studies, (4) possible public health impact, (5) public concern. In addition, there was the possibility to provide other rationale/comments in an open text box.

A list of 300 RF EMF experts was built with input from national representatives of the WHO International EMF Project, from professional networks and from the literature.

An invitation was sent to the experts with a link to the online questionnaire on 29 May 2018. Responses were received up to 24 June 2018. Basic contact information was requested, such as name, e-mail addresses, job title and country.

Using the number of participants that answered the question about a specific health outcome as the denominator, we calculated the percentage of responders who rated the outcome as unimportant (1–3), important (4–6) or critical (7–9). We used a cut-off at around 30% of the participants answering that an outcome was critical for decision making to include this outcome in a systematic review.

We categorized the answers to the open questions into different outcome categories using an iterative qualitative analysis approach, as usual in the analysis of qualitative data (Pope and Mays 1995). We went back and forth between outcome categories and answers until all answers were grouped under the most appropriate category.

3. Results

3.1. Response

The 300 invitations generated 164 responses resulting in a response rate of 54% among those that were invited. Not everyone provided a rating for each outcome and the number of respondents per question varied from 139 to 164. Responding experts came from 28 countries with most from the USA (n = 21), Germany (n = 17), UK (n = 14), Japan (n = 12), Italy and France (n = 10), and Australia, Finland and Switzerland (n = 9). Most respondents had scientific positions at universities or research institutions.

3.2. Priority health effects

The priority rating is provided in Fig. 1.

As a health outcome category, cancer was the one most frequently rated as critical. Tumours in the head and neck region were rated as critical outcomes by 64% of the respondents, and important by 22%. The respondents supported their choice with evidence from human studies (70%), from animal studies (22%), and because of public concern (70%), and to a lesser extent from concern over a potentially large burden of disease (34%) or evidence from *in to vitro* studies (14%), as shown in Fig. 2. Tumours elsewhere in the body and haematological cancer also

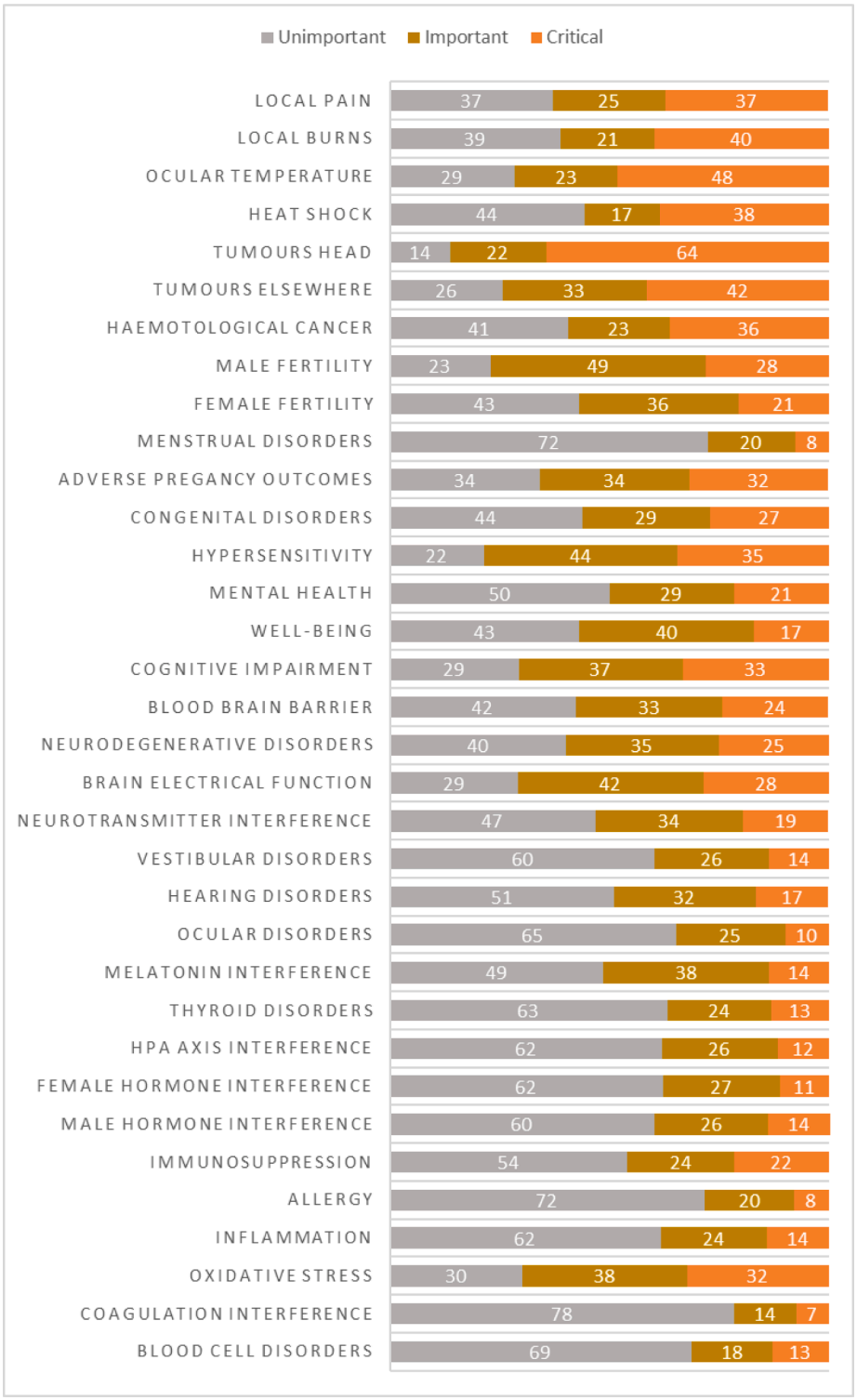

Fig. 1. Rating of potential adverse health effects of radiofrequency radiation as unimportant (rating of 1–3; numbers in bars indicate percentage of number of respondents rating that category,) important (rating of 4–6) or critical rating (7–9),. Total number of respondents varied from 139 to 164.

yielded high ratings with 42% and 36% of respondents, respectively, rating these as critical.

Heat-related effects were rated as critical by a large proportion of respondents: thermal ocular effects (48%), local pain (37%), local burns (40%), and heat shock (38%). However, almost the same proportion of respondents rated them as unimportant. Support for inclusion of these health effects were mostly underpinned by evidence from human or animal studies, and not because of burden of disease or public concerns.

In the category of fertility and birth outcomes, adverse pregnancy outcomes were rated highest with 32% as critical and 34% as important. This was based on public concern (55%), animal studies (51%), human studies (31%) and burden of disease (26%). Effects on male fertility (28% as critical and 48% as important) were more often rated as critical than effects on female fertility. Interference with male or female reproductive hormones were considered less important outcomes.

Among symptoms affecting health, electromagnetic hypersensitivity

Fig. 2. Arguments that experts used to rate the importance of the ten highest rated outcomes.

was rated as a critical outcome by 35% and by another 40% as an important outcome. This was based on public concern (67%), evidence from animal studies (43%) or human studies (39%). Mental health outcomes such as depression or well-being were not considered as critical outcomes by many respondents.

In the group of neurological impairment and neurological disorders, only cognitive impairment had high ratings, with a 33% rating as critical and 37% as important. Of those who rated this as important or critical, 65% based their rating on human evidence, 46% on animal evidence and 54% on public concern.

Few respondents considered neuroendocrine effects as critical outcomes.

In the group of immunological effects, oxidative stress was rated as critical by 32%, underpinned by evidence from animal (61%) and *in-vitro* studies (67%). Other outcomes in this group were well below the 30% cut-off.

None of the effects in the group of haematological outcomes were rated as critical by at least 30% of the participants.

Forty-two respondents provided suggestions for adverse health effects due to RF EMF exposure of humans in the open-ended response where additional suggestions could be given. While 14 of these suggested outcomes that were already listed in the questionnaire, 28 suggested at least one non-listed outcome, with the most frequently mentioned being effects on the cardiovascular system (n = 7), effects on sleep (n = 6), effects on genes and cell functioning (n = 5) and effects on the skin (n = 3).

4. Discussion

RF EMF experts rated cancer, heat-related effects, adverse birth outcomes, electromagnetic hypersensitivity, cognitive impairment, adverse pregnancy outcomes and oxidative stress as outcomes most critical regarding RF EMF exposure. For these outcomes, systematic reviews will be performed. For heat-related outcomes, the experts based their rating of the critical outcomes on their knowledge of human or animal studies, and for cancer and other outcomes, they based their rating also on public concern.

4.1. Strengths and limitations

A strength of the process is that we were able to engage a large group of experts in rating the importance of a relatively long list of outcomes that have been studied as potential adverse health outcomes of RF EMF exposure in the literature. Even though this was a convenience sample,

the experts came from a range of different countries spread over different continents. Therefore, we believe that these experts are likely to be representative of experts in this field. We had a relatively high response rate of 54%.

Also, we could provide the experts with a comprehensive list of outcomes to be rated and for which they could provide a rationale, and the opportunity to list additional health outcomes. Only a few experts added new outcomes to the list, and none of the additional outcomes reached the cut-off for inclusion. It is important to note that this is a list of potential outcomes that have been mentioned in the literature and inclusion does not imply a causal relation with RF EMF.

As far as we are aware, prioritization of potential adverse health effects of environmental exposures has not been done in a systematic way before. Adverse health outcomes were prioritized for the development of WHO environmental noise guidelines, but this was not based on a systematic approach (Jarosinska et al. 2018).

We did not ask the public about their concerns, but instead asked the experts what they thought was of public concern. There are some studies that indicate that in general exposure to RF EMF from various sources is not perceived as a large health risk in the general population but that a minority does perceive it as a high risk. In general, air pollution is considered a more important environmental health risk (Kristiansen et al. 2009; Schreier et al. 2006; Tseng et al. 2013). For cancer, adverse pregnancy outcomes, cognitive impairment and electromagnetic hypersensitivity, the experts opiniated that these effects were also of public concern. On the other hand, they did not base their rating of the heat-related outcomes on public concern. In our view, this gives a realistic impression of which outcomes are of public concern, regardless of their scientific underpinning.

Outcomes that were rated critical by many respondents were also rated as being important by others. This underpins the 30% cut-off point rating outcomes as critical for the inclusion of an adverse health outcome for systematic review. Given the limited resources available for systematic reviews, it was decided to include male fertility but not brain electrical function. The ratings of these two outcomes as critical were similar, but more experts rated male fertility as important.

The percentages are also influenced by the choice of the denominator. The ranking of outcomes is different if one chooses as the denominator all respondents or all respondents that answered the specific question. If we had chosen all respondents to any of the questions as the denominator for all outcomes, oxidative stress would not have been among the outcomes selected for systematic review. Given that a large proportion of respondents rated oxidative stress as important, the choice of denominator resulted in a more inclusive result.

4.2. Comparison with other studies

For the selection of the most important outcomes to evaluate studies of interventions, systematic procedures have been developed that are widely recognized such as the development of Core Outcome Sets. These outcomes should be used in all trials of that intervention to facilitate the interpretation and evidence synthesis. Similar steps have been set in the field of environmental health with the development of criteria to judge the validity of outcomes used in studies (Radke et al. 2019). Procedures for the development of a core outcome set involve all possible stakeholders and a formal consensus process. A similar more formal process of priority setting is needed in the field of environmental health. We hope that this study can be a first step towards such a process.

4.3. Implications

Given the many health outcomes studied in relation to RF EMF exposure, the survey showed that not all outcomes are considered equally important by RF experts. We decided at the outset of this survey that systematic reviews will be needed for those topics that are rated as critical by a large proportion of the RF experts. As part of the WHO health risk assessment on RF EMF exposure, WHO has recently commissioned those reviews through an open call for expressions of interest. A selection committee convened by WHO ranked the teams based on the criteria related to qualifications and skills mentioned in the calls, including expertise in systematic review methodology, RF EMF expertise and expertise in the outcome of interest. All team members were assessed for conflicts of interest, as per WHO's requirements. The protocols for the systematic reviews will soon be published in Environment International.

To assess health risks of an exposure in a robust manner, it is important to prioritize the health outcomes that should be systematically reviewed. Here we have shown that it feasible to do so in an inclusive and transparent way.

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Declaration of Competing Interest

MF was vice chairman (May 2016 – May 2020) of the International Commission on Non-Ionizing Radiation Protection, an independent body setting guidelines for non-ionizing radiation protection. She has served as advisor to several national and international public advisory and research steering groups concerning the potential health effects of exposure to non-ionizing radiation.

MRS is in the Scientific Council of the Swedish Radiation Safety Authority for preparing reports on the evaluation of the scientific literature related to electromagnetic fields and health.

GO is member of the International Commission on Non-Ionizing Radiation Protection. She has been member of groups appointed by Norwegian authorities to evaluate potential health effects of non-ionizing electromagnetic fields.

EvR was chairman (May 2016 – May 2020) of the International Commission on Non-Ionizing Radiation Protection and is currently vice-chairman. He is also member of the Scientific Council of the Swedish Radiation Safety Authority.

SM is a member of the International Commission on Non-Ionizing Radiation Protection's Scientific Expert Group. Within the UK, he is Secretary to the Committee on Medical Aspects of Radiation in the Environment and he was Secretary (until 2017) to the Advisory Group on Non-Ionising Radiation.

All other authors have declared no conflict of interest.

CRediT authorship contribution statement

Jos Verbeek: Conceptualization, Methodology, Writing - original draft. **Gunnhild Oftedal:** Conceptualization, Writing - review & editing. **Maria Feychting:** Conceptualization, Writing - review & editing. **Eric Rongen:** Conceptualization, Writing - review & editing. **Maria Rosaria Scarfi:** Conceptualization, Writing - review & editing. **Simon Mann:** Conceptualization, Writing - review & editing. **Rachel Wong:** . **Emilie Deventer:** Conceptualization, Data curation, Writing - review & editing, Visualization, Supervision.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Jos Verbeek: none. Gunnhild Oftedal: GO is member of the International Commission on Non-Ionizing Radiation Protection. She has been member of groups appointed by Norwegian authorities to evaluate potential health effects of non-ionizing electromagnetic fields. Maria Feychting: MF was vice chairman (May 2016 – May 2020) of the International Commission on Non-Ionizing Radiation Protection, an independent body setting guidelines for non-ionizing radiation protection. She has served as advisor to a number of national and international public advisory and research steering groups concerning the potential health effects of exposure to non-ionizing radiation. Eric van Rongen: EvR was chairman (May 2016 – May 2020) of the International Commission on

Non-Ionizing Radiation Protection and is currently vice-chairman. He is also member of the Scientific Council of the Swedish Radiation Safety Authority. Maria Rosaria Scarfi: MRS is in the Scientific Council of the Swedish Radiation Safety Authority for preparing reports on the evaluation of the scientific literature related to electromagnetic fields and health. Simon Mann: SM is a member of the International Commission on Non-Ionizing Radiation Protection's Scientific Expert Group. Within the UK, he is Secretary to the Committee on Medical Aspects of Radiation in the Environment and he was Secretary (until 2017) to the Advisory Group on Non-ionising Radiation. All other authors have declared no conflict of interest. Rachel Wong: none. Emilie van Deventer: none.

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