Role of equipment manufacturers for preventing equipment faults and other errors, and providing specific training

Nicole Denjoy
COCIR Secretary General
1. What is DITTA
2. Industry Continuous Improvement in Radiation Safety
3. Technology evolutions and improvements in Nuclear Medicine towards reduction of dose
4. Equipment Obsolescence
5. Role of manufacturers in training and education
6. DITTA recommendations
1. WHAT IS DITTA?
DITTA is a non-profit trade association, created in 2000 and incorporated in 2012. It represents more than 600 companies around the globe.

DITTA covers the following industry sectors:
1. Diagnostic imaging,
2. Radiation therapy,
3. Healthcare IT,
4. Electromedical
5. Radiopharmaceuticals

Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle.
WHAT IS DITTA?

- DITTA membership is currently comprised of COCIR (Europe), JIRA (Japan), ITAC (Canada), MEDEC (Canada), MITA (United States), THAIMED (Thailand), IMEDA (Russia), CAMDI (China), ABIMED (Brazil) and KMDICA (Korea)
- DITTA includes more than **600 companies worldwide**
- DITTA enables participating associations and their member companies to work more effectively with international policymakers, organizations, professional associations and stakeholders. To support this work we have established **9 dedicated Working Groups**
- Since 2015, DITTA has the status of NGO in official relations with **World Health Organisation** (status renewed in 2018)
- In May 2016 DITTA signed a partnership agreement with the **World Bank** to support procurement of medical technologies
2. INDUSTRY CONTINUOUS IMPROVEMENT IN RADIATION SAFETY
PREVENTING ACCIDENTAL AND UNINTENDED EXPOSURES

- Prevention of accidents is a **shared responsibility involving regulators, users and industry**. Industry plays an important role.
- Industry continues to work with clinicians to design and develop technologies to constantly **improve patient safety**.
- **Industry has advanced in technologies to optimize dose to patients, minimize risks while improving image quality and safety features to avoid accidental or unintended exposures.**

Continuous Improvement via ISO 14971 Risk Management & QMS processes
DITTA supports the **Bonn call for action.** Manufacturers key engagement towards radiation safety:

1. **Improved safety** of medical devices by enhancing the radiation protection features in the design of both physical equipment and software and to make these available as default features rather than optional extra features;

2. Support the development of technical solutions for **reduction of radiation exposure** of patients, while maintaining clinical outcome, as well as of health workers;

3. Enhance the provision of **training tools and support for users** that is specific to the particular medical devices, taking into account radiation protection and safety aspects;

4. Address the **special needs of health care settings** with limited infrastructure, such as sustainability and performance of equipment, whether new or refurbished;

5. **Strengthen cooperation** and communication with appropriate stakeholders, such as health professionals and professional societies;

6. **Efficient communication with health and radiation regulatory authorities** and their representative organizations.
3. TECHNOLOGY EVOLUTIONS AND IMPROVEMENTS
Today, most PET or SPECT are performed on instruments that are combined with CT scanners. The combined scans have been shown to provide more accurate diagnoses than the two scans performed separately.

Example of PET CT Brain scan:

- PET CT scan demonstrates postoperative hypometabolic changes to the right frontal lobe. No residual tumor is seen.
- PET scans are useful for evaluating the efficacy of surgical procedures and locating cancers.
PET COMBINED WITH MRI

- PET/MRI combines the unique features of MRI with the quantitative physiologic information that is provided by PET:
  - excellent soft tissue contrast
  - diffusion-weighted imaging
  - dynamic contrast-enhanced imaging
  - fMRI and other specialized sequences
  - MR spectroscopy.

- PET/MRI is preferred when imaging Brain; PET/CT and SPECT/CT have additional clinical indications for cancers and other diseases. These hybrid studies are valuable for physicians and patients and are able to change outcomes more frequently when studies are combined with a FUNCTIONAL study (PET/SPECT) and an ANATOMICAL study (MR/CT).
Higher **sensitivity** means getting more counts per image, improving image quality. The only way to increase counts is to either give more dose or get systems to find the counts more easily (sensitivity).

- The **newer PET/CT cameras** (as we transition to full digital systems) have increased the sensitivity, improved volumetric resolution, decreased noise and improved quantitative accuracy compared to an analog systems.
- **Full convergence iterative reconstruction algorithms** have been designed to improve image quality and quantitative accuracy, enabling use of lower doses to find smaller lesions.
- **Use of PET/MRI** in place of PET/CT for certain clinical applications does not change dosing on the PET side, but may decrease on the Anatomy side depending on protocol.
- **Routine quality assurance and quality control** of all imaging instrumentation and optimization of imaging protocols ensures proper operation at the highest sensitivity and efficiency.
REDUCING SPECT DOSE

- Digital Detectors using the new crystal technology (CZT) rather than the traditional NaI (Sodium Iodide) have significantly improved sensitivity to the point where doses may be decreased up to 75%.

- Multi-detector CZT systems for cardiac imaging have decreased doses and scan times significantly. Cardiac is generally the highest-volume scan in Nuclear Medicine.

- Iterative Reconstruction algorithms have enabled half-time or half-dose imaging on most traditional SPECT systems without loss of image quality.
In the last couple years, all major manufacturers nuclear imaging scanner combined with CT have introduced technology that can lower the CT dose required to produce a quality exam.

• In combined imaging CT dose could be dramatically reduced compared to the diagnostic protocol. For these procedures, non-diagnostic or lower CT dose parameters may be used.
• Iterative reconstruction reduces CT dose from a typical 7 to 8 mSv down to 0.3 mSv when CT is not needed for diagnostic purpose.
• Bias and noise in CT can be controlled in an acceptable range without introducing artifacts through CT-based attenuation correction.
• Advanced CT dose reduction technology, noise reduction and extremely fast detection electronics.
• Automatic exposure control can reduce the dose by 20%.
• CT doses contributing to SPECT/CT overall procedure doses since the advent of faster, internal CT components.
List of CT dose management features developed by manufacturers as disclosed in the COCIR Voluntary Agreement with HERCA (2010-2017).

- Predefined Protocols for Adults and Children
- Dedicated Infant Imaging Mode
- Dose alerts and notifications (Dose Check)
- Automatic tube current modulation (AEC)
- Advanced tube and collimator design
- Dose Modulation Options
- Beam Shaping and modulation
- Dose efficient x-ray detection
- Image Reconstruction and Post-processing
- Dose reporting (DICOM Radiation Dose Structured Reporting)
A new frontier in image reconstruction is represented by the use of deep learning. New systems (convolutional neural network) are proving to be potentially better at reconstruction compared with previous methods for ultra-low-dose PET data.

Fig. 2. Overall architecture of our proposed network.
• The uptake of new technologies is slow
• Different density and age profile in different Member States
• Density slightly decreasing

**COCIR 2016 report on density and ageing profile**
5. MANUFACTURERS’ ROLE IN TRAINING AND EDUCATION

- The role of education and training is also an extremely important tool to ensure safety.
- Manufacturer’s training is designed to support customer facilities in an effort to improve operating knowledge and increase the skill level of personnel. These programs consist of a variety of delivery mechanisms such as:
  - **Hands-on and didactic training** to reinforce skills needed to operate equipment
  - **Operator Manuals** to demonstrate information on dose optimization tools and dose reduction strategies
  - **Information on dose** related displays, indices, and where dose information is located
  - **Onsite training**, classroom instruction, remote instructor-led training and observation, online tutorial self-help, telephone support, publications, seminars, peer to peer physician training, and industry association educational material.
6. DITTA RECOMMENDATIONS

1. Ensure continuous training and education of users
   ✓ It is the healthcare providers’ responsibility to assess and maintain their equipment, their own staffs’ competency and to liaise with the relevant manufacturers for their training requirements as well as to enable their staff to participate to training and education

2. Adopt the latest technologies
   ✓ DITTA encourages healthcare providers to adopt the latest technologies, which provide the opportunity to improve quality, efficacy, patient safety and productivity. Currently, most purchase decisions are price-driven and fail to consider any ‘incremental value’ the technology or method provides

3. Replace obsolescent equipment that cannot be upgraded
   ✓ DITTA calls upon national and regional governments and policy-makers to support replacing technologically obsolescent equipment that cannot be upgraded to ensure comprehensive, coherent and sustained investment

4. Support smart and transparent procurement
   ✓ Support smart and transparent procurement processes are in place and include maintenance/servicing as well as training of users, to ensure fair competition

Industry remains committed in improving culture in radiation safety in healthcare by continuing to innovate and partner with regulators and clinicians.
THANK YOU!

www.globalditta.org