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

International Commission on Non-Ionizing Radiation Protection (ICNIRP)

Abstract—**Use of non-ionizing radiation (NIR) for diagnostic purposes allows non-invasive assessment of the structure and function of the human body and is widely employed in medical care. ICNIRP has published previous statements about the protection of patients during medical magnetic resonance imaging (MRI), but diagnostic methods using other forms of NIR have not been considered. This statement reviews the range of diagnostic NIR devices currently used in clinical settings; documents the relevant regulations and policies covering patients and health care workers; reviews the evidence around potential health risks to patients and health care workers exposed to diagnostic NIR; and identifies situations of high NIR exposure from diagnostic devices in which patients or health care workers might not be adequately protected by current regulations. Diagnostic technologies were classified by the types of NIR that they employ. The aim was to describe the techniques in terms of general device categories which may encompass more specific devices or techniques with similar scientific principles. Relevant legally-binding regulations for protection of patients and workers and organizations responsible for those regulations were summarized. Review of the epidemiological evidence concerning health risks associated with exposure to diagnostic NIR highlighted a lack of data on potential risks to the fetus exposed to MRI during the first trimester, and on long-term health risks in workers exposed to MRI. Most of the relevant epidemiological evidence that is currently available relates to MRI or ultrasound. Exposure limits are needed for exposures from diagnostic technologies using optical radiation within the body. There is a lack of data regarding risk of congenital malformations following exposure to ultrasound in utero in the first trimester and also about the possible health effects of interactions between ultrasound and contrast media.**

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INTRODUCTION

DIAGNOSTIC IMAGING with non-ionizing radiation (NIR) allows non-invasive assessment of the structure and function of the human body without the risks associated with imaging by ionizing radiation, and is widely employed in medical care. With advances in technology, increasingly sophisticated devices that exploit NIR are being introduced into clinical practice, and it is important to ensure that their use does not carry unwarranted risks to health.

ICNIRP has published previous statements in 2004 and 2009 about the protection of patients during medical magnetic resonance imaging (MRI), but not other forms of diagnostic NIR. Accordingly, ICNIRP here provides updated advice regarding a broad spectrum of diagnostic devices employing NIR, focusing on those that are currently used clinically.

The aims of this statement are to:

- Review the range of diagnostic devices employing NIR that are currently used in clinical settings;
- Document the regulations and policies governing the use of such devices for protection of patients and health care workers;
- Describe potential risks to the health of patients (representing volunteers and comforters also) and health care workers (representing carers also) as a consequence of diagnostic use of NIR; and
- Identify situations of potentially high NIR exposure to patients or health care workers from diagnostic devices, in which protection may not be adequate.

In regard to the last of these objectives, it is recognized that limits on exposure often incorporate reduction factors to allow for uncertainties in available scientific evidence, and that the magnitude of any such adjustment will depend on value judgements that are not simply a matter of science. Furthermore, diagnostic procedures can confer substantial

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benefits to health, such that, depending on the probability and severity of harm, a risk of adverse effects in patients may in some circumstances be acceptable. However, benefits must outweigh the risks in order to be ethical.

For these reasons, the statement does not form any judgement as to whether or not current regulatory limits are appropriate. Rather, it focuses on whether there is evidence that they fail to protect against demonstrable hazards and, if so, what risks could be expected. In addition, it identifies gaps in currently available evidence that might mask important, unrecognized risks, and that should be a priority for future research.

Consideration is limited to uses of NIR for diagnostic procedures in patients and does not extend to its application in diagnostic procedures conducted away from the patient (e.g., on tissue specimens in the laboratory), nor for use of NIR for therapeutic or cosmetic (the topic of a future ICNIRP Statement) purposes. NIR is taken to include static magnetic fields; time-varying electric, magnetic, and electromagnetic fields (EMF) with frequencies up to 300 GHz (wavelengths down to 1 mm in vacuum); optical radiation with wavelengths from 1 nm to 1 mm; and ultrasound with frequencies of 1 MHz to 40 MHz. Acoustic waves in the audible spectrum are considered only where they result from the use of NIR as defined above. Health effects which arise from the use of devices that employ NIR, but which are not a consequence of the NIR (e.g., claustrophobia from MRI scanners), are not addressed.

Even with these restrictions, the relevant scientific literature is large, and it was not judged practical or efficient to carry out a comprehensive systematic review of all pertinent primary research. Instead, the statement refers where possible to systematic reviews already published by ICNIRP or by other respected authorities (Stam and Bijwaard 2011; de Waard-Schalkx et al. 2015) with supplementary systematic searches of the literature to address any important gaps in their coverage (further details are given later).

DIAGNOSTIC TECHNOLOGIES BASED ON NIR

Diagnostic technologies have been classified by the NIR fields employed.

Electromagnetic fields

EMF with frequencies of 0 to 300 GHz are used in a range of diagnostic devices either directly on the patient to gather diagnostic information, or as a means of storing or transmitting data from monitoring of patients. The benefits of some of these devices are clear and they are used extensively (e.g., MRI) whereas the clinical value of others remains to be established (Table 1a).

Magnetic resonance imaging (MRI). MRI is a very widely employed method of clinical investigation which uses a static magnetic field, generally in the range 0.5 to

Table 1a. List of technologies applying NIR used for diagnostic purposes, static fields and up to 300 GHz (1 mm).

Field	Technology	Acronym	Frequency (Hz)	Purpose	Working principle
Static			Not applicable		
	Magnetic resonance imaging	MRI	Induced by movement: 0–100 Gradient: 0.5×10^3–5×10^3 RF: 8.5×10^6 – 5×10^8	Imaging	Nuclear magnetic moments are aligned with a static field 0.1–11.7 T, and excited with a radiofrequency field. The resulting realignment induces a detectable magnetic resonance signal which can be spatially encoded using time varying, non periodic magnetic field gradients.
LF	Transcranial magnetic stimulation	TMS	$5 - 2 \times 10^5$	Brain stimulation for imaging	Time-varying magnetic field is applied in pulses lasting several hundred microseconds to investigate brain activity and peripheral nerve function.
RF	Radiofrequency identification	RFID	1.2×10^5 – 5.8×10^5	Identification of patient/device	Active or passive RF transponder
	Wireless signal transfer		4.0×10^8 up to 1.06×10^{10}	Wireless transfer of data (temperature/ heart rate/images/medication use)	Miniature measurement device with RF transmitter
	Radar monitoring		1.0×10^{10} – 2.4×10^{10}	Measurement (vital functions/ pneumothorax/tremors)	Detection of varying reflections from body surface and tissue boundaries
	Radar imaging		1.0×10^9 – 15×10^9	Imaging and localization of tumors	Difference between dielectric properties of cancer and healthy tissue
	Volumetric EMF Phase-Shift Spectroscopy	VEPS	1.0×10^6 – 1.0×10^8	Measurement of intracranial hematoma	Detection of pathological changes in tissues, such as increased amount of fluid through external non-contact, multi-frequency EMF measurements
	Microwave-induced thermo-acoustic echography		8.0×10^8	Heat modification for imaging	A tumor causes higher dielectric losses of microwaves than healthy tissues, and therefore can be selectively heated. The expansion of a tumor because of the heat leads to a modification in acoustic waves when emitted towards, and reflected from, the tissue

7 Tesla (T) in combination with time-varying non-periodic EMF (approximately in the range 100–1,000 Hz) and radio frequency EMF (in the range 20–300 MHz). MRI can generate images providing contrast to a wide range of different aspects of organ structure or function. With technological advances, including increases in the strengths of static magnetic fields up to and beyond 7 T, sub-millimetre resolution can now be achieved.

Transcranial magnetic stimulation (TMS). Apart from its wide therapeutic use, electrical stimulation of brain cortex by magnetic induction is applied diagnostically to investigate brain activity. In addition, magnetic stimulation can be used to study peripheral nerve function. Typically, a time-varying magnetic field is applied in pulses lasting several hundred microseconds. The equivalent frequency based on pulse width and repetition rate can be in the lower kHz range.

RF identification (RFID). RFID employs EM fields to remotely identify patients, and depending on the characteristic of the device, data such as temperature or blood glucose levels can be acquired and exchanged at distances up to a hundred meters (ICNIRP 2008). More recently, RFID has been further developed as an "implantable" technology. The frequencies employed in RFID range from hundreds of kHz up to 6 GHz.

Wireless signal transfer. As well as monitoring of temperature, wireless signal transfer applications include heart rate monitoring, and exchange of this information between patient and carer. Wireless signal transfer uses miniaturized measurement devices (e.g., temperature sensors) equipped with an RF transmitter to acquire and transmit data. The operational frequency is fixed from 400 MHz to 10 GHz.

Radar for vital functions. Radar using pulsed and ultra-wide band RF and MW signals is being evaluated as a tool for non-invasive monitoring of vital functions. Two of the diagnostic applications most advanced in development are monitoring of breathing for early detection of pneumothorax and monitoring for tremors. The frequencies employed range from nearly 10 GHz up to 24 GHz.

Radar imaging. Radar imaging or MW tomography is used mainly in the diagnosis of breast and skin cancers with some trials on stroke detection emerging (De Santis et al. 2012). The technique exploits the difference between dielectric properties of cancer and healthy tissue, to image and localize tumors even in 3D. The method employs an antenna array that transmits and receives. The frequency range spans 1 GHz to 15 GHz.

Electromagnetic (EM) movement tracking. EM movement tracking is used for diagnostic purposes, for example in analysing jaw movements during mastication. An antenna inserted at a relevant site in the patient transmits information about position.

Volumetric EMF phase-shift spectroscopy (VEPS). VEPS is being developed to detect and measure intracranial hematoma and oedema. The technology uses frequencies from a few MHz up to hundreds of MHz and can detect pathological changes in tissues, such as increased amount of fluid, through external non-contact, multi-frequency EM measurements. VEPS is relatively inexpensive and therefore could be amenable for use in economically disadvantaged parts of the world.

Microwave-induced thermo-acoustic echography. The main application of microwave-induced thermo-acoustic echography is breast cancer imaging. It uses a combination of microwaves to heat tumors and acoustic waves to sense microwave absorption. A tumor causes higher dielectric losses of microwaves than healthy tissues, and therefore can be selectively heated, optimally at around 800 MHz. The expansion of the tumor because of the heat leads to a modification in acoustic waves when emitted towards, and reflected from, the tissue.

Optical radiation

Diagnostic applications of optical radiation employ wavelengths ranging from short wavelength ultraviolet radiation through the visible spectrum to near infrared radiation (Table 1b).

Near-infrared radiation applications. Near-infrared radiation (near IRR) is used as a light source for in vivo internal imaging of the upper gastrointestinal tract. The radiation is delivered through an optical fibre attached to swallowed graded-index lens optics which illuminate the mucosa and record the scatter of near IRR.

Another major clinical application of near IRR is optical coherence tomography. A short coherence superluminescent light diode (SLD) is used as the source. The primary beam is split into a reference path, which is reflected by a mirror, and a measurement path which is backscattered by the tissues. High lateral resolution of the target tissue requires it to be as close to a point source as possible, and therefore involving high irradiance. The technology is used as a standard diagnostic procedure in ophthalmology and also in dermatology.

Near-infrared radiation-visible radiation (VIR) applications. Diffuse optical tomography uses near IRR and long wavelength visible radiation, typically from an array of diode lasers, as a primarybeam and the backscattered radiation is detected for different wavelengths. The scattering and absorption topography is calculated to create a detailed three-dimensional image of the tissue.

Table 1b. List of technologies applying NIR used for diagnostic purposes, optical radiation.

Wave band	Technology	Source	Wavelength (nm)	Purpose	Working principle
Near IRR					
	Capsule endomicroscopy – optical frequency domain imaging	Laser	1250–1380	Imaging (gastrointestinal)	Difference between light scattered by tissue and reference beam (interferometry)
	Capsule endomicroscopy - spectrally encoded confocal microscopy	Laser	1220–1360	Imaging (gastrointestinal)	Scattering of three wavelengths of focused laser light from gut wall
	Endomicroscopy – angle-resolved low coherence interferometry	LED	822–842	Imaging (gastrointestinal)	Angular distribution of scattered near-infrared light as a function of tissue depth
	Optical coherence tomography (OCT)	Laser or SLD	800–1700	Imaging (ophthalmology, dermatology)	Time of flight difference between light scattered by tissue and reference beam detected by interference
Near IRR/VIR					
	Diffuse optical tomography	Laser	700–1000	Imaging (breast cancer/brain damage/joint damage/blood flow)	Detection of absorption and scattering of light by tissue
	Near-infrared spectroscopy (NIRS)	Laser or LED	700–1000	Measurement (cerebral oxygen/blood vessel lipid content)	Difference between emitted and transmitted or reflected light spectrally resolved
	Intraoperative fluorescence imaging	LED	700–800	Intraoperative visualisation of vital structures or tumours	Fluorescence spectrally resolved
	Diffuse correlation spectroscopy	Laser	650–950	Measurement of blood flow (skin/breast/ muscle/brain/prostate)	Detection of fluctuations in scattering of near-infrared photons by erythrocytes
VIR					
	Fast nonlinear spectral microscopy	Laser	760	Imaging (skin)	Natural fluorescence following multiple photon absorption
	Laser speckle imaging	Laser	633–785	Measurement of blood flow (skin/retina/joints)	Detection of fluctuations in random interference pattern of laser light caused by erythrocytes
	Photoacoustic tomography	Laser, pulsed	532–770	Imaging (breast cancer/skin perfusion/oxygenation)	Absorbed energy from laser causes tissue expansion that create ultrasound that is detected
	Fluorescence angiography	Laser	490–800	Imaging perfusion of skin, retina and teeth	Quantification of fluorescence in dye injected in circulation after excitation with laser light
	Surgical microscope illumination of the ocular lens	Incandescent/ Halogen light LED	White light	Imaging of the anterior segment during anterior segment surgery	Contrast due to spatially variable scattering
	Ophthalmoscopy	Incandescent light/ Halogen light LED	White light	Imaging of the retina.	Contrast in scattered light due to spatially variable spectral absorption
	Endomicroscopy – hypoxia imaging endoscopy	Laser	445–473	Imaging gastrointestinal mucosa	Difference between absorption spectrum for oxygenated haemoglobin in diseased and healthy tissue
VIR/UVR					
	Confocal laser scanning microscopy	Laser	352–633	Imaging (skin cancer/retinal disease/ gastrointestinal mucosa)	Detection of scattered and reflected light from scanning laser through pinholes

Table 1c. List of technologies applying NIR used for diagnostic purposes, ultrasound.

Category	Technology	Typical frequency (MHz)	Purpose	Working principle
Biometry	A-scan	40	Biometry of distances in the eye for estimation of intraocular lens power	Time of flight of echoes from reflecting surfaces is measured.
High resolution imaging				
	High frequency B-mode scanning	≥20	Imaging of small or superficial structures	High frequency allows high imaging resolution but less penetration depth.
Imaging		1–18		Time of flight of echoes against reflecting surfaces is measured.
	General Body B-Mode Scanners		2-D body imaging	
	Real time imaging at high frame rates (>15 frames s^{-1}). Computer synthesis of multiple 2-D B-scans into time resolved video.		Imaging of moving structures	
	3-D Imaging. High frame rates (>15 frames s^{-1}).		Viewing of fetus	
	Multiple sequential 2D scans are combined to visualize 3D-surfaces			
	Maternal labour monitoring 3-D imaging and tracking		Provide time resolved information on labour development	
Doppler devices			Blood velocity	Velocity is deduced due to the Doppler shift in frequency of returning echoes from erytrocytes or moving tissue
	Pulsed. Pulses are sent and received with the same crystal. The frequency distribution after a defined time is measured.	2–6	Depth resolved blood velocity.	Frequency shift in a specific echoe time window provides depth resolved velocity measurement
	Spectral Doppler	5 – 15	Pulse dynamics and turbulence	Frequency spectra are analyzed
	Continuous Wave. Separate transducers transmit and receive echoes.	1–6	Diffuse velocity measurement without depth resolution, e.g. foetal heart rate monitoring	
	Duplex Doppler	2–6	Visualize anatomy and blood velocity at the same time	
	Combined B-scan 2D imaging and visualization of flow in the same image			
	Elastography	2–6	Tissue mechanical properties	Tissue motion associated with mechanical stress is recorded

Near-infrared spectroscopy uses a laser or light emitting diode (LED) as the source and detects backscattered light, which is spectrally resolved to calculate cerebral and tissue oxygenation and estimate lipid content. Near-infrared diffuse correlation spectroscopy can be used to measure blood flow in brain, muscle and superficial tumors with a penetration depth of several centimeters. This technique quantifies the motion of red blood cells by measuring fluctuations in their scattering of near-infrared photons.

Intraoperative fluorescence imaging is used during surgical procedures, usually to distinguish tumor tissue from normal tissue. It employs LEDs as a source of near-infrared radiation or visible radiation, and image contrast is due to fluorescence. Irradiance should be below threshold for heating when in use.

Visible radiation applications. Fast non-linear spectral microscopy is used in dermatology in diagnosis of superficial skin cancers. A very short laser pulse induces multiple photon absorption with very high resolution, and secondary fluorescence is then detected. This requires a pulse time in the order of a picosecond, and with current detector technology, an irradiance that exceeds the ICNIRP exposure limit (ICNIRP 2013a).

Laser speckle imaging records fluctuations in random interference patterns of coherent light from a laser. It is used to quantify blood flow in superficial body tissues. Irradiances normally are below the ICNIRP exposure limit. In photoacoustic tomography, a short visible radiation pulse of high intensity is focused with high resolution. The energy that is absorbed causes a rapid increase in temperature and some of the energy is transformed into a mechanical pressure wave, an ultrasound pulse that is time-resolved and recorded for imaging. The magnitude of the ultrasound pulse from a defined depth depends on the optical properties of tissues in front of the focal point.

In fluorescence angiography, a fluorescent dye, fluorescein, is injected into a peripheral vein and the filling of the retinal vessels is observed over time by illumination with an excitation light and concurrent recording of fluorescence.

White light from an incandescent source, a halogen source or an LED lamp is used in ophthalmic surgical microscopes to induce light scattering and enable the structures of the patient's anterior segment to be visualized. The illumination, particularly with short wavelength visible radiation, exceeds the ICNIRP photochemical exposure limit (ICNIRP 2013b) and is hazardous for the patient's retina but the exposure is necessary for safe surgery. Thus exposure time is minimized as far as possible, with short wavelength visible radiation filtered out.

White light from the same sources used in ophthalmic surgical microscopes may be used also for illumination of the retina, the backscatter being observed by the examiner or recorded by a camera (fundus photography). Again the principle is to minimize irradiance and exposure time as far as possible (see below).

In endomicroscopy, light of different wavelengths from laser diodes is delivered via a fiber. The fibre tip is coupled into a miniature graded-index lens microscope that focuses the light on the mucosa of the upper gastrointestinal tract, and the backscattered light is imaged with the microscope and recorded as spectrally-resolved wavelength-dependent absorption images.

Visible radiation-ultraviolet radiation applications. In confocal laser scanning microscopy, the illumination is confocal with the focal point of the microscope. Typically, a laser emitting in the visible radiation waveband is used for illumination. The technique is used to image the mucosa of internal organs and for retinal and skin imaging.

Ultrasound

Ultrasound is a form of oscillating mechanical energy with frequency higher than 20 kHz, a cut-point which is above the audible frequency range for most people. Diagnostic ultrasound devices operate at between 1 MHz and 40 MHz.

Diagnostic ultrasound has advanced remarkably in the past 50 years. It can provide exquisite visualization of internal anatomy and is used extensively in clinical practice. Currently, pregnant women in most countries are examined with ultrasound at least once.

Diagnostic ultrasound machines operate with different modes. In the A mode the intensities of echoes from various depths are resolved in one dimension. In B-mode the ultrasound beam is scanned in two dimensions thus providing 2D information. In C-mode, several adjacent B-scans are stacked together to provide 3D information. In M mode, the B-scan or the C-scan is resolved over time thus showing motion in the tissue examined. In the Doppler mode the scan is used to assess the velocity of blood flow or a moving internal structure, which is determined by measuring the Doppler shift of frequency in returning echoes. A summary of ultrasound techniques is given in Table 1c.

INTERNATIONAL AND NATIONAL REGULATORY STRUCTURES

Several independent organizations have published guidelines on the avoidance of harm from exposures to NIR generated by diagnostic devices (Table 2). These guidelines may be used by governmental bodies that issue legally-binding regulations on exposures to NIR.

Regulation of medical devices is intended to ensure effective medical devices of good quality that are safe for the intended purpose. The essential requirements concern the protection of the users and the environment. In most

Table 2. Examples of organisations issuing legally binding regulation and guidelines for human protection against hazardous health effects of NIR.

Governmental organizations issuing legally binding regulations	
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
EU	European Union (Parliament and Council)
FDA	Food and Drug Administration (eg China, Korea, USA)
TGA	Therapeutic Good Administration (Australia)
NEA	National Environmental Agency (Singapore)
FSSCRHW	Federal Service for Supervision of Consumer Rights and Human Welfare (Russia)
Organizations issuing guidelines	
ACGIH	American Conference of Gavernmental Industrial Hygienists
ACOG	American Congress of Obstetricians and Gynecologists
ACR	Americal College of Radiology
AIUM	American Institute of Ultrasound in Medicine
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ASUM	Australasian Society for Ultrasound in Medicine (Australia, New Zealand)
BIR	British Institute of Radiology (UK)
BMUS	British Medical Ultrasound Society (UK)
ECMUS	European Committee of Medical Ultrasound Safety
HVBG	Hauptverband der gewerblichen Berufsgenossenschaften (Germany)
ICNIRP	International Commission on Non-Ionizing Radiation Protection
IEC	International Electrotechnical Committee
JSOH	Japan Society for Occupational Health (Japan)
MHRA	Medicines and Healthcare products Regulatory Authority (UK)
NHMRC	National Health and Medical Research Council (Australia)
PHE	Public Health England (formerly Health Protection Agency) (UK)
RCR	Royal College of Radiologists (UK)
SSK	Strahlenschutzkommission (Germany)
WFUMB	World Federation of Ultrasound in Medicine and Biology

countries that regulate medical devices, a national regulatory authority (NRA) sets regulatory controls in pre-market, on the market and post-market phases of the medical device. The safe use of medical devices in health care settings is usually not the responsibility of the NRA.

In European Union (EU) countries, EU Directives regulating exposures from NIR devices are implemented by transposition into national laws or regulations. Separate directives cover devices, patients and workers (Tables 3a–c; 4a–c). It is notable that in the recent EU Directive (2013/35/EU) limiting the exposure of workers to electromagnetic fields, exposures from MRI used in the healthcare sector could exceed the exposure limit values, provided other conditions were satisfied. On the other hand, EU member states are free to apply stricter limits for workers than those in the EMF directive and some (e.g., Poland) have already done so.

In the Russian Federation, medical devices and activities must comply with a federal sanitary regulation which lists fixed emission limits for NIR. In addition, there are federal regulations for workers with occupational exposure limits for EMF, infrared, and ultraviolet radiation. The occupational EMF limits are stricter than ICNIRP occupational reference levels and depend on the duration of exposure.

In many Asian countries, a law is passed by the country's legislative body creating an NRA that then issues the regulations. Examples of NRAs that regulate medical devices (mainly through registration of such devices) are the Food and Drug Administration of the Philippines, the Malaysia Medical Device Authority, the Thai Food and Drug Administration, the China Food and Drug Administration, the Hong Kong Medical Device Control Office, the Ministry of Food and Drug Safety of Korea, and the Vietnam Department of Medical Equipment and Health Works. In Singapore, the National Environment Agency regulates use of devices while the Health Sciences Authority regulates production, import, export, sale, and distribution of medical devices. In the Philippines, the Food and Drug Administration regulates not just the production, import, export, sale, and distribution of medical and radiation devices but also their use, when applicable. In November 2014, the Association of Southeast Asian Nations (ASEAN) signed the ASEAN Medical Device Directive (AMDD), which establishes a harmonized regulatory model for medical device regulation

Table 3a. Examples of legally binding regulations associated with diagnostic devices based on NIR for protection of patients, static fields and time varying electromagnetic fields less than 0.3 THz.

Region	Year in force	Regulator	Document and principle
Australia	1989, 2002	Therapeutic Goods Administration (TGA)	Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002.
China	2000	Food and Drug Administration (FDA), China	Regulations for the supervision and administration of medical devices.
Hong Kong	2012	Hong Kong Dept. of Health	Pharmacy and poinsons ordinance, Radiation ordinance, Telecommunications ordinance.
Taiwan	2015	Taiwan FDA	Pharmaceutical affairs law-Regulations for governing the management of medical devices, regulations for registration of medical devices
EU	1993, 2007	European Union (EU)	Council Directive 93/42/EEC concerning medical devices. Local regulation is delegated to national notifying authorities in each member state. Devices may be placed on market if they do not comprimise safety and health of patients, users and other persons. Appendix 11 specifies requirements on radiation emission. To be replaced by Medical device regulations.
Japan	2014	Pharmaceuticals and Medical Devices Agency (PMDA), Ministry of Health Labour and Welfare	Act on Securing Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics
Korea	2010	Food and Drug Administration (FDA), Dept. of Health, Korea	Medical Device Act
Malaysia	2012	Medical Device Authority, Ministry of Health	Medical Device Act
Philippines			
	2009	Food and Drug Administration Philippines (FDA), Dept. of Health	Food and Drug Administration Act and the appropriate regulation for registration of medical devices 2016.
	2004	Bureau of Health Devices and Technology, Dept. of Health	Radiation protection standards for radiofrequency radiation in the range 3 kHz–300 GHz
	2007	Bureau of Health Devices and Technology, Dept. of Health	Amendment to implementing rules and regulations of code of sanitation of the Philippines.
Russia	2010	Chief Medical Officer, Federal Service for Supervision of Consumer Rights Protection and Human Welfare (FSSPCRHW)	SanPiN 2.1.3.2630-10, Organization of medical activities
Singapore			
	2014	National Environment Agency	Radiation Protection (Amendment) Act 2014
	2016	Health Sciences Authority	Health Products Act
USA			
	1998	Food and Drug Administration USA (FDA)	Guidance for the submission of premarket notifications for MR diagnostic devices
	2003	Food and Drug Administration USA (FDA)	Criteria for significant risk investigations of MRI devices
	2005	Food and Drug Administration USA (FDA)	Federal food, drug and cosmetic act, regulates marketing of radiation emitting products, additional requirements for medical devices
	2008	Food and Drug Administration USA (FDA)	Establishing safety and compatibility for passive implants in the magnetic resonance (MR) environment

for its member states. The regulation will come into force upon ratification.

The U.S. Food and Drug Administration implements its federal Food, Drugs, and Cosmetics Act by issuing regulations which become part of the U.S. Code of Federal Regulations. Individual states of the U.S. may have further regulations for the use of NIR medical devices. Arizona, which is an example of a state with regulations on the use of NIR devices, requires the registration of non-ionizing radiation facilities. At the same time, a non-governmental organization, the American College of Radiology (ACR), operates a scheme for accreditation of MRI facilities (and offers this service internationally). Similarly, the American Institute of Ultrasound in Medicine accredits clinical facilities using ultrasound. Although accreditation is voluntary, it is required for reimbursement by many private health insurance companies.

In many countries, there is no legislation/regulation governing the use of NIR in diagnostic devices. Instead, practitioners refer to guidelines issued by national or

Table 3b. Examples of legally binding regulations associated with diagnostic devices based on NIR for protection of patients, optical radiation (1 nm-1 mm).

Region	Year in force	Regulator	Document
Australia	1989, 2002	Therapeutic Goods Administration (TGA)	Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002.
China	2000	Food and Drug Administration (FDA), China	Regulations for the supervision and administration of medical devices.
Hong Kong	2012	Hong Kong Dept. of Health	Pharmacy and poinsons ordinance, Radiation ordinance, Telecommunications ordinance.
Taiwan	2015	Taiwan FDA	Pharmaceutical affairs law-Regulations for governing the management of medical devices, regulations for registration of medical devices
EU			
	1993 2007	European Union (EU)	Council Directive 93/42/EEC concerning medical devices. Local regulation is delegated to national notifying authorities in each member state. Devices may be placed on market if they do not comprimise safety and health of patients, users and other persons, appendix 11 specifies requirements on radiation emission (no specific limits)
Japan	2014	Pharmaceuticals and Medical Devices Agency (PMDA), Ministry of Health Labour and Welfare	Act on Securing Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics
Korea	2010	Food and Drug Administration (FDA), Dept. of Health, Korea	Medical Device Act
Malaysia	2012	Medical Device Authority, Ministry of Health	Medical Device Act
Philippines	2009	Food and Drug Administration Philippines (FDA), Dept. of Health	Food and Drug Administration Act and the appropriate regulation for registration of medical devices 2016.
Russia	2010	Chief Medical Officer, Federal Service for Supervision of Consumer Rights Protection and Human Welfare (FSSPCRHW)	SanPiN 2.1.3.2630-10, Organization of medical activities
Singapore			
	2014	National Environment Agency	Radiation Protection (Amendment) Act 2014
	2016	Health Sciences Authority	Health Products Act
USA	2005	Food and Drug Administration (U.S. FDA)	Federal food, drug and cosmetic act, regulates marketing of radiation emitting products, additional requirements for medical devices

international or professional associations. These guidelines may or may not be followed.

Legislation/Regulation for protection of patients

Legally-binding regulations associated with diagnostic devices based on NIR intended for protection of patients are listed in Table 3a–c.

Legislation/Regulation for protection of health workers

Legally binding regulations associated with diagnostic devices based on NIR intended for protection of workers are listed in Table 4a–c.

EPIDEMIOLOGICAL EVIDENCE FOR HEALTH RISKS ASSOCIATED WITH EXPOSURE TO DIAGNOSTIC NIR DEVICES

Most of the relevant epidemiological evidence that is currently available relates to MRI or ultrasound.

MRI

Research on possible adverse effects from diagnostic use of MRI was identified by a non-systematic review of the literature for relevant epidemiological studies and clinical reports and by hand-searching references of key reports.

Overall, MRI has been used clinically for about three decades with apparently few serious side effects aside from well-documented acute injuries resulting from effects on implanted electronic devices or acceleration of ferromagnetic materials towards the scanner by the magnetic field, or from RF-induced burns due to poor positioning of the patient in the scanner.

Previous reviews of the health effects of fields of MRI equipment do not suggest long-term adverse health effects (HPA 2008a; ICNIRP 2009a). This is particularly the case for static fields (WHO 2006; HPA 2008b; ICNIRP 2009b), for which there is no substantiated evidence for any health effect that could inform the design of an epidemiological

Table 3c. Examples to show range of legally binding regulations associated with diagnostic devices based on NIR for protection of patients, ultrasound.

Region	Year in force	Regulator	Document
Australia	1989, 2002	Therapeutic Goods Administration (TGA), Dept. of health	Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002.
China	2000	China Food and Drug Administration (CFDA), China	Regulations for the supervision and administration of medical devices.
Hong Kong	2012	Hong Kong Dept. of Health	Pharmacy and poisons ordinance
Taiwan	2015	Taiwan FDA	Pharmaceutical affairs law-Regulations for governing the management of medical devices, regulations for registration of medical devices
EU	1993, 2007	European Union (EU)	Council Directive 93/42/EEC concerning medical devices.
Japan	2014	Pharmaceuticals and Medical Devices Agency (PMDA), Ministry of Health Labour and Welfare	Act on Securing Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics
Korea	2010	Food and Drug Administration (FDA), Dept. of Health, Korea	Medical Device Act
Malaysia	2012	Medical Device Authority, Ministry of Health	Medical Device Act
Philippines	2009	Food and Drug Administration Philippines (FDA), Dept. of Health	Food and Drug Administration Act and the appropriate regulation for registration of medical devices 2016.
Russia	2010	Chief Medical Officer, Federal Service for Supervision of Consumer Rights Protection and Human Welfare (FSSPCRHW)	SanPiN 2.1.3.2630-10, Organization of medical activities
Singapore			
	2014	National Environment Agency	Radiation Protection (Amendment) Act 2014
	2016	Health Sciences Authority	Health Products Act
USA	2005	Food and drug Administration (U.S. FDA)	Federal Food, Drug and Cosmetic Act, section 513, regulates marketing of radiation emitting products, additional requirements for medical devices

study. However, the effect of RF power deposition in tissues should be investigated.

Patients: Acute perceptual and cognitive effects. Acute perceptual and cognitive effects are well recognized effects that have been reported by subjects undergoing diagnostic MRI. They occur particularly when high static magnetic fields are employed (Rauschenberg et al. 2014), but symptoms have sometimes been reported in relation to field strengths as low as 1.5 T (Heilmaier et al. 2011). The largest study available was a multicentre trial that used 7 T and 9.4 T MRI systems and collected data through 3,457 completed questionnaires (Rauschenberg et al. 2014). The study aimed to separate sensory side effects during movement on the patient table from those experienced while lying still at the isocenter. Most participants (82%) rated the examination at least as tolerable; 8% felt discomfort; and only 1% of the image acquisitions had to be terminated prematurely. No adverse events occurred in any examination. Only 1% of the subjects were unwilling to undergo further ultra-high field MRI examinations. Long duration of examination was the most frequent cause of discomfort, followed by acoustic noise and lying still. All magnetic-field-related sensations were more pronounced when moving the patient table compared to resting at the isocenter position (19%/2% of the subjects felt unpleasant vertigo during the moving/stationary state). Vertigo was the most frequently reported sensory side effect overall, and was more pronounced at 9.4 T than at 7 T, although its prevalence varied substantially between the different trial sites. Several mechanisms have been proposed to explain this vertigo including differences in magnetic susceptibility between the vestibular organs and surrounding fluid, induced currents acting on hair cells (Glover et al. 2007) or the Lorentz force inside the lateral semi-circular canal (Roberts et al. 2011).

Patients: Developmental effects of prenatal MRI. A large prospective observational study examining the effects of prenatal exposure to 1.5-T MRI on developmental outcome (Bouyssi-Kobar et al. 2015), as assessed by a norm-referenced, psychometrically sound functional assessment scale, found no association with adverse functional outcomes or hearing impairment.

Medium- to long-term ill-effects of undergoing diagnostic MRI are believed to be few, though there is a dearth of epidemiological studies to evaluate this. This may reflect the difficulty of designing patient-studies that are not substantially confounded. Firstly, both the medical indication for the scan and the range of associated investigations and treatments may have their own health consequences.

Table 4a. Examples of legally binding regulations associated with diagnostic devices based on NIR for protection of workers, static and time varying electromagnetic fields less than 0.3 THz.

Region	Regulation type	Country within region	Frequency	Year in force	Regulator	Document
Australia	Code, Guideline			1985, 1991	Australian Radiation Protection and Nuclear Safety Authority (ARPANSA)	Code of Practice for the Safe Use of Shortwave (Radiofrequency) Diathermy Units (1985), Code of Practice for the Safe Use of Microwave Diathermy Units (1985), Safety guidelines for magnetic resonance diagnostic facilities (1991).
China				2007	Ministry of Health	GBZ 2.2-2007, Occupational exposure limits for hazardous agents in the workplace, Part 2: Physical agents
EU	Legislation					
				1989	European Union (EU)	Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, sets general requirements. EU Directives are implemented and regulated in member states, usually by Ministry of Labour & Health & Safety Inspectorate
				1993	EU	Directive 93/42/EEC of 14 June 1993 concerning medical devices
				2013	EU	Directive 2013/35/EU of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)Limits do not apply to MRI workers; alternative limits may be applied to military staff
	Examples of additional regional regulation					
		Bulgaria		2016	Ministry of Labour, Ministry of Health	Ordinance No. RD-07-5, State gazette 95/2016 for the minimum requirements for providing health and safety of workers exposed to electromagnetic fields, directly implemented EU Directive 2013/35/EC
		Croatia		2014	Local legislator	Regulations on Protection from Electromagnetic Fields (Official Gazette no. 98/11) Stricter action values but same ELV as EU Directive
		Greece		2015	Greek Atomic Energy Comission (GAEC)	Decision P/112/363/13.11.2015 Licensing of MRI facilities - radiation protection requirements
		Italy	RF	1993	Ministry of Health	Ministerial Decree 3-8-1993 on the Updating of regulations for authorization to installation and use of magnetic resonance diagnostic equipments.
		Italy	Static	1991	Ministry of Health	Ministerial Decree 2-8-1991 on the Authorization to installation and use of magnetic resonance diagnostic equipments. Possible changes expected after implementation of EU Directive (deadline: 1-7-2016).
		Poland		2014	Ministry of Labour, Poland	Ordinance 6-6-2014 on acceptable maximum concentration and intensity of harmful elements for health in work environment, stricter limits apply than the EU Directive
		Sweden		1987, 2016	Swedish Work Environment Authority	AFS 2016:3, Regulation on radiofrequency electromagnetic fields.
Japan				2015	Ministry of Health, Labour and Welfare	Industrial Safety and Health Law, Art 22. "Employer shall take necessary measures for preventing health impairment due to radiation, …, high temperatures, …, ultrasonic waves"
Russia				2003	Chief Medical Officer, Federal Service for Supervision of Consumer Rights Protection and Human Welfare (FSSPCRHW)	SanPiN 2.2.4.1191-03 Electromagnetic fields in occupational conditions
				2010	Chief Medical Officer, Federal Service for Supervision of Consumer Rights Protection and Human Welfare (FSSPCRHW)	SanPiN 2.1.3.2630-10, Organization of medical activities
USA				1970	OSHA	Occupational safety and health act (general requirements)

Table 4b. Examples of legally binding regulation associated with diagnostic devices based on NIR for protection of workers, optical radiation (100 nm–1 mm).

Region	Regulation type	Country within region	Waveband (nm)	Year in force	Regulator	Document
Australia	Regulations			1999	Australian Radiation Protection and Nuclear Safety Authority (ARPANSA)	Radiation Protection and Nuclear Safety Regulations 1999, Regulation 4, optical source other than a laser product, emitting UVR, IR or visible light.
China			1 nm–1 mm	2007	Ministry of Health	GBZ 2.2-2007, Occupational exposure limits for hazardous agents in the workplace, Part 2: Physical agents, Ministry of Health; limits for heat, ultraviolet, laser
EU						
	Legislation		100 nm–1 mm	1989	European Union (EU)	Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work, sets general requirements
			100 nm–1 mm	2006	EU	Directive 2006/25/EC of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation)
	Additional regulation					
		Poland	180–3000 nm	2014	Ministry of Labour. Poland	Ordinance 6-6-2014 on acceptable maximum concentration and intensity of harmful elements for health in work environment; limits identical to those in Directive 2006/25/EC
Japan				2015	Ministry of Health, Labour and Welfare	Industrial Safety and Health Law. Art 22. "Employer shall take necessary measures for preventing health impairment due to radiation, …, high temperatures, …, ultrasonic waves"
Russia				1988	Chief medical Officer USSR	Sanitary Norm 4557-88, ultraviolet radiation in industrial premises
				1997	Ministry of Health	SanPiN 2.3.4.548-96, microclimate (infrared/heat)
			0–5 MHz	2010	Chief Medical Officer, Federal Service for Supervision of Consumer Rights Protection and Human Welfare (FSSPCRHW)	SanPiN 2.1.3.2630-10, Organization of medical activities, states that limits for medical workers are specified in previous sanitary norms
USA			1 nm–1 mm	1970	Occupational Safety and Health Administration (OSHA)	Occupational safety and health act (general requirements)

Table 4c. Examples of legally binding regulation associated with diagnostic devices based on NIR for protection of workers, ultrasound.

Region	Regulation type	Country within region	Year in force	Regulator	Document
Australia	Standard		2004	Australian Radiation Protection and Nuclear Safety Authority (ARPANSA)	AS/NZS 2243.5 Safety in laboratories – Non–ionizing radiations –Electromagnetic, sound and ultrasound
EU					
	Legislation		1989	European Union (EU)	Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work, sets general requirements
	Additional regulation				
		Poland	2014	Ministry of Labour, Poland	Ordinance 6-6-2014 on acceptable maximum concentration and intensity of harmful elements for health in work environment
Japan			2015	Ministry of Health, Labour and Welfare	Industrial Safety and Health Law, Art.22, "Employer shall take necessary measures for preventing health impairment due to radiation, …, high temperatures, …, ultrasonic waves"
Russia			2010	Ministry of Health	SanPiN 2.1.3.2630-10, Organization of medical activities

Secondly, MRI is often associated with the administration of contrast agents which themselves can have clear short- and medium-term effects (e.g. accumulation of gadolinium from contrast agents in the body). Using a control group who have had a CT scan, for example, is not feasible since CT carries its own, established health risks. A future opportunity to obtain unbiased data about possible health effects of diagnostic MRI arises from its use in large population-based longitudinal studies. For example, the UK Biobank project is planning to phenotype 100,000 apparently healthy subjects in the next few years using MRI, although their exposure will be limited. There are also other groups (such as workers and consumers involved in neuro-marketing) who volunteer for MR scans and receive regular, high exposure over several years. While these voluntary exposures vary considerably and may be confounded by other exposures such as to ionizing radiation, such groups may be a useful resource for epidemiological research in the future. While molecular changes have been demonstrated following in vitro experimental exposures to magnetic fields (with and without contrast agents) (Fiechter et al. 2013; Lancellotti et al. 2015; Vijayalaxmi et al. 2015), such findings have not been reflected in the limited evidence that is available on health outcomes.

Health workers: Acute perceptual and cognitive effects

It has long been known that people working in the vicinity of MRI scanners can experience transient vertigo (as well as a metallic taste in their mouths). These effects occur not only with movement in the field, but also when people are stationary, and they become pronounced when staff work inside or close to the end of the bore (where the field can be particularly high for shielded magnets). Underlying mechanisms that have been proposed include hydrodynamic effects in the vestibular system (Schenck 2005; Glover et al. 2007), and a direct magnetic susceptibility effect on the sensory hair cells (Glover et al. 2007), but currently the accepted mechanism is a Lorentz force on the dark current within the vestibular system (Roberts et al. 2011).

A study among 361 healthcare and research staff working with MRI scanners in the Netherlands (Schaap et al. 2014) assessed the incidence and association of transient perceptual symptoms with static magnetic field exposure based on diaries reporting work activities and symptoms during work shifts inside and/or outside an MRI facility. Participants included both MRI staff and radiographers who never worked with MRI. Symptoms (mainly vertigo and metallic taste) were reported during 16–39% of the MRI work shifts, and there were significant positive associations with increasing scanner strength, ranging from 2-fold increases at 1.5 T to 4-fold increases at 7.0 T. 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. Further research into this possibility is needed.

Health workers: Pregnancy outcomes

One study compared self-reported pregnancy outcomes of female MRI workers from the 1990s (Kanal et al. 1993) (when fields were lower than today but extended further to non-MRI workers) adjusted for age, smoking, and alcohol use. No increase in risk of spontaneous abortions, delayed conception, early delivery, low birth weight, or male sex of offspring was seen compared to when they were employed elsewhere before working with MRI.

Optical radiation

A current literature search did not reveal any studies indicating adverse effects associated with the use of optical radiation in diagnostic procedures. Surveillance programs for workers using laser applications had not revealed any unexpected health hazards by the early 1990s, and since then have been abandoned in most countries.

Ultrasound

Research on possible adverse effects from diagnostic use of ultrasound was identified from a previous systematic review (HPA 2010), and through a systematic search of the Embase and Ovid Medline databases, looking for relevant epidemiological studies and clinical case reports. Information was found concerning potential acute effects, longer term obstetric and developmental outcomes following use of ultrasound during pregnancy, and risk of childhood cancer after prenatal exposure to ultrasound.

Acute effects

Possible acute effects that have been investigated include stimulation of foetal movements during the later stages of pregnancy (Fatemi et al. 2001); altered electroencephalographic (EEG) activity in neonates during and after ultrasound examination (Kohorn et al. 1967); erythrocyte fragility in women exposed to continuous ultrasound monitoring during labor (Bause et al. 1983); and structural changes in the brain (assessed by MRI) following insonation through the temporal bone (Schlachetzki et al. 2002). Adverse outcomes reported to follow ultrasound imaging of the liver (Piscaglia et al. 2006) and heart (van der Wouw et al. 2000) may have been a toxic effect of contrast agents (such as microbubbles with high echogenicity used to enhance the sonogram), and cannot be attributed to ultrasound exposure per se with certainty. They could also reflect an interaction between ultrasound and contrast agents. Study findings to date do not point clearly to any acute

adverse effects of human exposure to diagnostic ultrasound, but further research on possible interactions with contrast agents would be useful.

Pregnancy and birth outcomes

B-scans are used for dating conception, identifying multiple pregnancies, fetal abnormalities, and placental location. Later in pregnancy, Doppler studies, usually employing continuous wave sources, may be used to study blood flow in the umbilical artery as a guide to fetal well-being, while low intensity Doppler ultrasound is often used to monitor fetal heart rate (cardiotocography). The progressive adoption of these techniques over the last 50 years has been so extensive that in many countries, almost all pregnancies now entail some exposure to ultrasound. Thus most research on humans has compared higher with lower exposures rather than exposure with no exposure.

A substantial number of observational studies have assessed outcomes of pregnancy in relation to exposure to diagnostic ultrasound, but in some investigations, associations may have been confounded by the clinical indications for ultrasound examination. Such confounding could occur if diagnostic ultrasound were used more frequently in patients already at higher risk of adverse outcomes. However, results of more than 25 randomized controlled trials of ultrasound scans at different stages of pregnancy, or of Doppler studies of the umbilical artery, do not suggest any adverse effects of ultrasound examination on miscarriage rate, gestational age at delivery, or perinatal mortality (Bucher and Schmidt 1993; McKenna et al. 2003; Skråstad et al. 2013). Similarly, the balance of evidence does not indicate any adverse effect of prenatal ultrasound on anthropometric measures at birth or neonatal morbidity (Alfirevic and Neilson 1995; McKenna et al. 2003; Skråstad et al. 2013), though evidence about specific congenital malformations is limited (Hellman et al. 1970; Mukubo 1986; Tikkanen and Heinonen 1992). In theory, congenital malformations might be an adverse outcome, especially from high intensity exposures in the first trimester, since they may be induced by heating. However, it is unlikely that increases in temperature from diagnostic ultrasound as currently used would be sufficient to cause congenital abnormalities.

Developmental outcomes

Research using various designs, including case-control and cohort studies and randomized controlled trials, has explored the relationship of diagnostic ultrasound in pregnancy to a wide range of developmental outcomes in childhood—namely, growth, vision, hearing and speech, reading and intellectual performance, handedness and mental health (Salvesen et al. 1992a and b, 1993a and b; Kieler et al. 1997, 1998a and b, 2001, 2002, 2005). Among these, the only possible association to emerge has been with non-right-handedness (Salvesen et al. 1993b) (a possible marker for adverse impacts on neurological development). However, the findings on this have not been entirely consistent, and it cannot be regarded as an established effect.

Childhood cancer

Case-control studies of the risk of childhood cancer collectively suggest that prenatal exposure to ultrasound does not increase the risk of any of the most common types of childhood cancer (Shu et al. 1994, 2002; Sorahan et al. 1995). Although the results of some studies may have been biased by selective participation (e.g. controls being unrepresentatively affluent or better educated) or by mothers' inaccurate recall of exposure, it seems unlikely that this would have obscured important associations. Moreover, studies that ascertained exposures only from medical records (Naumburg et al., 2000; Stålberg et al. 2008) did not suggest higher risks.

Risks to patients

The balance of evidence now available does not point to any serious adverse effects in patients from exposure to diagnostic ultrasound as used in normal clinical practice, in the absence of ultrasound contrast agents.

Risks to workers

No studies were found that directly examined potential health risks in health care workers using diagnostic ultrasound. However, given the apparent absence of harm in patients, and the low exposure of operators (perhaps most likely to occur if they informally test the ultrasound probe on their arm before applying it to the patient), no risk would be expected from current exposures.

Uncertainties

Among the uncertainties in the current evidence base, highest priorities for further research are the risks of congenital malformations following exposure to ultrasound in utero (particularly in the first trimester), and the potential for adverse effects from interactions between ultrasound and contrast media, on which relatively little information is available.

POTENTIAL HEALTH RISKS NOT COVERED BY LEGISLATION/REGULATION AND IMPORTANT AREAS OF UNCERTAINTY

Static magnetic field and radiofrequency EMF

Apart from MRI, specific guidelines or regulations to limit exposure and/or quantify dose in patients or health workers are few. For example, while there are occupational studies (Karlström et al. 2006) and safety guidelines (Rossi et al. 2009) concerning TMS, these mostly concern therapeutic applications. Evaluation of health effects or safety risks for many NIR diagnostic methods is therefore difficult and deserves further research.

Potential effects on the patient. MRI is associated with several adverse effects in patients, including a potential for uncomfortable exposure to acoustic noise, heating, and sensory disturbances (in particular vertigo). However, all of these effects are reversible and can be prevented or ameliorated. There is insufficient evidence on which to draw firm conclusions about long-term health effects, although there is little theoretical reason to expect any permanent damage if scanners are operated in line with existing regulations. A priority for further research is to investigate any potential harmful effects from exposure to the fetus during pregnancy, particularly during the first trimester.

Potential effects on health workers. In normal clinical practice, staff working with MRI scanners may experience transient vertigo and related sensory disturbances which might carry a risk of personal injury. Again, there is insufficient evidence from which to draw solid conclusions about long-term risks to health, although theoretical considerations suggest that a hazard is unlikely. More information on any long-term effects in well-defined MRI worker cohorts would be useful.

Optical radiation

No reports were found of adverse short- or long-term health effects, either in patients or in health care workers, from diagnostic technologies using optical radiation that complied with current guidelines.

Potential risks to the patient. Regulations for avoidance of skin and eye damage from diagnostic exposure are based on tissue-specific estimates of thresholds across the optical spectrum for short-term onset (within a week), and cover exposure times from femtoseconds to hrs. Accidental ocular exposure is potentially hazardous and data on thresholds for effects from exposures to repetitive short pulses are limited. However, the reduction factor that is applied in current regulations and guidelines for safe exposure should be sufficiently conservative to protect against injury.

As there is little or no systematic information on threshold doses for harm from exposures to optical radiation within the body, no specific regulations have been developed. However, exposure limits for such exposures would be useful.

Potential risks in health workers. Regulations place controls on the geometry of spaces where diagnostic technologies using optical radiation are used. Moreover, special warning lights must be mounted outside such spaces, where exposures could exceed regulatory limits. Both of these requirements are intended to avoid any exposure without use of protective equipment.

Optical radiation can efficiently be blocked by safety goggles. Appropriate use of safety goggles in a space where diagnostic technologies using optical radiation are used is required by regulations and eliminates any risk for health workers being exposed to harmful doses.

Ultrasound

The balance of evidence now available does not point to any harmful effects, either in patients or health care workers, from exposure to diagnostic ultrasound as used in normal clinical practice, in the absence of contrast agents.

It would, however, be useful to carry out further research on the risks of congenital malformations following exposure to ultrasound in utero (particularly in the first trimester), and the potential for adverse effects from interactions between ultrasound and contrast media.

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