NIR diagnostic applications in clinical practice

ICNIRP Project Group 'Intended human exposure to NIR for diagnostic purposes'

Task: Draft a statement about intended human exposure to NIR for diagnostic purposes

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Project Group Aims:

- 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 and health care workers as a consequence of diagnostic use of NIR
- Identify situations of potentially high NIR exposure to patients or health care workers from diagnostic devices, in which protection may not be adequate

Project Group Methods:

- Inventory of diagnostic applications: web searches, expert consultation, existing literature reviews
- Inventory of regulations and policies: web searches, expert consultation, existing regulatory database (RIVM)
- Risk to patients and health care workers: systematic literature search on devices with longest history in clinical practice (e.g. MRI, ultrasound)
- High NIR exposure and inadequate protection: Project Group and Commission discussions
- Information gathered by individual Project Group members, conclusions, draft texts discussed in Project Group meeting (March 2016) & via e-mail

Devices: EMF (0 - 300 GHz)

Mitch Moore, US Navy

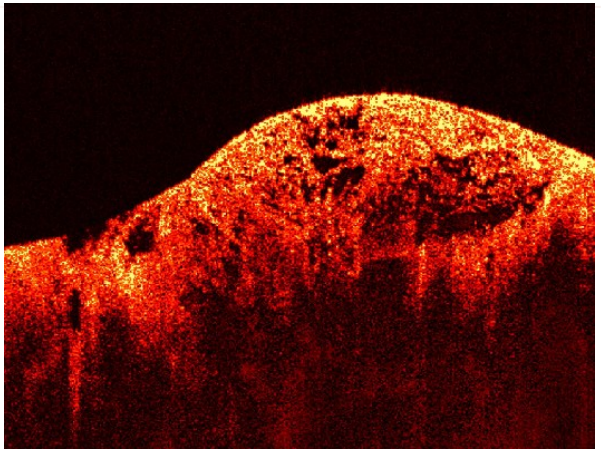
A. Intentional exposure of patient

- Magnetic Resonance Imaging (MRI): static, LF, HF
- Transcranial magnetic stimulation for diagnosis: LF
- Volumetric EM phase shift spectroscopy: HF (26-166 MHz)
- Microwave-induced thermoacoustic echography: HF (800 MHz), e.g. breast
- Radar imaging: HF (4–10 GHz), superficial imaging, e.g. skin
- Radar monitoring: HF (10–24 GHz), respiration, heart rate

B. Unintentional exposure of patient, worker

- RFID: HF (120 kHz–400 MHz), storing of patient or device information
- Wireless signal transfer: HF (400 MHz), miniature measurement device, e.g. heart rate, temperature, medication use
- EMF movement tracking: HF, e.g. jaw

Devices: optical radiation



Stephen Boppart, U.Illinois

A. Detailed imaging of superficial structures via absorption, scattering, fluorescence

- Terahertz imaging: IR ($3 \cdot 10^4$–10^6 nm), e.g. breast
- Tethered capsule endomicroscopy: IR laser (1220–1380 nm), gut
- Catheter endomicroscopy: IR LED (822–842 nm), gut
- Optical coherence tomography: IR laser (800–1700 nm), e.g. retina, skin
- Diffuse optical tomography: IR laser (700–1000 nm), e.g. skin, muscle
- Fast nonlinear spectral microscopy: laser (700–800 nm), e.g. skin
- Photoacoustic tomography: pulsed laser (532–770 nm), e.g. breast, skin
- Fluorescence angiography: laser (490–800 nm), e.g. retina, skin
- Hypoxia imaging: laser (445–473 nm), gastrointestinal
- Confocal laser scanning microscopy: laser (352–633 nm), e.g. retina, skin, gastrointestinal

Devices: optical radiation

Joshua Valcarcel, US Navy

B. Illumination/Visualization

- Opthalmoscopy: visible incandescent/halogen/LED, imaging during surgery
- Surgical microscope: visible incandescent/halogen/LED, imaging of retina

C. Measurement

- Near-infrared spectroscopy (NIRS): laser/LED (700–1000 nm), oxygenation, lipid content, e.g. cerebral cortex
- Diffuse correlation spectroscopy: IR laser (650–950 nm), blood flow, e.g. breast, skin, muscle, brain, prostate
- Laser speckle imaging: IR laser (633–785 nm), blood flow, e.g. retina, skin

Devices: ultrasound

Artem Aseev

A. Biometry (40 MHz)

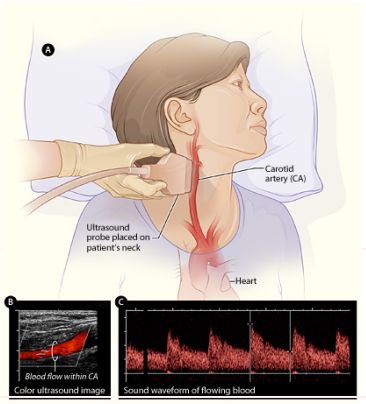
- A-scan, biometry of distances in eye

B. Imaging (1–20 MHz)

- High frequency B-mode scanning, imaging of small/superficial structures
- General body B-mode scanners, most common 2D body imaging
- Real-time imaging at high frame rates, imaging of moving structures
- 3D-imaging, computer synthesis of multiple 2D scans, foetus/labour

C. Doppler devices (1–6 MHz)

- Continuous wave, low resolution blood velocity
- Pulsed doppler, high-resolution blood velocity
- Duplex doppler, combined imaging and blood velocity
- Elastography, recording tissue motion associated with mechanical stress



NIH

Regulation: patients

- Medical device (marketing) regulation and associated technical standards, e.g. Medical Device Directive (EU), Federal food, drug & cosmetic act (USA)
- Regulations of national regulatory agencies (e.g. Malaysia, Philippines)
- National legislation with fixed limits for NIR-emitting devices (e.g. Russia)
- Guidelines issued by national or international professional associations (e.g. World Federation of Ultrasound in Medicine and Biology)
- Usually any risks to the patient are balanced against medical necessity (medical professional judgment)

Regulation: health care workers

- Legislation with binding exposure limits (e.g. EU, Russia)
- General health and safety legislation (e.g. Japan, USA)
- Technical standards related to medical device legislation
- Guidelines issued by national or international professional associations (e.g. ACGIH)

Risks: EMF

MRI:

- Acute perceptual, cognitive effects (vertigo, nausea)
- Acute nerve stimulation effects
- Acute heating effects
- Possible delayed effects? (accidents in workers)
- Developmental effects: few studies (no effect), confounding (e.g. contrast), suitable control group

Other applications:

- Few data on specific devices, would depend on exposure level vs. limits
- TMS: magnetic fields can exceed occupational reference levels
- Microwave tomography: patient and worker exposure expected to be below general population reference levels for thermal effects

Risks: optical radiation

- Acute damage to cornea, lens, retina
- Acute damage to skin
- Increased risk for skin cancer (UV)
- No unexpected health risks in worker surveillance for laser applications

Risks: ultrasound

- Acute effects: no adverse outcomes for nervous system, haematological parameters
- Reported adverse effects (heart, liver) may be due to contrast agent or interaction between ultrasound and contrast agent

Kjetil Lenes

- Developmental effects: exposure almost universal, confounding (clinical indication); comparison high versus low exposure gives no indications for effects on miscarriage, perinatal mortality, postnatal growth, vision, hearing, speech or cognitive effects, childhood cancer
- Workers: low or incidental (test) exposure, no risk expected

Adequacy of regulation, uncertainty (1)

EMF

MRI:

- Risks associated with acute effects (sensory effects, nerve stimulation, heating) adequatey covered by exisiting guidelines and regulation

- Further research into possible harmful (thermal) effects on foetus

- Further research into possible long term effects in workers

Other applications:

- Further research into exposure/dosimetry of novel imaging techniques

Adequacy of regulation, uncertainty (2)

Optical radiation

- Occupational exposure limits potentially exceeded in some applications, but acute risks (eye, skin) covered by existing regulation and guidelines
- Further research on risk threshold of repetitive short pulses
- Further research on internal exposure limits (gut)

Ultrasound

- Balance of evidence does not indicate adverse effects in patients
- Further research on potential risk of malformation after early exposure (first trimester) and interaction between ultrasound and contrast media