

Perspective

Developing Policy in the Face of Scientific Uncertainty: Interpreting 0.3 μ T or 0.4 μ T Cutpoints from EMF Epidemiologic Studies

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There has been considerable scientific effort to understand the potential link between exposures to power-frequency electric and magnetic fields (EMF) and the occurrence of cancer and other diseases. The combination of widespread exposures, established biological effects from acute, high-level exposures, and the possibility of leukemia in children from low-level, chronic exposures has made it both necessary and difficult to develop consistent public health policies. In this article we review the basis of both numeric standards and precautionary-based approaches. While we believe that policies regarding EMF should indeed be precautionary, this does not require or imply adoption of numeric exposure standards. We argue that cutpoints from epidemiologic studies, which are arbitrarily chosen, should not be used as the basis for making exposure limits due to a number of uncertainties. Establishment of arbitrary numeric exposure limits undermines the value of both the science-based numeric EMF exposure standards for acute exposures and precautionary approaches. The World Health Organization's draft Precautionary Framework provides guidance for establishing appropriate public health policies for power-frequency EMF.

KEY WORDS: Electric and magnetic fields (EMF); epidemiology; exposure guidelines; policy; precautionary approach

1. INTRODUCTION

There has been considerable scientific research on understanding the potential link between residential and occupational exposures to extremely low-frequency (ELF) power-frequency electric and magnetic fields (EMF) and the occurrence of cancer

and other diseases. This research has been successful in resolving important scientific questions and narrowing the focus of future research. There is a general consensus regarding the following key issues: (1) EMF results from the use of electricity, and exposures are ubiquitous in industrial societies; (2) there are established biological effects from acute exposures at high levels (say well above 100 μ T) that are explained by recognized biophysical mechanisms; (3) chronic exposure to power-frequency magnetic fields, low-level EMF, has been categorized as "possibly carcinogenic" based on consistent studies of childhood leukemia and negative animal data; (4) there are no accepted biophysical mechanisms that would suggest that low-level EMF exposures are involved in specific carcinogenic pathways.⁽¹⁻⁶⁾ The combination of widespread exposures, established biological effects

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from acute, high-level exposures, and the possibility of leukemia in children from low-level, chronic exposures has made it both necessary and difficult to develop consistent public health policies.

The need for such policies results from the undisputed value of safe, reliable, and economic electricity to society to maintain all the benefits that this provides. Creating effective policy in light of these critical considerations has proven to be difficult; the result has been the dependence on two distinctly different paradigms for policy making. The first is the use of numeric standards to address high-level, acute exposures.^(3,4,7,8) The second is to implement “precaution-based” policy approaches to address scientific uncertainty associated with chronic, low-level exposures. The problem, and the subject of this article, is when arbitrary numeric standards for chronic exposures are created. We argue against using arbitrary exposure limits while maintaining that policies based on precaution are feasible and that such policies do not require the adoption of numeric values.

2. POLICIES

2.1. Acute Exposure Standards

Most country-specific standards for EMF are based on the guidelines set by the International Commission on Non-Ionizing Radiation Protection (ICNIRP)⁽⁹⁾ and are augmented by independent panels of scientific experts. The Institute of Electrical and Electronics Engineers (IEEE) also sets acute exposure guidelines. These guidelines are based on acute effects, which show specific thresholds or a minimum biologically effective quantity for the effect to occur. Some uncertainty in this assessment is compensated for by the use of safety factors that set the exposure restrictions below the established thresholds for critical effects, defined as the lowest level of exposure for an established adverse health effect. For example, ICNIRP applies a safety factor of 10 or more to derive occupational exposure limits and a safety factor of 50 for the general public. See Table I for international limits and countries where they have been adopted. Note that exposures above the guideline levels rarely occur (except in some occupational environments), making their implementation relatively noncontroversial.

All guideline-setting committees consider the epidemiologic evidence as not sufficiently strong for guideline development.^(7,8) Nevertheless, it is

precisely these data, along with widespread public exposure, scientific uncertainty, and public pressure that has led a number of countries and local governments to opt for exposure limits far below those proposed by ICNIRP.

2.2. Precaution-Based Policy Approaches

The attempts to introduce caution into EMF policies have been based on an application of the precautionary principle.⁽¹⁰⁾ It is intended for use in drafting tentative responses to potentially serious health threats until adequate data are available for a more scientifically based response. When first used for EMF this approach was referred to as “Prudent Avoidance,” defined as taking steps to keep people out of fields by relocating facilities and redesigning electrical systems and appliances to reduce the fields emitted, at low-to-modest costs.⁽¹¹⁾ This proved to be difficult in practice as both “out of fields” and “low-to-modest costs” were not specified. In the last 15 years precaution-based policy approaches resulted in an inconsistent patchwork of policies at the national, state, and local levels. These fall into three categories: setting limits lower than ICNIRP, restrictions based on distance from electric utility facilities, and precautionary measures that call for reduced exposure without providing guidelines or limits.

Several countries established exposure limits on the order of 10 to 100 times lower than those recommended by ICNIRP (Table I). The numbers chosen, e.g., 1 or 10 μT , are arbitrary. There is neither evidence of possible acute effects at that level nor evidence from epidemiologic studies of leukemia to believe that an exposure of 1 is safer than 10 or 100 μT .

Another strategy has involved limiting the construction of new facilities (particularly those where children might spend a substantial amount of time) within a certain distance of high-voltage transmission lines, or choosing routes for new transmission lines away from existing schools (Table I); no change in existing facilities is recommended.

In contrast to setting specific exposure limits, recommendations to reduce exposures without providing any specific limits regarding exposure levels are being successfully used (Table I). The goal is reducing exposure where it is easily achievable. This includes taking into account EMF when designing new transmission and distribution facilities, and in siting them away from sensitive areas.

Table I. Various Types of EMF Exposure Guidelines

Agency/Country	Limits	Comments
Exposure Guidelines for Acute Effects		
ICNIRP, 1998	100 μ T (50 Hz)	Adopted in a number of countries, e.g., Germany, 1996; European Union, 1999; Korea, 2001; Singapore, 2000; Taiwan, 2001; UK, 2004
	83 μ T (60Hz)	
IEEE, 2002	904 μ T (60Hz)	
Precautionary Policies Based on Exposure Limits		
Switzerland, 1999	100 μ T 1 μ T	Stationary installations “Sensitive use locations” (places where people regularly remain for long periods of time)
Israel, 2001	1 μ T	Newly constructed facilities
Italy, 2003	100 μ T 10 μ T	
	3 μ T	Attention value applies to exposures that occur for more than 4 hours per day
		Quality target that only applies to new lines and new homes
USA	15–25 μ T	Under max. load conditions; established by regulations in some states (e.g., Florida) and by informal guidelines in others (e.g., Minnesota)
	0.4 μ T	Adopted in some local ordinances (e.g., Irvine, California)
Precautionary Policies Based on Separation of People from Sources of Exposure		
Ireland, 1998	No new transmission lines or substations closer than 22 meters from an existing school or building within this distance	Local government will not grant construction permits for electrical power installations in vicinity of schools and day-care center
The Netherlands, 2004	Increased distance to new school facilities so that exposure will not exceed 0.4 μ T	Adopted by the California Department of Education Adopted by the State of Connecticut
USA	Restrictions on siting new schools close to existing electric transmission lines New lines must be underground unless technically infeasible and buffer zones near residential areas, schools, day-care facilities, and youth camps	
Precautionary Policies Based on Costs		
USA	No- or low-cost alterations to the design or routing if substantial field reduction (more than 15%) can be achieved; 4% used as benchmark of project cost	Adopted by the Public Utilities Commission for the State of California
Precautionary Policies Based on Nonquantitative Objectives		
Australia, 2003	Reduction of exposure where it is easily achievable	Includes taking into account EMF when designing new transmission and distribution facilities, and in siting them away from sensitive areas
Sweden, 1996	Reduction of exposure with no recommendations regarding levels	

2.3. The Precautionary Framework

The arbitrary and inconsistent policy applications described above have created the need for rational and workable EMF policies. This has motivated the World Health Organization (WHO) EMF Project (<http://www.who.int/emf>) to develop a practical framework for developing health protection measures in areas of scientific uncertainty based on the application of the precautionary principle⁽⁶⁾ with the

goals of (1) anticipating and responding to possible threats before introduction of an agent or technology, (2) addressing public concerns and minimizing an uncertain health risk after introduction of an agent, and (3) developing and selecting options proportional to the degree of scientific certainty, the severity of harm, the size and nature of the affected population, and the cost. In terms of EMF exposure limits, the framework specifically argues against a replacement of

science-based guidelines with exposure limits based on precaution. The framework places emphasis on exposure reduction where possible while considering the benefits and costs of proposed reduction.

We describe the historical development of cutpoints in epidemiologic studies of EMF childhood leukemia below and consider whether it is appropriate to base exposure limits on these cutpoints.

3. EVIDENCE

3.1. Use of Cutpoints in Epidemiology

Exposure cutpoints in epidemiology are not usually selected to evaluate potential policies or actions related to the exposure of interest. Instead, epidemiologic exposure cutpoints are typically model- or data-driven categories. The amount of data and ease of communication opted for typically dictate the number of categories made by the investigator. Creating too many categories may complicate otherwise concise data summarization. In reality, data are usually limited, and with more categories, cells quickly become sparse. Boundaries are delineated by a variety of methods; often, there are meaningful boundaries inherent in the exposure variable itself; for example, in clinical epidemiologic studies of pharmaceuticals, exposure categories usually represent typical doses.⁽¹²⁾ Similarly, where biologically relevant levels or dose-response functions are known, boundaries are made to capture them.

In the absence of *a priori* knowledge regarding the potential boundaries, a typical method is to set boundaries at fixed percentiles of the variable. Although easy to interpret, such boundaries can lead to misleading results when most people are exposed to a very limited range and there is little difference between the categories.⁽¹²⁾ Furthermore, creating exposure categories based on resulting effect estimates leads to biased estimates.

3.2. Historical Development of Cutpoints in EMF Research

The earliest studies of EMF and childhood leukemia used wire codes, a categorical metric where exposure is estimated by combining the likely current load carried by electrical power lines outside homes (e.g., the thickness of the wires), distance to the wires, and the spatial arrangements of the wires (e.g., wiring configurations). After the development of EMF measurement instruments, studies using spot measure-

ments, 24- to 48-hour measurements in the child's bedroom as well as shorter measurements in other areas inside and outside the home, personal exposure measurements, and calculated fields all used category boundaries for their exposure measurements (see Table II). The early studies used boundaries based on percentiles⁽¹³⁻¹⁵⁾ or set cutpoints based on the exposure distribution in the study.⁽¹⁶⁻¹⁸⁾ Although there are exceptions,^(13,19,20) studies after 1993 used either 0.2 μT ^(14,21,22) or 0.4 μT ⁽²³⁻²⁵⁾ as their highest exposure categories. Although not explicitly stated in a number of studies, the rationale behind boundary choice was likely to be driven by adequate sample size to support the analysis and, in later studies, the desire for comparability with prior studies. Most epidemiologic studies have observed small, elevated odds ratios for the exposure categories above 0.3 or 0.4 μT , although most are not statistically significant. Two pooled analyses^(26,27) used internally standardized exposure categories and provided the most convincing evidence for an association between EMF exposure and childhood leukemia at cutpoints of 0.3 and 0.4 μT ; the odds ratios were 1.68 (95% CI: 1.23, 2.31) and 2.00 (95% CI: 1.27, 3.13), respectively.

4. DISCUSSION

The plethora of field characteristics that could be relevant make avoidance strategies that fall short of avoiding EMF exposure entirely (which could be accomplished only by not using electricity at all) both difficult to formulate and potentially counterproductive. Unlike the situation with many toxic substances, for which substitutes might be available, this situation only allows us to strive to identify and reduce possible risks, while maintaining the benefits provided by electricity. Against a consistent association found in epidemiology stands the absence of a clearly elucidated, robust, and reproducible mechanism of interaction of EMF with biological systems and negative animal data. In addition, we argue that even epidemiologic studies do not provide justification for setting exposure limits at levels of 0.3 and 0.4 μT or below.

4.1. Uncertainty in the Epidemiologic Association

Although the apparent consistency in results of the two pooled analyses suggests that there may be a causal relation between EMF and childhood leukemia, as with all observational studies, it is important to consider whether these results can be due

Table II. Epidemiologic Studies on the Association Between EMF and Childhood Leukemia

Study	Measurement	Lowest and Highest Exposure Categories (μT)	Cases/Controls	Total Cases in Highest Category (%)	Total Controls in Highest Category (%)	OR (95% CI) Highest Exposure Category Compared to Lowest	Rationale
Tomenius, 1986 ⁽³¹⁾	Spot*	<0.3 ≥0.3	239/202 4/10	0.8 (4/486)	0.2 (10/424)	0.3–	None explicitly given
Savitz <i>et al.</i> , 1988 ⁽¹⁷⁾	Spot*	<0.065 ≥0.25 and <0.2 ≥0.2	75/134 10/12 31/NR 5/NR	0.8 (10/128) 13.9 (5/36)	0.6 (12/207) 7.7 (16/207)	1.5 (0.6–3.6) Low power 1.9 (0.7–05.6) Low power	Based on exposure distribution, w/ intention of isolating the high values
Myers <i>et al.</i> , 1990 ⁽³²⁾	Calculated fields	≤0.1 ≥0.1	358/567 1/4	0.3 (1/374)	0.7 (4/588)	0.4 (0.04–4.3)	Comparability with other studies (none referenced)
London <i>et al.</i> , 1991 ⁽¹⁵⁾	24-hr bedroom	<0.067 ≥0.27	85/69 20/11	12.2 (20/164)	7.6 (11/144)	1.5 (0.7–3.3)	Based on percentiles of distribution of cases and controls
Feychting <i>et al.</i> , 1993 ⁽³³⁾	Calculated fields	≤0.09 ≥0.3	27/475 7/32	15.5 (7/45)	5.1 (32/633)	3.8 (1.4–9.3)	None explicitly given
Olsen <i>et al.</i> , 1993 ⁽³⁴⁾	Calculated fields	<0.1 ≥0.4	829/1,658 3/1	0.4 (3/841)	0.1 (1/1685)	6.0 (0.8–44)	OR significantly raised at cutpoint above 0.4 μT
Verkasalo <i>et al.</i> , 1993 ⁽¹⁸⁾	Calculated fields	<0.01 ≥0.2	NR 3/NR	NR	NR	1.6 (0.32–4.5)	Based on exposure distribution and taking into account typical residential level of 0.1 μT
Linnet <i>et al.</i> , 1997 ⁽¹⁶⁾	24-hr bedroom, weighted by spot measurements	<0.065 ≥0.2	206/215 58/44	12.5 (58/463)	9.5 (44/463)	1.5 (0.91–2.6)	Based on exposure distribution of controls
Tynes & Haldorsen, 1997 ⁽²⁰⁾	Calculated fields	<0.05 ≥0.14	139/546 1/14	0.7 (1/148)	0.2 (14/579)	0.3 (0.0–2.1)	Median value for the controls equal to 1.4 μT

(Continued)

Table II. (Continued.)

Study	Measurement	Lowest and Highest Exposure Categories (μT)	Cases/Controls	Total Cases in Highest Category (%)	Total Controls in Highest Category (%)	OR (95% CI) Highest Exposure Category Compared to Lowest	Rationale
Michaelis et al., 1997 ⁽²¹⁾	24-hour bedroom	<0.2 ≥0.2	NR 9/8	5.1 (9/176)	1.9 (8/414)	2.3 (0.8–6.7)	Comparability with meta-analyses (Meinert & Michaelis, 1996; Ahlbom, 1993)
Dockerty et al., 1999 ⁽²²⁾	24-hour bedroom	<0.1 ≥0.2	31/33 5/1	12.5 (5/40)	5.0 (2/40)	15.5 (1.1–225)	Comparability with Savitz et al., 1988; Feychting et al., 1993; Michaelis et al., 1997
Green et al., 1999 ⁽¹³⁾	48-hr personal	<0.03 ≥0.14	14/33 29/33	33.0 (29/88)	24.2 (33/131)	4.5 (1.3–15.9)	Based on quartiles, because no a priori knowledge to show linear relation & small cell size in high exposure groups using cutpoints
McBride et al., 1999 ⁽¹⁴⁾	48-hr personal	<0.08 0.27–1.61 and <0.2 ≥0.2	149/147 32/37	10.9 (32/293)	10.9 (37/339)	0.7 (0.4–1.3)	Based on percentiles; no reason given for 2 μT cutpoint
UKCSS, 1999 ⁽²⁵⁾	Two-phase**	<0.1 ≥0.4	995/977 5/3	0.5 (5/1094)	0.3 (3/1030)	1.7 (0.4–7.0)	Comparability with Linet et al., 1997; Michaelis et al., 1997; McBride et al., 1999
Bianchi et al., 2000 ⁽¹⁹⁾	Calculated fields	≤0.001 > 0.1	92/401 3/3	3.0 (3/101)	0.7 (3/412)	4.5 (0.9–23.2)	None explicitly given
Schuz et al., 2001 ⁽²⁴⁾	24-hr bedroom	<0.1 ≥0.4	456/1,188 3/3	0.6 (3/514)	0.2 (3/1301)	5.9 (0.8–44.1)	None explicitly given
Kabuto et al., 2002 ⁽²³⁾	1-wk bedroom	<0.1 ≥0.4	276/542 6/5	1.9 (6.312)	0.8 (5/603)	2.6 (0.8–8.9)	Comparability with Ahlbom et al., 2000

*Tomenius, 1986: Max. uniaxial value outside front door; Savitz et al., 1988: Arith. mean of low-power measurement in ≥3 locations (child's bedroom, parent's bedroom, other room occupied by child > 1 hour/day, front door).

**48-hour home measurement used if shorter measurement or other indication showed high EMF.

NR = Not reported.

to chance or systematic biases, which include selection bias, misclassification, and unmeasured confounding.

Given the rarity of high exposure, smaller studies had few observations at higher exposure categories. Though many studies have attempted to include large sample sizes, any study is only as informative as its smallest cell, which is most often the highly exposed leukemia cases category. Small effect estimates are notoriously hard to evaluate because it is difficult to achieve enough precision to distinguish a small risk from no risk. Additionally, small effect estimates are more likely to result from biases that often go undetected. Epidemiologic studies quantify only one aspect of this uncertainty (random error or chance) by reporting confidence intervals. Though studies often engage in discussion regarding plausibility or direction of biases, uncertainty due to systematic biases are rarely quantified. When quantified, they substantially widen the presumed distribution of effect estimates. Overall, it appears unlikely that chance explains the observed association between EMF and childhood leukemia.⁽²⁸⁾ While misclassification is likely to be present, it is unlikely to provide the sole explanation for the observed association. It does, however, introduce a great deal of uncertainty into the potential dose response.⁽²⁸⁾ Substantial confounding of the observed

association is also unlikely. Although there is some evidence for and against selection bias, it stands out as a possible explanation.⁽²⁹⁾

4.2. Uncertainty in Putative Exposure

Because EMF exposures are complex, numerous parameters have been used to characterize them, including transients, harmonic content, resonance conditions, and peak values, as well as average levels. It is not known which of these parameters or what combinations of parameters, if any, are biologically relevant. Exposure measurements in epidemiologic studies have been typically based on a time-weighted average of the field, a measure that is related to, albeit imperfectly, the other characteristics of the fields mentioned above.⁽³⁰⁾ Note that the exposure assessments used in the epidemiological studies bear no relationship to the known mechanisms of interaction and because little is known about the biologically relevant mechanism, the choice of exposure categories is arbitrary. Furthermore, it seems unlikely that present-day measurements could differentiate between exposures of 0.1 versus 0.4 μT occurring several years in the past. An average exposure of 0.3 or 0.4 μT can represent a wide range of exposure scenarios (see Fig. 1). Clearly,

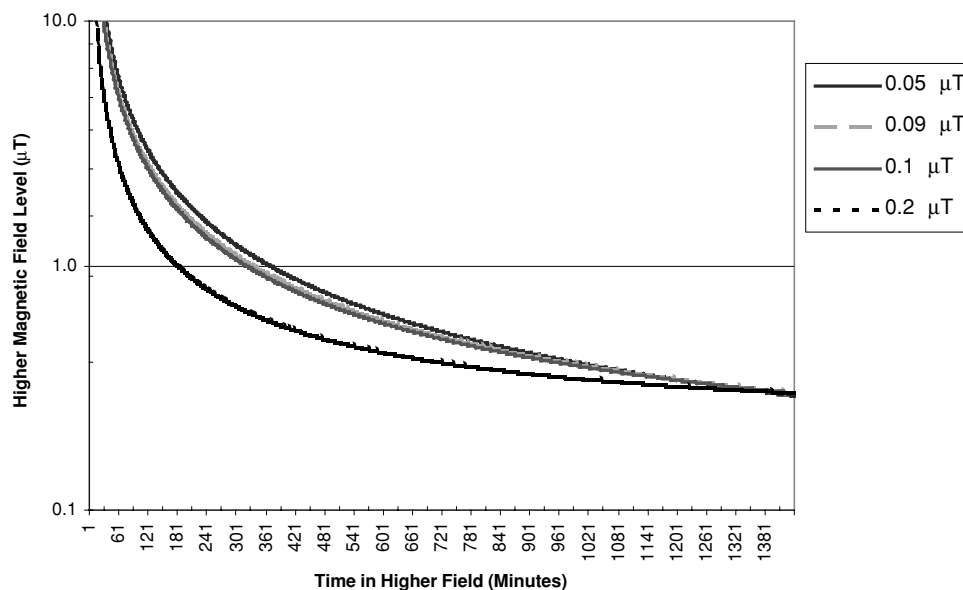


Fig. 1. Magnetic field level versus time in higher field in order to reach a 24-hour time-weighted average exposure of 0.3 μT assuming remainder of time is spent in background fields of 0.05, 0.09, 0.1, and 0.2 μT . A time-weighted average exposure of 0.3 μT based on 24 hours of measurements can be achieved in a number of ways, a few examples include: (1) approximately 0.3 μT exposure for full 24 hours, (2) 0.5 μT exposure for 12 hours (for example, sleeping near an alarm clock) with the remainder of time at background of 0.09 μT , (3) 1.0 μT exposure for about 6 hours (for example, working at the computer) with the remainder of time at background of 0.09 μT , and (4) a little over 60 μT exposure for 5 minutes (for example, using a hair dryer) with the remainder of time at background of 0.09 μT .

an average measurement can reflect a number of different possibilities that blur the differences between peak levels and constant fields, which can be problematic if they do not reflect the same biologically relevant exposure and, more importantly, would lead to different mitigation strategies and require different policies. However, a policy aimed at reducing overall exposure (without a limit to achieve) is reasonable under a working assumption that measures that reduce any aspect of average exposure across the population would indeed reduce the risk, if there is one, and that it can be assumed not to increase other risks.

4.3. Costs and Feasibility

In addition to the scientific uncertainty, policy decisions cannot be made without consideration of costs; but costs must be placed in context with the benefits. In the case of EMF, it is estimated that approximately 4% of the U.S. population is exposed to average levels of 0.4 μT and greater; this equates to close to 12 million people.⁽³⁰⁾ Exposure limits at 0.4 μT or lower would be costly and are not technologically feasible in certain cases.

Given the small estimated effect of EMF and the rarity of leukemia and high exposures, and the uncertainty in determining the relevant exposure metric, the likely benefit, in terms of avoided leukemia cases, of limiting exposure to less than 0.3 or 0.4 μT can easily be overshadowed by large costs. Policies advocating exposure reduction must take into account such cost-benefit considerations.⁽⁶⁾

5. CONCLUSIONS

Although epidemiologic data are invaluable to our scientific understanding and are properly accorded the greatest weight in any human health risk assessment, they often do not provide solid grounds for policy decisions, as epidemiologic studies are rarely designed or analyzed with a policy perspective in mind. In addition, uncertainty and costs and benefits must be considered along with scientific evidence in health-related policy decisions. The impetus to introduce exposure limits for EMF of 0.3 or 0.4 μT is largely the result of misinterpretation of the epidemiologic evidence. Indeed, there appears to be consistency in the association between childhood leukemia and EMF based on the pooled analyses; however, there is also a considerable degree of uncertainty in these estimates as related to the average exposures of 0.3 or 0.4 μT . In view of these uncertainties, the

WHO has suggested, in its draft Precautionary Framework, a working assumption that measures that reduce any aspect of average exposure across the population would indeed reduce the risk if there is one; and it recognizes that any specific measure that reduces exposure is unlikely to reduce precisely the relevant aspect of exposure and thus would not be fully efficient. Furthermore, costs and benefits of reducing exposure must be considered and have not been adequately addressed in the EMF literature. It is likely, however, that while it might be advisable to adopt general no- and low-cost exposure reduction measures, adoption of specific numbers below those of ICNIRP, particularly 0.3 or 0.4 μT levels or below, cannot be justified from the available science. Both uncertainty and policy simulations can contribute greatly to our understanding of the implications of exposure reduction policies and associated benefits and costs.

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