

### **INTERSUN PROGRAMME**

7<sup>th</sup> International Advisory Committee Meeting

Remisens Premium Hotel Metropol Congress Center Portorož, Slovenia Wednesday 20 – Thursday 21 June 2018

Rapporteur – Martin Gledhill, representative of the Ministry of Health of New Zealand

### Wednesday 20 June

#### **UV** session

## Opening of the meeting

**Dr Darina Sedláková**, Head of WHO Country Office, Slovenia, welcomed participants and thanked the Slovenian Ministry of Health for providing some funding to support the meeting. Dr Sedláková noted the importance of the International Advisory Committee (IAC), especially in view of the general lack of public awareness of UV and in helping prepare for climate change. On the other hand, there is much public awareness and debate about EMFs.

**Dr Peter Gajšek**, the local organiser, also welcomed participants and added his thanks to the Slovenian Ministry of Health for their support.

*Emilie van Deventer* welcomed participants and led a round of introductions. Craig Sinclair was appointed meeting chair. The agenda was adopted and the minutes of the  $6^{th}$  UV IAC meeting accepted as circulated.

**Update on the INTERSUN programme activities** (*E. van Deventer, WHO, Switzerland*) 2018 is the 70<sup>th</sup> anniversary of WHO, and Emilie van Deventer provided an overview of the organization's structure and functions, and the Sustainable Development Goals (SDGs). The third SDG (good health and well-being), which has prevention of non-communicable diseases as one its strong commitments, is of primary concern to the IAC. 23% of premature deaths are linked to the environment.

The Intersun programme started in 1995 and works with other UN agencies and external organizations such as NGOs and Collaborating Centres. This year a new Collaborating Centre has been designated: the Italian National Institute of Health (ISS) - National Center for Radiation Protection and Computational Physics.

A paper summarizing the 2015 WHO/ARPANSA/CCV/ICNIRP UV Index workshop in Australia has been published in Health Physics. The recently published WHO brochure on artificial tanning devices is now available for sale as this provides further visibility through the WHO bookshop, and a version in Spanish has been prepared in collaboration with IRPA. A questionnaire on the UV IAC meetings was distributed in 2017 and the agenda for this meeting has been shaped by the responses received.

#### Review of recent research activities

Ozone depletion, UV radiation and health in a changing climate: an update 2018 (*Professor R. Lucas, Australian National University, Australia*)

Until now, much of the research on environmental UV exposure has focused on ozone depletion. However, climate change affects behavior, so even though the Montreal Protocol has been successful in reducing stratospheric chlorine, there are new factors that can affect sun exposure.

We still see risky sun behavior, and in most places the incidence of skin cancer is increasing. The adverse effects are a combination of DNA damage and immune suppression. Countries with well-established sun protection programmes are seeing a decrease in skin cancers Australia). There is a lot of new data on genetic risk factors.

UV exposure also has beneficial effects, such as Vitamin-D production. There is little data on Vitamin-D deficiency from low and middle-income countries, and its role in health beyond bone health remains contentious. Vitamin-D supplementation has possible health benefits. UV also provides some health benefits for some skin diseases, auto-immune diseases, reduced blood pressure, reduced all-cause mortality (although this is based on only two studies) and reduced myopia (possibly an effect of blue light).

On the protection side, new Standards for clothing have been introduced and there is a proposal to change sunglass testing to take account of deterioration of protection over time. While regular sunscreen use reduces the number of naevi, it is often poorly applied, especially around the eyes and mouth. There is also concern about possible environmental effects of sunscreen in waterways.

There is some concern about the UVI and that current protection messages might be flawed as they do not take account of exposure time, especially for UVI <3 and long exposure times as this can still lead to erythema and immune suppression. This information does not come across with simple messages that sun protection is needed if the UVI >3.

In the future, climate change and ozone recovery could lead to more clouds at high latitudes but clearer skies in other areas. Increased numbers of people working outdoors (for example in renewable energy) could increase UV risks. Climate change could also produce longer periods when plant-sourced airborne allergens are present and affect food security. The UNEP 2018 Quadrennial Assessment by the Environmental Effects Assessment Panel (EEAP) report is in preparation.

Health economic impact of increased sunbed regulation in Europe and North America (L. Gordon, QIMR Berghofer Medical Research Institute, Australia)

Louisa Gordon is updating previous work on the benefits of sunbed regulation. It will cover in situ melanomas (not previously considered), keratinocyte cancers (KCs), various age cohorts and geographical regions. The work will compare current practices, such as banning under-18s and a full ban on sunbeds.

Results show that banning use by under-18s in Europe would avoid 53,400 deaths and provide big cost savings. Similar results would be obtained for a full ban, and comparable results would be found in the USA. In Australia a full ban is expected to provide savings of A\$103M. A sensitivity analysis shows cost savings under all assumptions.

Strengths of the study include using recent evidence and improved models. Weaknesses include the use of pooled data, large variations in prevalence of use and difficulties estimating KC incidence.

The study should be published towards the end of 2018.

Discussion after the presentation noted that:

- In France the main sunbed operator is going bankrupt. Tanning is being considered less attractive.
- A recent Canadian study shows decreased prevalence of sunbed use.

#### **UV-related disease burden**

Global burden of cutaneous melanoma attributable to ultraviolet radiation in 2012 (M. Arnold, IARC, France)

Around the world there are >230,000 new melanoma cases and 55,000 deaths per year. UV is a strong risk factor, so it is of interest to estimate the avoidable burden of disease as this helps to assess the effect of interventions.

The baseline of melanoma cases has been estimated from minimally exposed populations, primarily the UK 1903 birth cohort, with three African cancer registries used for secondary analyses. This shows that 76% of all new melanoma cases (1.2% of all new cancers) in 2012 were attributable to UV. These were mostly in the USA and Europe. The data is available on a new website <a href="http://gco.iarc.fr/causes/uv/home">http://gco.iarc.fr/causes/uv/home</a>. The work has been <a href="published">published</a> in the International Journal of Cancer.

WHO/ILO Joint Methodology for estimating the work-related burden of disease and injury: skin cancer and cataract attributable to solar UVR (F. Pega, WHO, Switzerland)

This WHO/ILO project is designed to estimate the work-related deaths and Disability Adjusted Life Years (DALYs) from UV and is being conducted with ICOH and INAIL (National Institute for Insurance against Accidents at Work, Italy). The researchers are performing systematic reviews of occupational exposures to UV, and the effects of occupational exposure to UV on cataracts and skin cancer, to determine the overall burden of disease. The work is co-funded by the ILO with external grants from other organizations such as CDC and NIOSH, with in-kind contributions from national experts.

### **Break-out groups**

The meeting broke into five groups to discuss UV issues and national experiences, and report back to the meeting on how WHO can help increase information and outreach regarding UV radiation protection. Feedback on this question is summarised below.

- WHO could act as a searchable repository of information on UV matters a central database like the GHO database on sunbed legislation around the world. The type of information held could include links to national information, and links to projects on topics such as shade provision.
- Publicise successful communication practices and strategies for making the public aware of UV risks, protection, targeting different population groups.
- Update the EHC on UV to take account of recent IARC conclusions, but also look at other health outcomes as some (e.g. cataracts) are of more interest to some countries (e.g. Asian countries) than skin cancer.
- Promote research and risk assessment of effects in non-European populations (e.g. African, Asian), including outcomes other than skin cancer (e.g. effects of blue light from screens).
- Use WHO's influence to promote regulation of sunbeds.
- Help States understand which behaviours should be changed to promote UV protection, and how this can be achieved. Share material that has been successful.
- Use proactive communication (e.g. on social media) rather than passive website.
- Provide a framework for States to evaluate the cost-effectiveness of different interventions

for UV protection (like that available for radon). This should consider non-cancer outcomes, and include the option of no action.

- Publish a UV research agenda.
- Maintain and update the GHO pages on sunbed legislation as this is a valuable resource.
- Formalise the translation of WHO documents on UV.
- Assist with the communication of information about the UV index, including consideration of Vitamin-D in sun-protection messages.
- Expand the Intersun programme to include visible light and cosmetic applications.
- Provide WHO recommendations on the regulation of UV and optical radiation.

The exercise was well-received, as it made people talk more to each other and obtain different perspectives. There was a suggestion that future exercises like this should have pre-allocated groups to increase efficiency.

Dr van Deventer reminded countries to update their national UV information pages and invited them to send annual UV country reports. The Sunprotection list server is available for providing feedback and publicising new publications. Membership is restricted and should not include the sunbed industry. Emilie asked whether webinars would be of interest and invited participants to propose topics. A WHO statement on Vitamin-D could be prepared but would require funding from Member States.

## **Optical radiation**

<u>Challenges and opportunities of enlarging the scope of the InterSun project for public health</u> interventions (J. O'Hagan, Public Health England, United Kingdom)

John O'Hagan gave a wide-ranging presentation exploring the issues around both UV and visible radiation and health. Intersun was formed in response to concerns about environmental UV but the scope was later expanded to include sunbeds. Now people are more aware that some UV is needed to maintain good health.

Public health issues with visible light have long been recognized. Compact fluorescent lamps and now LEDs have given rise to new public concerns. Tests on LED lamps, however, have shown that they produce less blue light than incandescent lamps or than is present on a sunny day. Poor design of LED street lights has caused problems with glare. There has been some poor journalism about device screens and LED lights.

Malicious use of laser pointers (e.g. for targeting aircraft) is also a problem.

The CIE has published a draft Standard on measuring light exposure considering the responses of all photoreceptors. This could be useful in studies on, say, shift work where the usual 24-hour light/dark cycle is disrupted. However, the standard does not propose how doses from the different receptors should be combined. Blue light is known to affect the circadian rhythm. Temporal light modulation affects some people more than others. Flickering, even at high rates, can confuse the brain and produce blurry images when moving the head, and the effects can be serious in affected individuals. The CIE has a research forum on the topic. It is thought that the increase in myopia might be caused by people spending insufficient time

Discussion after the presentation noted that:

outdoors using distance vision.

 In response to questions Dr O'Hagan said he felt that some organization should look at the benefits and detriments of light across the full spectrum. About LED lighting, in his opinion, there is no risk. A risk might only arise through staring at an LED light for a long time.
 Many of the current perceived problems are due to LED lamps being designed by electronics companies, not lighting companies - we don't like bright lights in our faces.

- There was general agreement that it would be good for Intersun/the UV IAC to cover the full optical spectrum (including lasers), but concern about trying to do this with limited resources.
- Lighting can be compared to sound there are sounds we like and sounds that we don't like. It can be difficult to cover a topic where the personal response may form part of the answer.
- In Italy there has been a review of the literature on macular degeneration from blue light with the conclusion that there is no effect (although an effect is seen for sunlight).

In response, Emilie van Deventer noted that it would make sense to include all optical radiation, but that WHO is short of staff and funding. However, WHO works in partnership with other organizations, especially ICNIRP, who are working on statements in this area. ICNIRP commented that their statements should be completed next year.

### **Recent developments**

<u>Summary of the 4th International Conference on UV and Skin Cancer Prevention</u> (*C. Sinclair, Cancer Council Victoria, Australia*)

There have been many successes in skin cancer prevention, such as less indoor tanning and good evidence supporting the cost-effectiveness of prevention. Policy development is rarely linear, and we must grasp opportunities when they arise. The impact of a personal story (as well as evidence) on policy development can be important.

Technology is providing new opportunities for skin cancer prevention/early detection. Intermediary organizations, such as workplaces and schools, provide good opportunities for skin cancer prevention. There is good evidence supporting methods to prevent skin cancer — but they need government buy-in. The barriers for government intervention include the long delay between investment and outcome. A small sector is pushing for reform, and there is a risk that this could be only a "summer" issue and, despite the cost, as not a big health issue. There is also a risk of confusion by Vitamin-D advocates.

Solarium use and risk of melanoma: what is the controversy? (*P. Autier, IPRI, France*) Two recent papers criticised the SCHEER 2016 report and WHO 2017 artificial tanning devices booklet. Autier *et al* wrote a response, but the journal did not publish it. In one of the critical papers, the authors found the same results as previous authors, so their criticism is hard to understand. In the other, SCHEER and the WHO were accused of cherry-picking the evidence, and the paper made some assumptions unsupported by evidence (for example, that suberythemal exposures may be protective). Regarding the Vitamin D issue, the article does not at all mention comprehensive reviews and meta-analyses showing that around 600 randomised studies published so far generally found no favourable effects of vitamin D supplementation on chronic (e.g., cancer, cardiovascular diseases, diabetes) and acute diseases. Autier et al will try to get their response published elsewhere.

### Open mike from international and national optical experiences

<u>Update on Norwegian national UV/skin cancer strategy</u> (*L. T. Nilsen, NRPA, Norway*)

Despite its high latitude, Norway has a high incidence and mortality of skin cancer. A working group was set up to develop a strategy to reduce skin cancer. This is currently in draft form and has four strategic goals:

- Prevention in management and administration
- Increased knowledge and awareness regarding prevention (as Norwegians like to tan) -

this will cover schools and universities, and increase training for doctors on detection

- Consider stricter sunbed regulations
- Earlier detection of skin cancer

<u>Update from the International Commission on Occupational Health (ICOH)</u> (*F. Gobba, Italy*) The December 2017 ICOH meeting in Helsinki, Finland, covered solar UV and occupational diseases. There were also two solar UV sessions at the 2018 ICOH Congress held in Dublin, Ireland. All presentations have been published.

## Australian sunscreen summit (R. Tinker, ARPANSA, Australia)

The "Sunscreen Summit", hosted at the QIMR Berghofer Medical Research Institute in Brisbane, Australia was held on 19-20 March 2018 and brought together 100 stakeholders who provide advice to the public and workers to create sunscreen policy. Currently there are a lot of inconsistent policies. The summit considered the effectiveness of sunscreen, and barriers to using it (e.g. Vitamin-D concerns, use of nanoparticles).

# The proposed policy says that sunscreen:

- Should be used every day as part of morning routine
- Should be used with other measures and reapplied every 2 hours.

# <u>Update on Swiss sunbed regulations</u> (E. Stempfel, FOPH, Switzerland)

A June 2017 law allows regulation of sunbed use. Public consultation on regulations has just ended, with 200 submissions. The Ordinance covers sunbeds, laser pointers (>1M), laser shows, sound shows, certificates of competence for cosmetic use of IPL, and ultrasound. Provisions for sunbeds include a ban for minors, a duty of operators to warn of risks, and a 0.3 W/m² irradiance limit. Submissions are now being analysed, with implementation planned for 2019.

## CDRH/FDA update (S. Miller, US FDA, USA)

In 2014 sunbeds were reclassified from Class 1 to Class 2 devices, which requires premarket application before they can be sold. This change is now effective, along with a 10% tax on tanning sessions. Sunbed manufacture has decreased by 50% since then.

At the end of 2015 it was proposed to restrict access to sunbeds for under-18s and update the sunbed performance Standard. To date there has only been slow progress on this proposal. The CDC website on sun safety has been updated, and CDC continues to monitor behaviours related to sun safety. There has been progress on regulating the types of sunscreen that can be sold.

In response to a question about the effectiveness of the 10% tax, Sharon said that she had not been involved in work looking at this, and that the decrease in activity of the sunbed industry was perhaps more related to the economy. Industry is lobbying for the tax to be discontinued.

### Others (C. Sinclair)

Craig noted that Ireland has implemented a tax on solaria. Ireland are strong advocates for a ban but there are EU implications.

### **UV** session

## Recent developments on occupational activities

Sunbed regulations in Belgium: what are the legislative options? (B. Boonen)

In Belgium there are 37,000 new cases of skin cancer per year. 20% of Belgians will develop skin cancer. Sunbeds are widely used but this is decreasing. There are 1154 registered operators, but probably a grey market as well. Before 2016 (when a ban was recommended), there was a ban on under-18s, people with skin type I or who had had skin cancer, and on people taking sensitising medications. There was also a limit on the effective irradiance. In 2017, additional requirements were put in place: operators make no claims of benefits from a sunbed and must display a warning that sunbeds cause skin cancer. In 2019 there will be new requirements (despite the efforts of the sunbed industry) for medical certification of skin type and personal electronic ID for sunbed users. A ban was recommended in 2016.

An inspection survey in 2017 found that 71% of operators do not comply with the law. Several campaigns against sunbed use have been undertaken – operators went to court to try and stop one of these but were unsuccessful.

In the EU, sunbeds must comply with the low voltage directive and the 60335-2-27 technical Standard. This Standard requires product safety but does not specify safety of the services provided. Lobbyists use various strategies to work against sunbed controls (e.g. reassurance, litigation, etc).

Several options for further sunbed controls have been investigated. EU law would probably prevent a ban and attempting to ban tanning centres would have an uncertain outcome. Another possibility is taking legal action against the State for not taking sufficient action to protect the population – while this would also have an uncertain outcome it would generate a lot of publicity. Alternatively, there could be legal action against operators – this would require evidence of a link between UV from a sunbed and skin cancer and would best be taken by a person with cancer caused by UV.

Occupational skin cancer. Progress and pitfalls in the current EU legislative process, occupational UVR-exposure measurements and the ICD11. (S. M. John, ILDS)

Currently there is uneven reporting across the EU of skin cancers as occupational diseases. In Germany skin cancers are >10% of all occupational diseases notified. The risk of an outdoor worker developing skin cancer is 80-100% greater than the general population, and more recent data suggests it could be 300% higher. The UV doubling dose for KCs is about 6,500 SED.

ICD-11 was released in June 2018. It allows coding whether skin cancers have been caused by occupational exposure as a main factor or co-factor. This is an important step in helping reveal the causes of these diseases. The ILO is preparing guidance notes on diagnostic and exposure criteria.

EU COST Action TD 1206 is developing EU Standards on the prevention of occupational skin diseases. This will include patient notification forms for use where skin cancer is caused occupationally and help increase awareness of the role of UV. These are minimal Standards for helping prevent skin cancers − workers need education as most are poorly informed. Other activities are also in progress to ensure that the EU is aware of the role of UV in occupational skin cancer as there is currently poor recognition of this despite the huge health burden from skin cancer in the EU (about €36B/year). Occupational health specialists would

like environmental UV to be included in the 2006 EU Optical Radiation Directive (which currently only considers artificial sources).

Measurement campaigns show that the maximum recommended exposures of 1 SED/day are often exceeded by a factor of 5 or more – this would not be tolerated for other carcinogens. A very recent meeting considered the inclusion of KCs in cancer registries. At present this is only done in 12 countries. After developing one KC another is likely to be developed within the next year or so. The EU GDPR do not help cancer registrations. It is strongly recommended that population-based cancer registries are developed, and KCs are recorded.

### Joint UV/EMF session

## Opening of the meeting

Opening remarks (Dr M. Gobec, Director General of Directorate of Public Health at the Ministry of Health of the Republic of Slovenia)

Dr Gobec welcomed participants on behalf of the Slovenian Ministry of Health. She noted that NIR is an important topic, and the importance of up-to-date information on the subject. Good evidence is needed to respond to the public's interest in NIR.

Craig Sinclair thanked Dr Gobec for the welcome and the Ministry's support for the meeting.

Participants introduced themselves.

## International standards for Non-Ionizing Radiation (NIR) Protection

Overview of the project and goals of the day (R. Tinker)

Rick Tinker provided the background for the NIR Standards project, which was initiated after the request of a Member State in 2012. This project has been discussed since 2014 in the annual meetings of the WHO International Advisory Committee (IAC) on Non-Ionizing Radiation. In the 2017 IAC meeting, the draft structure of the NIR basic safety Standards along with the potential main recommendations were presented and discussed.

An example of regulatory framework can be found in the area of ionizing radiation with the IAEA International Ionizing radiation Basic Safety Standards (BSS) which have been developed as a collaborative approach between eight international organizations (EC, FAO, IAEA, ILO, NEA, PAHO, UNEP and WHO), and reflects member States' interest in clear guidance based on harmonised Standards. Similarly, the intention is to develop international Standards for NIR that reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of non-ionizing radiation. The target audience of these voluntary Standards includes policy makers, radiation regulators and relevant employers. The scope of the project covers the non-ionizing radiation (NIR) spectrum, including electromagnetic radiation (from static field to optical radiation), as well as acoustic radiation (ultrasound and infrasound), in line with accepted definition (e.g. ICNIRP, FDA). There is an analogy with the approach for IR, in which the scientific basis (e.g. from UNSCEAR) leads to recommendations (philosophy, principles, dose criteria etc) from the ICRP, which form the basis of the IAEA Safety Standards for IR (safety requirements in regulatory language) to national regulations. The equivalent in NIR are the WHO reviews (scientific basis), ICNIRP/ICES/CIE etc recommendations (philosophy, principles, limits etc), the proposed International Standards for NIR (safety requirements in regulatory language) and national regulations.

A core group convened by WHO developed draft Fundamental Safety Principles (along the IAEA

IR model) but following feedback from the IAC this work was postponed in favour of development of the International Standards for NIR.

The proposed structure includes an introduction, general recommendations, and then recommendations for public, occupational and medical exposures for all types of NIR. The recommendations for each group will cover several areas (e.g. assign responsibilities, exposure and risk assessment, compliance and market surveillance, considerations for specific areas, etc).

Applications of non-ionizing radiation on humans: The German Draft National Regulations (*B. Keller, Ministry for Environment, Nature Conservation and Nuclear Safety, Germany*)

Germany has drafted regulations regarding cosmetic and other non-medical applications of devices that apply NIR to the body for commercial purposes. They do not apply to medical uses or UV radiation equipment. The types of device to which the regulations apply, based on, for example, power output, laser class or the exposure they produce, are defined. The regulations require specific training for some types of use (e.g. use of lasers in beauty therapy, magnetic field stimulation for fitness applications) and some uses are restricted to medically qualified people (e.g. ultrasound for adipose tissue reduction, laser for tattoo removal). The training requirements are yet to be defined.

<u>Break-out sessions on Public, Occupational and Medical Exposures</u> (Facilitators: R. Tinker, E. Karabetsos, J. O'Hagan)

Rick introduced the programme of the day which consisted of plenary and parallel sessions focusing on key exposure categories. The main goal was to provide an opportunity for individual and collective feedback and to ensure transparency. The objectives of this session were to (i) share the current work of the Core Group, (ii) gather knowledge from different country experiences, and (iii) identify gaps and further opportunities.

The participants were assigned to one of three groups based on their expertise in order to ensure coverage of the different exposure categories (public, occupational and medical) and NIR modalities (EMF, optical and infra/ultrasound). The three groups, of around 20 people each, included a facilitator and a rapporteur.

Three break-out sessions were scheduled, one for each of the three exposure categories (public, occupational and medical). Each session followed a similar pattern with two steps. First, participants were asked to provide a quick and short answer to a set of questions (on Post-It notes) to collect views and opinions from different countries. The questions are provided in Table 1.

## Table 1. Post-It notes exercise

## **Public exposure session**

- What are the top 3 consumer products that present a challenge in your country?
- What are the top 3 sources of public exposure which are not consumer products that present a challenge in your country?
- What would be the 3 main opportunities for your country from international guidance on NIR protection?

## Occupational exposure session

- What are the top 3 occupational activities that present a challenge in your country?

- What are the top 3 sources of occupational potential over-exposure that present a challenge in your country?
- What would be the 3 main opportunities for your country from international guidance on NIR protection?

# **Medical exposure session**

- What are the top 3 medical activities that present a challenge in your country?
- What are the top 3 non-medical (e.g. cosmetic) products/activities that present a challenge in your country?
- What would be the 3 main opportunities for your country from international guidance on NIR protection?

Second, at the beginning of each session participants were provided with a questionnaire to be completed and returned by the end of the session. The questionnaire included the proposed Standards for each exposure category (Table 2). The participants were required to rate the relevance of each Standard within their country using a Likert scale (Low/Medium/High) and invited to add any further comments/proposals. A group discussion was then scheduled to gather individual and collective views.

# **Table 2. Proposed Standards**

## **Public exposures**

- Responsibilities of the government, governmental bodies, manufacturers/supplier, etc.
- Determination of exposure and assessment of risks
- Exposure limitation
- Exemptions
- Compliance and market surveillance
- Information, education and training
- Environmental monitoring and recording
- Arrangements for protection of specific subpopulations
- Specific arrangements for solar radiation
- Cosmetic applications using medical NIR equipment for purposes other than medical

### **Occupational exposures**

- Responsibilities of the government, governmental bodies, employers, workers, manufacturers/suppliers, etc.
- Determination of exposure and assessment of risks
- Exposure limitation
- Exemptions
- Compliance by employers and workers
- Information, instruction, education and training
- Incident investigation and feedback
- Monitoring and recording of occupational exposures
- Arrangements for protection of specific subgroups of workers
- Specific arrangements for solar radiation

## **Medical exposures**

- Responsibilities of the government, governmental bodies, health care professionals and institutions, manufacturers/suppliers, etc.
- Information, instruction, education and training
- Justification of medical exposures

- Optimization of protection and safety
- Registration
- Monitoring device compliance
- Unintended medical exposures
- Investigation and feedback of information on operating experience
- Human imaging using NIR for purposes other than medical diagnosis, medical treatment or biomedical research
- Cosmetic applications using medical NIR equipment for purposes other than medical

At the end of the day each group gave a short presentation on their conclusions. Feedback from the groups is summarised below.

## Group 1

### **Public exposures**

Top 3 products presenting a challenge:

• Mobile phones, Sunbeds, Medical sources, Laser pointers

*Top 3 sources presenting a challenge:* 

• Sun, Power lines, Base stations

Benefits available through this process:

Broad themes are:

- Opportunities for improved regulation (gap-filling, clearer justification of regulations to ease implementation)
- Risk communication getting clear messages through to the public about scientific evidence and how the measures taken ensure their protection
- Raising public awareness of risks such as sunbeds, IPL and laser pointers.

There are different appetites for regulation in different countries. How do you provide a framework that is flexible enough to cover everything in NIR but still detailed enough to be useful? Maybe use a top-level document to call up more specific documents on particular issues.

#### Occupational exposures

Top three occupational activities posing a challenge:

- Working outdoors in the sun.
- Risk assessment is a key issue, but this needs to consider benefits linked to the work and reflect the national situation.
- There is a need for more evidence about cancer risks in countries with darker skinned populations to warrant any change in the way things are currently handled.

Top three sources with respect to over-exposure:

- MRI highly rated felt to be relatively recent technology, lack of long-term studies on health risks. A few procedures require clinicians close to the magnet.
- No issues identified with occupational ultrasound sources as it does not tend to propagate in air.

Three main opportunities

- Improve risk assessment make it holistic, tailored
- Risk communication and awareness
- Recording of exposures big data? Opportunities to carry out studies, but there are governance questions around monitoring individuals. Can still store exposure data

about the job with the risk assessment.

## **Medical exposures**

Top three medical activities posing a challenge:

- If public/occupational limits exceeded need to justify exposures (also need to optimise so that no more exposure used than necessary).
- Concern over possible over-use of ultrasound in pregnancy need to show that benefit exceeds harm.
- MRI, especially interventional and on foetus.

Top three non-medical (use of medical equipment) activities posing a challenge:

• Main issue around cosmetic applications – IPL/lasers/LEDs for hair removal, tattoo removal.

## Main opportunities:

- Evidence-based guidance to reduce risks
- Identify which treatments work and have good support from evidence
- Education and training of users manufacturer documentation may not be sufficient.

## Group 2

For public exposures, there are lots of similarities between different parameters. It is good for international organisations to develop a framework for allocating and coordinating responsibilities within the state.

There is a need for harmonised international guidance on exposure and risk assessment. Exposure limits need to be scientifically based and cover the whole spectrum. A gap analysis must be made (for example, infrasound and ultrasound are not currently covered). Reference levels are needed for public exposures, but for some exposures (e.g. solar UV) we may only be able to give guidance. We need to recognise that technologies evolve.

A regulatory framework needs exemptions. Evaluations should follow international guidance, and there should be criteria for market surveillance and this should include new technology. There should also be criteria for the application of the precautionary principle. For environmental monitoring there is a need for guidance on what should be monitored. Subpopulations (e.g. children) need to be considered.

### Group 3

#### **Public exposures**

Consumer products posing a challenge:

- Laser products, mobile phones, Wi-Fi, sunbeds, induction cooktops
- Non-consumer products posing a challenge:
- Base stations, UV and solar radiation, Powerlines, MRI, Wi-Fi, Welding, Blue light Expectations from WHO:
  - Harmonisation of exposure guidelines
  - Science-based recommendations
  - Support harmonised risk/hazard communication
  - Support member states in implementation of recommendations/guidelines
  - Clear quantitative limits

### Occupational exposures

Challenges in occupational activities

Outdoor exposures

- Medical exposures from e.g. MRI and UV
- ELF exposures from e.g. HV power lines and welding
- Base stations
- Lasers

### Occupational over-exposure sources

- Solar UV, RF from base stations and radar, Lasers, Welding, Induction heating Expectations from WHO:
  - Harmonisation of occupational exposure guidelines/recommendations
  - Recommendation on solar UV exposure levels
  - Support in risk assessment
  - Standards for protective equipment
  - Protocols to follow (over)exposure.

## **Medical exposures**

# Challenges in medical activities

- MRI and ultrasound
- RF ablation
- Laser surgery
- UV phototherapy
- EMF stimulation, medical UV

### Non-medical devices

- Laser treatments
- High intensity ultrasound
- Cosmetic UV treatment devices
- Transcranial stimulation
- RF/ultrasound treatment for fat reduction

### Expectations from WHO

- Standards for non-medical applications
- Clear definition of medical and non-medical devices
- Recommend ban on tanning beds
- Compile list of relevant equipment Standards
- Assess effectiveness of non-medical applications

## Next steps (R. Tinker)

The information gathered during this session will be used to better inform the next twelve months' work and develop the recommendations further. Today the building blocks have been presented, the next step is to build the rationale and details needed to establish Standards. At the next IAC there will be a draft available for review and feedback. There will also be a need for feedback from others, especially in the medical fraternity.

### Round up (E. van Deventer)

E. van Deventer thanked all participants for their active involvement and contributions. Feedback from the participants on the format of the meeting will be useful to inform future meetings.