WorkGroup 4

Q1: Technical development in nuclear medicine: how to instil radiation protection from the outset

Workgroup 4 participants

- Research reactors
- Early stage manufacturing
- MPE (hospital)
- Radiobiological research
- Regulatory body
- Dosimetry

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Does radiation protection/ALARA need more consideration in the development of new radiopharamaceuticals?

- **Lack of data**: for both patients and workers (radio)biological data is missing
- NM is at the same stage in **evolution** as radiotherapy in the 1950-1960 (‘lost in translation’). Also available resources at the moment much lower in NM than in RT.
- When dosimetry is concerned in NM do we need to be precise? Also here lack of data to answer the question.
- What is driving optimization?
  - Interest of companies, selling point
  - Reduction of dose in diagnostics accomplished, not yet in NM

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Problems encountered

- **Lack of involvement MPE** in radiopharmaceutical production
- Need for proper **dose calibration and metrology**
- Relation with proper physical measurements (activity)
- Lack of appropriate software for (patient) dosimetry

Are more regulations for development and research with new radiopharmaceuticals required?

- What about the **environment**?
  - Activity applied to patients ends up in environment: Is this ALARA?
  - Regulatory decisions required
- **Waste problem**: long-lived contaminants in radiopharmaceuticals (like 177m-Lu)
- Limited volume of decay tanks in hospitals
- Use of alternative radionuclides renium instead of 131-I less activity required: biological evidence is lacking
- Field of NM is growing: need for **collaboration in EU**
- **NM-specialised MPEs**: differences in EU: **harmonisation**?

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Improvement required

Workers:

- increase ALARA for new radiopharmaceuticals (alpha-emitters)
- More data needed on exposure of different parts of the body prior to putting it on the market
- Scale enlargement may also increase dose for workers
- **Accurate measurements** important for dose of workers

MPE

- MPE only involved at late stages of drug development as is radiobiology
- MPE not recognised as health professional in some countries

Waste

- Waste problem in animal research, mixing of radionuclides
- Use of alpha-emitters
- Waste: new radiopharmaceuticals and impurity

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Improvement required

- More **holistic approach** required:
- taking into account the whole chain from development to production, application in the patients and finally to waste.
- A social debate is required
- ALARA seems to be competing with beneficence of the patient, this slows down the process

- **RP and patient dosimetry should be considered in development of new radiopharmaceuticals**
  - Role of pharma
  - Prioritisation
  - Alpha versus beta emitters: different labs

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- Theranostic (therapeutics+diagnostic) techniques are on the rise. Is RP considered from the outset?
  - Depends on the **stage** in drug development. After production radioisotope (also requires RP), research is conducted by other institutions.
  - Oversight complete process necessary. Promote **provision/exchange of information including RP** to next phase. Is not in place. Are developed by recipient, challenges for actinium-225. Role for pharma-industry? May give conflict of interest. **Collaboration between institutions.**
  - Take RP up in procedures (SOP) in research field. Also needs to be included in thesis/PhD thesis: separate chapter on RP.
  - Include in project descriptions (required in UK). Permission required prior to use of RN.

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Who should/could instil RP in nuclear medicine: the manufacturers, a regulatory authority, professional associations, ... ?

- Joint effort; difficult
- Requirement of undertaking, delegated to RPE, depends on license (broad/restricted)
- Dosimetry for patients, push manufacturers? Example Luthatera, fixed dose.
- Posology, patient specific? Easier in small scale radiopharmaceutical production (Holmium) based on dose calculated by MPE/NM-specialist.
- Need for **specialised software** for dose calculation.
- RP for worker or for patient should be given as soon as data is available.

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Who should/could instil RP in nuclear medicine: the manufacturers, a regulatory authority, professional associations, ... ?

- Dosimetry should be possible even if information is confident, until product is placed on the market.
- How to deal with uncertainty? Measurements, risk of contamination. For example, RP in use of 225Ac and ingestion/inhalation.
- Role of **regulatory body**? May be too strict. Should be involved **early in the process.**
  - Soft/coaching auditing? Equal level playing field. Inclusion in clinical trials.
- **Ownership of risks**. Awareness?

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Recommendations

radiation protection/ALARA need more consideration in the development of new radiopharamaceuticals

For patient (and workers: exposure risk)

- More (radio)biological data is required to understand the way radiopharmaceutical works
- **MPE** should be involved in radiopharmaceutical production
- Acurate measurements of activity as well as personalised dosimetry are needed. Requires the development of specialised dosimetry software.
- Use a **Holistic approach**: taking into account the whole chain from development to production, application in the patients and finally to waste. A social debate is required.

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Recommendations

radiation protection/ALARA need more consideration in the development of new radiopharamaceuticals

For patient (and workers: exposure risk)

- Be aware of waste problem: long-lived contaminants in radiopharmaceuticals (like 177m-Lu) in environment
- Promote **provision/exchange of information including RP** throughout development radiopharmaceuticals>
- Adequate RP-training at all stages of radiopharmaceutical development and use, for all individuals, including the patients needs to be provided.