

ICNIRP STATEMENT ON DIAGNOSTIC DEVICES USING NON-IONIZING RADIATION: EXISTING REGULATIONS AND POTENTIAL HEALTH RISKS

Dear Editors:

WE READ with great interest the *ICNIRP Statement on Diagnostic Devices Using Non-ionizing Radiation: Existing Regulations and Potential Health Risks*, published in the March 2017 issue of *Health Physics* (ICNIRP 2017). Our interest concerned in particular the evaluation of potential health risks related to exposure to (stray) static magnetic fields resulting from diagnostic MRI procedures in patients. Given that ICNIRP is recognized as an official collaborating NGO by international organizations such as the World Health Organization and the International Labour Organization, and that ICNIRP is consulted by the European Commission, its statements are considered as authoritative. We therefore expected that their hazard evaluation would be based on a systematic and up-to-date review summarizing the complete available evidence in a balanced and unbiased way. To our surprise, however, the authors of the ICNIRP Statement pointed out their assessment of possible adverse effects from diagnostic use of MRI was based on “a non-systematic review of the literature for relevant epidemiological studies and clinical reports and by hand-searching references of key reports.” Furthermore, it is unclear what period is covered in the ICNIRP Statement. The WHO, HPA, and ICNIRP review reports that were cited covered only the years up to 2009, while the reference list included a few more recent papers. The potential for biases of such a non-systematic reviewing of the scientific literature are well recognized, and to mitigate this, protocols for transparent reporting of systematic reviews and meta-analysis (PRISMA) (Moher et al. 2009), as well as for the assessment of remaining biases (ROBIS) (Whiting et al. 2016), have been developed and the Cochrane Collaboration (<http://www.cochranelibrary.com/>) has been established.

Although a full assessment of potential biases and missed research is beyond the scope of this letter, it became obvious to us that the readers are unfortunately withheld relevant available literature (published in the past few years). The results of several experimental studies have not been

included. For example, several (double-blind) randomized controlled trials provided convincing evidence of effects on neurocognitive performance and postural body sway as a result of exposure to MRI-related stray fields (de Vocht et al. 2003, 2007a and b; van Nierop et al. 2012, 2013, 2015). Also, a study by Heinrich et al. (2014), which reported dizziness among volunteers exposed to homogeneous static magnetic fields (SMF) inside bores of MRI-scanners with different magnet strengths, was not discussed. This work has been supported by experimental studies that examined the effect of a strong SMF on vestibular responses in human subjects and found an effect on involuntary eye movements and vertigo, both of which were associated with the direction of the SMF in relation to the vestibular organ (Roberts et al. 2011; Mian et al. 2013; Ward et al. 2014). ICNIRP did report that “A meta-analysis of 5 studies published during 1992–2007 found the only neuropsychological effect relating to static magnetic field exposure to be visual impairment,” but no reference was presented. It most likely refers to a paper by Heinrich et al. published in 2011. However, this paper suffered from methodological flaws (de Vocht et al. 2012).

Another example of available research not included in this ICNIRP statement relates to realistic occupational scenarios of workers in MRI production and MRI technicians in health care and scientific research. This research has been indicative of exposure-dependent associations between exposure to (stray) SMFs and transient symptoms (de Vocht et al. 2006, 2015; Wilen and de Vocht 2011), which was also confirmed in patients (Heilmaier et al. 2011). An observational study among MRI technicians reported an association between vertigo and measured exposure to MRI-related SMF in an exposure-dependent manner (Schaap et al. 2016). Finally, with regard to potential health effects from long-term occupational exposure to SMF from MRI scanners, ICNIRP highlights that “well-defined MRI worker cohorts would be useful,” yet the ICNIRP statement (2017) does not present the available results from a cohort study among workers from an MRI manufacturing facility (Bongers et al. 2016). Analyses in this cohort study are ongoing, but as yet an association was found between MRI-related occupational SMF exposure and an increased risk of accidents leading to injury, and for commute-related (near) accidents during the commute from home to work. This finding needs confirmation and merits follow-up.

Given the examples above, it is clear to us that ICNIRP, by performing a non-systematic review, has unfortunately provided the readership of *Health Physics* with an incomplete,

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not up-to-date, and biased overview of the scientific literature on health risks and symptoms associated with exposure to MRI-related (stray) fields. Nevertheless, in line with the authors' conclusions, we postulate there is at present no evidence that the patients' benefit/harm trade-off of MRI would be anything other than positive, and we agree that further research into health effects of (long-term) SMF exposure is warranted given recent findings for workers exposed to these extreme static magnetic fields. It would have been better if the readership had been provided with the results of a systematic review. This would have helped pointing out gaps in knowledge and guidance as to what lines and topics of further research would be most helpful/informative.

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