Member-state field report and good-practice examples

Czechia

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**Table of content**

- Disclosure
- Introduction and Background
- Czech Legal Framework and Implementation
- Active Scientific-Regulatory Collaboration in Czechia
- Research
- Dosimetry - State of the Art
- Current Challenges and Future Outlook
Disclosure

• I hereby declare that I have no relevant financial or non-financial interests to disclose in relation to the subject matter of this meeting. This includes, but is not limited to, any personal, professional, contractual, or financial relationships that could be viewed as a potential conflict of interest.

• Some of the information presented in this document is derived from the project TITOSUJB907, which has been supported by the Technology Agency of the Czech Republic (TAČR).
Disclosure

• Some information might be unsettling, as it turns out that some of the procedures we are now initiating have actually been implemented before. Yet, through a series of almost theatrical turns of fate, a sort of comedy of errors, these key pieces of information were lost in the ether, never adequately passed on, whether due to complex interpretation of results or the impossibility of in-depth data analysis.

So here we stand, paradoxically ready to start again, almost as if we were writing our own farcical version of 'reinventing the wheel'. And some shout that it's spinning and there's no need to find out why it squeaks when our ears are plugged. Smearing the whole wheel with oil might not...
Introduction and background

• The dosimetry used to be set up in treatment planning long time ago
Introduction and background

• Treatment planning was done in accordance with dosimetry results originally
Introduction and Background

- 2014 – 2016 preparation of new legislation SÚJB (State Office for Nuclear Safety)
- SÚRO (National Radiation Protection Institute)
  - SÚJB support though no experts on NM (2016)
- Reflection of 2013/59 Euratom issues
  - terminology: Dose [Gy] / „Dose“ [MBq] / Activity
  - Science VS Fiction - treatment is planned individually though not the right „Dose“
  - Why should be anything changed?
  - Dosimetry is just a chimera
Introduction and Background

• Council Directive 2013/59/Euratom

• 2014 – 2016 preparation of new legislation (Atomic Law) SÚJB (State Office for Nuclear Safety)

• 2016 a new Atomic Act, came into effect in 2017.
  • legislation notably incorporated the requirement for dosimetry in nuclear medicine
  • Professional community „MUST averse“ effect – justification, reimbursement, HR

• Much closer collaboration became inevitable
Czech Legal Framework and Implementation

• Atomic Act: Act No. 263/2016 Coll., atomic act

• Decree No. 422/2016 Coll., on radiation protection and security of a radioactive source (official transl.):
  • For medical exposure of patients for radiotherapeutic purposes, including the therapeutical applications of radionuclides, exposures of target volumes shall be individually planned for every person undergoing the treatment and their delivery appropriately verified taking into account that doses to non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.

• The “Czech” version: MUST
The position of Czech NM Physicians

• Council Directive 2013/59/Euratom does not reflect the clinical reality in the Nuclear Medicine as it is mainly formulated for the purposes of external radiotherapy.

• The role wide-scale applied dosimetry in the radionuclide therapy is questionable:
  • missing individualisation based on patient, disease characterisation, and type of therapy
  • lack of reliable, reproducible methodologies
  • demanding logistics of current dosimetric procedures (time, costs, reimbursement)
  • limited healthcare providers’ capacity to perform complete dosimetry in every patient with direct influence the availability of the care
  • lack of reliable data supporting the need of dosimetry planning in the view of potential clinical impact
Czech Legal Framework and Implementation

• Literally strict obligation x Simply recommendation
• Individualisation considering real clinical impact on treatment outcome, patient will and actual health condition!

• Centralisation and international recommendation and studies were expected
• Small-scale projects on dosimetry 2016 -2018
  • basic SUJB recommendation and recherche BETA (2017 – 2018)
Active Scientific-Regulatory Collaboration in Czechia

• The issue was underlined on several local conferences

• 2017 SÚRO established Working Group in Nuclear Medicine
  • physicists, physicians, inspectors and SÚRO researchers included
  • multidisciplinary approach, elevating safety standards and optimizing dosimetric practices to prevent future problems

• Based on seminars and discussions SÚJB:
  • financially supported small-scale projects on dosimetry
  • few bigger grant request (Ministry of Health) were rejected
  • seek for larger scale solution

• The Czech Society of Nuclear Medicine (ČSNM) collaborating with Working Group for Nuclear Medicine and SÚJB and developing positions and statements
Active Scientific-Regulatory Collaboration in Czechia

• 2018 – 2019 ČSNM statement on BETA version of recommendations (2017)
  • 131I for benign thyroid use – dosimetry not required (MUST be reasoned why not, fixed activity to be justified by physician)
  • 131I for DTCA dosimetry not required (MUST be reasoned why not), recommended for young patients and generalized illness
  • In general – physician responsibility

• Lack of solid data in favor and reasoning of dosimetry

• Few dosimetry done in general
Active Scientific-Regulatory Collaboration in Czechia

• The problem is to get it paid

• Cooperation of SÚJB and ČSNM
  • Dosimetry reimbursement in the Czech Republic has been actively addressed by professional societies, leading to its formal integration into healthcare practices. This development reflects the collaborative efforts of various stakeholders in standardizing and recognizing the importance of dosimetry
  • Signal (DRG) codes were set up (are being used in case of dosimetry) / for statistical purpose only till today

• Still not solved
Research 2019-2022

• Technology Agency of the Czech Republic (TAČR) supported project TITOSUJB907

• Main goals:
  • Foreign praxis analysis in planning and verification for therapeutic I131 and Y90 administrations
  • Optimized procedures for planning and verification in the administration of radiotherapy with I-131 and Y-90
Research Foreign Praxis Analysis (2021)

- Article 56 of Directive 2013/59/EURATOM is generally not emphasized
- Wider recommendations in general still under preparation
  - Some released during 2021-2023
  - Limited clinical procedure (still improving)
- Some procedures can be locally adapted
  - Best praxis X Summary of Product Characteristics
- For ongoing radionuclide therapies
- dosimetry **larger scale study** inevitable
Research - Prospective Study

This project has received funding from the European Commission under Service Contract N° ENER/2022/NUCL/SI2.869532.0
Research - conclusion

• Due to collaboration more dosimetry was done and more physicians are willing to require it
• Some treatment procedure deviates – lower treatment effectivity
• Still a lot of work to do
  • few data for fine statistical analysis
  • treatment schedules differ
  • dose calculation is better estimation
• Local dosimetry guide prepared
• Data gathered, reanalysis and dose effect study can be done!
Current Dosimetry State of the Art

- Benign thyroid – planning, verification very limited
  - patient will and wealth
- $^{177}$Lu – 1$^{st}$ cycle 6, 24, 48 h; 72 or 168 h kidneys, WB all cycles

- $^{131}$I mIBG – for children, adults only limited

- $^{131}$I DTCA – limited (targeted tissue, WB – met. dissemination)
  - 2 out of 5 dept. planning and limited verification
Current Challenges and Future Outlook

• Reimbursement of current dosimetry studies
• Physicians vs Physicists
  • optimisation respecting the providers’ capacities and patients’ comfort
  • obtaining data for individualization and treatment optimization
• New therapies – Shouldn’t dosimetry be obligatory till final recommendation?
• Ethics
  • blinded study radionuclide treatment vs placebo
  • may dosimetry limit the access to the healthcare? The cost-benefit must be thoroughly evaluated
Current Challenges and Future Outlook

• Out/ inpatient challenges in waste management persist and are currently being addressed

• General radiation protection principles are questioned (increasing number of patients, public burden increment)

• Inconsistency in approaches to new therapies

• Unified guidelines and a collaborative international effort to streamline practices in nuclear medicine (current, tested and planned radionuclide therapies including dosimetry) needed / thanks for
Conclusion

Personally: The way to the hell is lined straight. Though Dosimetry in Nuclear Medicine is akin to navigating a minefield marathon; at any moment, you're just a step away from detonating a complex problem or setting off a chain reaction among other stakeholders (non unified historically based treatment scheme, limited finance, HR problems etc.)

• Unified guidelines and a collaborative international effort to streamline studies, research and practices in nuclear medicine is required including current treatments and all the new ones
Thank you for your attention

I would like to conclude this presentation by extending my heartfelt gratitude to everyone involved in this collaboration (SÚJB, SÚRO, ČSFM). A special thank you to my colleagues from TITOSUJB907 for their invaluable collaboration and to our co-researchers for their hard work and dedication, which were instrumental in achieving our goals. I also wish to express my appreciation to the participating hospitals for providing the essential data that made this research possible.
This project has received funding from the European Commission under Service Contract No. ENER/2022/NUCL/SI2.869532.

Bonuses

patient 13

\[ \frac{A_{therap}}{A_{diag}} = 110\% \]

patient 14

\[ \frac{TIA_{therap}}{TIA_{diag}} = 56\% \]

patient 15

\[ \frac{TIA_{therap}}{TIA_{diag}} = 56\% \]

patient 16

\[ \frac{TIA_{therap}}{TIA_{diag}} = 83\% \]
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**Bonuses**

![Graph showing normalized accumulation over time with fitting parameters for diagnostics and therapy.]
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Bonuses

- **diagnostics fit parameters**
  - $A_0 = 0.44$
  - $T_{ef} = 5.27$
  - $T_{up} = 0.18$

- **therapy fit parameters**
  - $A_0 = 0.26$
  - $T_{ef} = 30.16$
  - $T_{up} = 0.1$

![Graph showing normalized accumulation over time](image)