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Constant improvement in quality and safety of radiology, radiotherapy and nuclear medicine through clinical audit

QuADRANT

D2.4: WP2 Workshop Report

February 2021

Start date of project:	December 27, 2019	Duration: 30 months
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	Review by all consortium members	
For the attention of:	European Commission, Directorate General for Energy, G. Simeonov	

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List of contents

Abbreviations

AB	Advisory Board
EC	European Commission
EANM	European Association of Nuclear Medicine
ESR	European Society of Radiology
ESTRO	European SocieTy for Radiotherapy and Oncology
HERCA	Heads of the European Radiological Protection Competent Authorities
IAEA	International Atomic Energy Agency
SG	Steering Group
WHO	World Health Organization
WP	Work Package

1 Introduction

The Work Package 2 (WP2) workshop was held as a series of webinars on 14th, 15th, and 16th December 2020 and was one of two workshops that will be held as part of the QuADRANT project (the other will be held in January 2022 as part of Work Package 4 (WP4)).

The aim of the WP2 workshop was to discuss with representatives of Member States the state of play of clinical audit in the EU27 (plus Iceland, Norway, Switzerland, and the UK) and raise awareness about the legal requirements and the benefits of clinical audit in diagnostic and interventional radiology, radiotherapy and nuclear medicine. The focus of the workshop was on presenting different comprehensive auditing practices to ensure safety and quality for patients rather than merely on equipment quality controls, on product safety of applied radiopharmaceuticals and contrast agents or on radiation protection practices.

During the first progress meeting, in June 2020, it was decided that the workshop should definitely go ahead in December 2020 despite the COVID-19 pandemic and it was agreed that a series of webinars would be preferable to a full 1.5-day online meeting should a face-to-face meeting not be possible. The webinar plan was subsequently modelled on the ESR's online congress, held from 15th-19th July 2020, in which pre-recorded presentations were mixed with live Q&A sessions.

The planning of the workshop was the responsibility of the WP2 team, consisting of Prof M. Brada (ESTRO) as lead, Dr A Brady (ESR) and Dr W. Wadsak (EANM) as co-leads and Prof D Howlett (ESR, Project Lead) with the support of ESR Office Staff (M. Hierath and J. Clark). This report details the workshop planning, content, and outcomes.

2 Workshop attendees

The first QuADRANT workshop aimed at bringing together Member States' health authorities, competent authorities for radiation protection, auditing organisations, the main medical specialties concerned and European and international organisations with experience in clinical audit (e.g. IAEA, WHO), who were invited to submit presentations.

In order to identify the appropriate contact persons within the various national and international authorities and organisations etc., a pre-survey was conducted as part of WP3. A pilot version of the QuADRANT pre-survey was circulated to consortium members on 26th February 2020 with a request to complete the pilot survey by 4th March 2020. The goal of the pilot was to test the functionality of the survey. Based on feedback received, minor amendments were made to the pre-survey.

The finalised pre-survey was then circulated by ESR, EANM, and ESTRO to members of their national societies in mid-March. The final pre-survey questions can be found in Annex 2. By 30th April 2020 responses had been received from all countries (albeit not explicitly covering all specialities) and the pre-survey was closed.

In total, eighty-seven responses were received to the pre-survey, plus seven to the pilot survey (questions were refined/amended before the final pre-survey was disseminated, but the pilot survey responses still include useful data).

For some countries (Ireland, Luxembourg, and Norway), only a single response was received. For other countries multiple responses were received (France, Hungary, and Italy generating the highest number of responses, with five each). Analysis revealed that, where multiple responses were received, some information appeared inconsistent. It also became apparent during analysis that in many cases the respondent had not given sufficient information for the establishment of a contacts list for the purposes of WP2. In many cases, only generic email addresses were provided.

On 1st July 2020, an email was sent to all the contact email addresses provided in response to the pre-survey requesting that they provide a personal contact within their agency for the purposes of the QuADRANT project. In some cases, the respondents suggested contacting different agencies and follow-up emails were sent accordingly. Follow up work continued throughout the autumn and a final list of persons to be invited to the workshop was generated (see Annex 1).

A 'save the date' message was sent out to identified contacts on 28th September 2020. This message included a request that anybody interested in giving a short (10-12 min) presentation of their national experience of clinical audit contact the project management office. This request generated responses from more countries than expected and the webinar programme was amended to accommodate them (see section 3).

Formal invitations to the workshop, including the finalised programme and a link to a Survey Monkey page for registration for the webinars, were sent out on 2nd November 2020.It was decided that registration would be required to facilitate the circulation of login details only to those that intended to attend the workshop. Reminder messages

were sent to those that had not yet registered two weeks and one week before the first webinar.

At the request of ESTRO, it was agreed with the EC that an invitation could be extended to chairs of relevant society committees. On this basis, the EANM invited the chairs of its Radiopharmacy Committee, Radiation Protection Committee, and Ethics Committee, as well as their Scientific Liaison Officer. The ESR invited its Audit and Standards Subcommittee members and selected EuroSafe Imaging contacts.

Ultimately, invitations were sent to 156 people by the ESR Office Staff. In addition, HERCA extended the invitation to their Working Group on Medical Applications. The EC invited members of the Euratom Article 31 Group of Experts (GoE), the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (SGPP), as well as EC staff members from within the DG Energy and DG Sante.

Ultimately, a total of 132 people registered to attend the workshop (see Appendix 1); however, some of those who registered did not actually attend the workshop or attended only in part (i.e. attended only one or two of the three webinars). Webinar 1 was attended by 110 people. Webinar 2 was attended by 86 people. Webinar 3 was attended by 80 people.

Of those that attended at least one webinar, 40 were contacts identified as part of the pre-Survey attempts to establish contacts within national Health Authorities (or other authority e.g. Environment Agency in the case that an alternative agency is responsible for clinical audit in the relevant country) or Radiation Protection Authorities, or otherwise identified by the pre-Survey as being a key player in clinical audit at the national level.

The following countries did not have national Health Authority or Radiation Protection authority representatives identified by the pre-Survey attending at any point in the workshop: Austria, Croatia, Cyprus, Germany, Greece, Hungary, and Poland.

Nevertheless, there were representatives from all these countries in attendance (except Cyprus) e.g. Boris Brkljacic (QuADRANT consortium member and workshop speaker) from Croatia and Anna Plachinska (QuADRANT Steering Group member) from Poland.

All other countries in the EU 27 (plus Iceland, Norway, Switzerland, and the UK) - i.e. 24 out of 31 countries - were represented by at least one Health Authority or Radiation Protection Authority representative in the workshop.

3 Workshop programme

According to the Inception Report, the workshop programme was to aim "to achieve as far as possible an understanding of the status of clinical audit in the member states, a clearer definition of the purpose of clinical audit in the [three] disciplines and to inform the final report on the guidance given with respect to future EU actions. In this respect participation by government bodies and auditing organisations from each member states will be invited, to include both presentation of best practice and abstracts providing examples of measures and outcomes which resulted in improved practice."

It was agreed during the Kick-off meeting that abstracts should not be requested due to limitations imposed by the length of the workshop. In subsequent discussions with the EC, it was agreed that the "Steering Group and Advisory Board might be asked for suggestions for presentations or if they have experiences they wish to share".

Following the first progress meeting and feedback to the draft first progress report from the EC, the workshop programme was circulated to the Steering Group (SG) and Advisory Board (AB)on 13th July 2020 and their input requested. This feedback is detailed in Appendix 2. At this stage, it had still not been decided to hold the workshop online. This decision was agreed with the EC in September 2020 and it was agreed with the EC that the webinar format would follow a mixture of pre-recorded presentations and live discussion rounds.

The workshop programme was then amended by the WP2 team and sent to the SG and AB for feedback. At this stage some concerns were raised by members of the SG and AB that they had not been provided with adequate time to provide their input. Subsequently two teleconferences were held on 8th October and 15th October to address these issues and discuss the WP2 programme in detail. During these discussions the final times for the webinars were agreed (extending the length of each webinar by 30 minutes from 15:00-17:00 to 14:30-17:00). Following the meetings, the programme was adjusted accordingly, and a revised draft circulated on 11th November 2020. All feedback from the SG and AB was incorporated, and the workshop programme went through a further round of revision following a teleconference with the EC held on 25th November 2020. A final version of the workshop programme was agreed with the EC on 26th November (see Appendix 3).

Speakers at the workshop had previously been sent instructions for pre-recording their presentations and uploading them to Dropbox a week in advance of the first webinar to allow moderators sufficient time to prepare for the live Q&A sessions.

4 Webinar summaries

Following the webinars, all speakers were contacted with a request to provide their consent for the sharing of their presentation slides on the QuADRANT website. All speakers responded affirmatively. All slides from the workshop presentations are thus available on the QuADRANT website: http://www.eurosafeimaging.org/clinical-audit/quadrant/wp-2

Webinar 1: Monday 14th December 2020

14:30 Welcome & Introduction from the European Commission and Project Leadership Team

Participants in the workshop were welcomed to the webinar, the first of three on consecutive afternoons, by **D. Howlett**.

Michael Hübel (the Head of the Radiation Protection and Nuclear Safety Unit in DG ENER of the European Commission) also welcomed participants. He said that the challenge of this project is to bring together all stakeholders in radiology, radiotherapy and nuclear medicine in an integrated way, to address issues relating to radiation protection and audit.

D. Howlett (Project Leader and chair of the European Society of Radiology Audit & Standards Subcommittee) introduced the project leaders and thanked the administrative team (especially Monika Hierath and Jonathan Clark of the ESR) for their hard work in making these webinars possible.

14:40 Setting the Scene

Georgi Simeonov (Policy Officer, Radiation Safety and Nuclear Safety Unit in DG ENER, European Commission) explained the background history of Euratom's safety standards for the protection of the health of workers and the general public against dangers arising from ionising radiation. These standards have been regularly updated and revised; the latest version dates from 2013.

Medical imaging, and in particular the increased use of CT, represents the single biggest source of exposure of the population to ionising radiation. The development of hybrid imaging modalities has added to this exposure. This increased exposure has conferred significant benefits upon the public, but issues of justification and optimization have become more significant concerns as exposure has increased. Increased access to and use of radiotherapy has also impacted on population exposure, with a remarkable rise in the use of proton therapies in particular. In recent years, nuclear medicine has developed increased diagnostic and therapeutic applications. The latter especially are attracting more attention and require special attention.

Clinical audit is the one requirement of the BSSD that establishes a link between radiation safety and improved quality of outcome for patients. RP159, published in 2009, defined how audit should be applied in this context.

The Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA), which is the EC's contribution to European Cancer Plan, was introduced. The EC is in the final stages of publishing the SAMIRA Action Plan, the general objective of which is to ensure that EU citizens have access to high quality radiological and nuclear technologies in medicine, at the highest safety standards.

SAMIRA has 3 main action areas:

1. Supply of medical radio-isotopes
2. Quality and Safety of medical applications
3. Innovation and technological development of medical ionising radiation applications

The QuADRANT project is one of the first actions under action area 2 of SAMIRA.

Under the Quality and Safety action area, the EC is planning to launch a European Initiative on Quality and Safety (EIQS) in 2021, with four elements:

1. To build EU governance
2. To coordinate legal implementation
3. To facilitate EU support action
4. To share good practice

QUADRANT is intended to impact on and support items 1,3 and 4 of this list.

14:50 An Introduction to the QuADRANT Project

David Howlett introduced the QuADRANT project by explaining the acronym (**Qu**ality Improvement through **A**udit in **D**iagnostic and Interventional Radiology, **R**adiotherapy **a**nd **N**uclear Medicine including **T**herapies), and the EC tender which led to the project.

QuADRANT involves the European Society of Radiology (ESR), the European Society of Radiotherapy and Oncology (ESTRO) and the European Association of Nuclear Medicine (EANM). Its objectives are to:

1. Review the status of clinical audit implementation in EU Member States;
2. Identify good practices and available guidance and resources for clinical audits at national, European and international level;
3. Provide further guidance and recommendations on improving the implementation and integration of clinical audits into national healthcare systems; and,
4. Identify potential for further co-ordinated EU action on quality and safety in radiology, radiotherapy and nuclear medicine.

The 30-month project, led by the ESR, began in January 2020. It involves five Work Packages (WPs), and encompasses support and input from a Steering Group and Advisory Board, and from key professional societies and organisations, including the IAEA, WHO and HERCA.

WP1 covers the overall project management and implementation.

This series of Webinars constitutes WP2 and comprises a workshop to discuss the current state of play of clinical audit within the EU, to discuss the legal requirements and benefits of clinical audit, to identify good practices and existing guidance, and to disseminate information to and involve key players and healthcare/administrative representatives from the 27 EU Member States (plus Iceland, Norway, Switzerland, and the UK).

WP3 comprises a pre-survey to collect information about individuals and bodies involved in clinical audit in the EU+4 countries (which is now complete), and the main survey (to be circulated after WP2), which is intended to gather detailed information

on clinical audit practices and processes across Europe. WP3 will include a literature review and expert interviews.

WP4 will be another workshop, to take place in late 2021, presenting the WP3 survey results and discussing and presenting a way forward with Member State representatives and professional experts.

WP5 will involve writing a report for the European Commission based on the previous WPs indicating best practices and making recommendations for improving implementation and integration of clinical audit into national healthcare systems.

15:00 Clinical Audit as Defined in the European Basic Safety Standards Directive

Alexandra Karoussou-Schreiner (chair of the HERCA Working Group on Medical Applications) explained the work of HERCA and outlined its view of Clinical Audit, including its subtypes.

- HERCA (Heads of European Radiological protection Competent Authorities) is a voluntary association in which radiation protection competent authorities work together to identify and discuss common interests, comprising 32 countries, with observers from the IAEA, WHO, OECD, the EC and the FDA.
- Clinical audit was defined in 1997 by UK National Institute for Health and Clinical Excellence (NICE) as:
    - "a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, process and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery".
- Clinical audit was also included in 1997 as part of the Medical Exposure Directive in 97/43/Euratom, where it was defined as:
    - "a systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary".
    - The Directive included requirements for clinical audit and stated "clinical audits shall be carried out in accordance with national procedures".
    - This Directive required member states to include some requirement for clinical audit in their legislation and regulations relating to radiation protection.
- Guidance from the EC's Working Party on Medical Exposure in 2009 (RP159) advised that European guidance should be developed on the implementation of clinical audit of medical radiological procedures. The report describes:
    - The basic principles and prerequisites of clinical audit
    - The interrelation of clinical audit with other audit systems
    - The interrelation with regulatory control
    - The practical implementation of clinical audit
    - Generic criteria of good practice
    - Specific audit criteria
- RP159 states that the general objectives of clinical audit should be to:
    - Improve the quality of clinical care
    - Promote the effective use of resources

    - Enhance the provision and organisation of clinical services
    - Further education and training
- The Basic Safety Standards Directive (BSSD) 2013/59/Euratom replaced 97/43/Euratom, and repeats the requirements for clinical audit, using virtually the same definition.
- In November 2016, HERCA carried out an Action Week on the inspection of justification in radiology in 17 European countries. The main weaknesses identified concerning clinical audit were:
    - The concept of clinical audit is not fully understood
    - Lack of national or local procedures for performing clinical audits
    - Clinical audits are rarely performed in medical imaging
    - Review of national regulatory frameworks indicated that clinical audits were not fully implemented at a national level.
- In 2017 and 2018, meetings between HERCA and ESR, EANM and ESTRO revealed some lack of understanding within the radiological community as to how regulatory requirements for clinical audit should be met, and the differences between clinical audit and inspection.
- In October 2019, HERCA published a position paper on "Clinical audit in medical radiological procedures", which states that:
    - Clinical audit is intended to improve the outcome of patient care
    - Clinical audit should be systematic and ongoing
    - There is a role for both internal and external clinical audit
    - Clinical audit should be carried out by individuals with a comprehensive understanding of audit technique
    - Internal clinical audit is to be carried out by the establishment itself (individual, department, hospital) at a local level on its own initiative, consistent with national requirements, with objectives set by the department or hospital. External direction may be used, e.g. provided by an external body, such as a national professional society. Auditors may come from another department of the establishment (ideal), or as self-assessment within the audited department.
    - External clinical audit is done by external auditors (international, national or regional audit organisations), with objectives agreed between the establishment to be audited and the auditing organisation. Auditors should be independent of the audited establishment, to avoid bias.
    - Other types of audits include:
        - Dose audits of staff and patient doses
        - Healthcare audits (more global audits)
        - Regulatory audits to verify compliance with regulations and standards. This can be helpful to an employer, but does not constitute clinical audit, and does not replace the need for inspection.
    - Inspection is "an investigation by or on behalf of any competent authority to verify compliance with national legal requirements". It is different from clinical audit; both are required. An inspection will result in a pass/fail/measures need to be taken outcome, while a clinical audit will result in recommendations and suggestions for improvement. A table was presented to highlight the differences between inspection and clinical audit.
- The understanding of competent authorities regarding clinical audit *vis-a-vis* inspection is:
    - Inspection must identify whether clinical audit is being carried out
    - Clinical audit provides an ongoing assessment of clinical practice in a way inspection cannot

- Clinical audit is a continuous process, and can demonstrate whether or not quality and safety are embedded within a service
- Inspection takes place periodically, is of short duration and only focuses on legal compliance
- Clinical audits are not meant to replace inspections as a means of demonstrating regulatory compliance
- Clinical audit and inspection are complementary processes
- Clinical audit on a national scale can provide a mechanism for transfer of best practice between institutions, and the setting of higher and more appropriate standards. It can also demonstrate cooperation between professional groups
- HERCA believes that it is the responsibility of those who carry out clinical audit to bring non-compliance with radiation protection principles and specific regulatory requirements to the attention of the audited organisation/undertaking, and that the undertaking should carry out corrective measures. Financial and human resources for audit should be made available, as should education and training of auditors. Establishment of national auditing organisations to coordinate and develop clinical audit is recommended.

15:20 Clinical Audit & Quality Improvement

Adrian Brady (ESR 2nd. Vice President, and QuADRANT project Co-Lead) explained the process and aims of clinical audit, emphasising the ESR Clinical Audit Tool (Esperanto). He used simple examples to show how audit can be done and outlined a specific clinical audit from his own department which has had some benefit for patient outcomes.

- A simple definition is that audit involves improving the quality of patient care by looking at current practice and modifying it where necessary, or measuring what we do against a standard
- The ESR believes that Audit should be ALPINE:
  - **A**chievable
  - **L**ocal
  - **P**ractical
  - **I**nexpensive
  - **N**on-threatening
  - **E**asy
- The variants of audit (internal, internal with external direction, external and inspection) were again explained, and the audit cycle was illustrated.
- Article 58e of the 2013 BSSD mandates that clinical audits shall be carried out in accordance with national requirements
- The steps to perform a clinical audit were explained:
  - Choose a topic/title
  - Identify the resources needed
  - Define the standard (and its source) against which the audit topic is to be compared
  - Set the target / compliance % to be achieved
  - Confirm the item or variable to be audited
  - Set the details for sample size, data collection, time period etc., and collect the data needed
  - Analyze the data, identify if the target has been met, and, if not, document the possible reasons for failure to meet the target

    - Present the data, identify the changes to be made, and agree the timing for a re-audit after changes have been implemented
- A theoretical (and whimsical) example was described, in order to show how simple audits may be conducted
- The ESR has published a guide to clinical audit and a tool to assist performance of audits, called Esperanto (2nd edition published March 2019, available on the ESR website)
    - This contains an explanation of audit, a blank template, 23 suggested regulatory audit topics and templates and 7 suggested clinical audit topics and templates
    - Examples of a regulatory and a clinical audit from these lists of topics were outlined
- An audit from the speaker's own radiology dept. on the efficacy and justification of plain abdominal radiography (PFAs) in the Emergency Dept was presented. This audit was initially performed in 2011 and revealed that too many unjustified PFAs were being performed, partly attributable to a lack of understanding among referrers of appropriateness criteria, and partly to limited access to rapid cross-sectional imaging.
    - Following an educational program for referrers, and improved rapid access to Ultrasound and CT, a repeat of the audit in 2016 showed a substantial improvement in the % of justified exposures.
- In conclusion, clinical audit is intended to improve patient outcome, is easy, and does not always require a lot of resources. Is should be a continuous activity, a self-reflective part of regular clinical activity.

15:40 Round Table Discussion & Q&A-forum

- **D. Howlett** asked how inspectors check clinical audit when inspecting facilities
    - **Alexandra Karoussou-Schreiner** answered that, in this context, they will check that a hospital has done clinical audits, not regulatory audits, and that they will be interested specifically in their impact on patient outcomes
- **Amparo Garcia-Burillo** (Nuclear Medicine, Spain) asked how national organisations can ensure clinical audits are performed by properly qualified people, and not politicians etc.
    - **A. Karoussou-Schreiner** explained that performance of clinical audits should be done by professional groups working in the relevant areas, e.g. doctors, radiographers, medical physicists, etc. The key requirements are a willingness to engage in teamwork, and provision of appropriate training.
    - **A. Brady** described how, in Ireland, performance of clinical audit has become a requirement for maintenance of licensing for doctors and radiographers. While time has not been allocated within work plans for this, they have found that it is generally quite easy to do. Radiology trainees participate in much of the work, as a means of learning research and audit processes. Radiographers often set aside time for a monthly meeting to present ongoing audit work, and to encourage activity.
    - **Georgi Simeonov** expressed the belief that national level resources and supports for clinical audit should be put in place in EU member countries; he expressed hope that the QuADRANT project will help convince authorities of the payback value to be obtained from

resourcing audit. National leadership from national authorities is lacking in many countries.

- **Nuria Jornet** (Medical Physicist, Barcelona) asked about the impression created in A. Brady's talk that clinical audit does not include dosimetry audits
  - **A. Brady** explained that he did not intend to suggest this, but simply wanted to help participants understand that dosimetry was not all that constituted audit, and that other, simple patient-focused audits (that did not necessarily relate to regulation), have value and can help departments begin audit programmes.
  - **N. Jornet** felt that this type of activity represented Quality indicator monitoring rather than a comprehensive clinical audit.
  - **A. Karoussou-Schreiner** said that a clinical audit is what A. Brady had described. Quality indicator monitoring can be the same thing as an audit.
  - **A. Brady** said that he did not believe it mattered an awful lot what the process is called, once it has the appropriate goal, of improving patient outcomes by measuring (and potentially improving) what we do against a standard.
  - **Mary Coffey** (ESTRO) answered that there is a spectrum of audits, including voluntary audits for improvement that are not regulatory.
- **Nils Reynders Frederix** (Belgian Ministry of Health) asked for examples of the establishment of national auditing organisations.
  - **A. Karoussou-Schreiner** said these could involve National professional Societies, healthcare authorities etc. She believed there were relevant ministerial bodies (involving professional societies, ministerial and financing bodies) in existence in Belgium, Luxembourg, Switzerland and Germany, among others.
- **Erik Briers** (Belgium, patient representative) asked is there a place for patient involvement in clinical audit
  - **A. Brady** answered that patient involvement is crucial in audits that directly impact on patient experience. Direct patient involvement may not be appropriate in dosimetry audits, for example, but if auditing direct patient experience (waiting times, contacts with staff members etc.) patient input is vital. In some circumstances, it may be valuable to have patient groups define what the standard ought to be, against which we measure our present activity.

16:10 International Atomic Energy Agency Experience of Clinical Audit: QUAADRIL, QUANUM and QUATRO projects

Diana Paez (Section Head, Nuclear Medicine and Diagnostic Imaging Section, Division of Human Health, Dept of Nuclear Sciences and Applications, International Atomic Energy Agency (IAEA)) explained the nature, functions and aims of the IAEA. She outlined projects and tools developed by the IAEA to support audit activity for radiotherapy, nuclear medicine and diagnostic radiology.

- The IAEA:
  - An independent, intergovernmental, science- and technology-based organisation within the United Nations family
  - It serves as the global focal point for nuclear cooperation worldwide
  - 172 member states
  - Supports its member states under 3 pillars:
    - Safeguards and Verification: ensuring that member states comply with their commitments under the Nuclear Non-

Proliferation Treaty and other agreements to use nuclear materials and facilities only for peaceful purposes
        - Safety and Security: developing nuclear safety standards & promoting high levels of safety, as well as the protection of human health and the environment against ionising radiation
        - Nuclear Sciences and Applications: assisting member states in the context of social and economic goals through the planning and use of nuclear science and technology for various peaceful purposes
- Division of Human Health – role is to strengthen capabilities of member states to address the needs related to the prevention, diagnosis and treatment of health problems through the application of nuclear and related technologies
- Recognising the need to audit medical radiation technology (diagnostic and therapeutic), the IAEA published International Basic Safety Standards in 2003, revised in 2014, including the need to audit medical radiation technology. These standards are endorsed by the WHO and follow the EC Directive 97/43/Euratom. IAEA methodology for clinical audit has been published for radiotherapy, nuclear medicine and diagnostic radiology
- Quality Assurance (QA) is a set of activities intended to establish confidence that quality requirements will be met. QA is one part of Quality Management (QM)
- QM includes all the activities that organisations use to direct, control and coordinate quality. These activities include formulating a quality policy and setting quality objectives. QM encompasses:
    - Quality planning
    - Quality control
    - Quality assurance
    - Quality improvement
- Deming (PDCA) cycle is the basis for this continuous QM process
    - **P**lan a process or a change
    - **D**o – implement the plan and performance measurement
    - **C**heck the results
    - **A**ct to correct discrepancies or adopt a new process
- IAEA vision is to implement QM in radiation medicine, independent of complexity or location
    - Provide best possible service to patients
    - At the lowest possible risk
    - At adequate costs for patients and community, including the environment
    - Improve satisfaction of customers and providers
- QM audit process (one of the main elements of the QM process) described
    - Review and evaluate quality of all elements involved in all the different processes
        - Staff and professional competence
        - Equipment and procedures
        - Patient protection and safety
        - Performance of the dept., interaction with external services
    - Assist facilities in maintaining and improving quality of service for patients, referring physicians and other stakeholders
- First IAEA dose audit service in radiotherapy started in 1969. Joint programme of IAEA and WHO. Over 13000 beam checks performed in about 2300 radiotherapy centres in 133 member states over 50 years
    - Since 2004 IAEA supports over 25 Dosimetry Audit Networks (DANs) through blind dose comparisons. Dosimeters sent to radiotherapy

centres for irradiation to verify the beam output used for patients' treatments

- IAEA framework developed for comprehensive radiotherapy audit in 2005 – Quality Assurance Team for Radiation Oncology (QUATRO)
  - Has trained auditors and run regional workshops in all world regions over 15 years. 96 QUATRO missions have taken place to date in 80 countries.
- Second programme developed 2007 for Nuclear Medicine – Quality Management Audits in Nuclear Medicine Practices (QUANUM). Periodically updated – currently working on version 3.0
  - Encourages a routine of conducting periodic and systematic audits in the clinical environment
  - Provides independent quality audits through comprehensive reviews of nuclear medicine practices
  - Focuses on the peer review of nuclear medicine practices and management in nuclear medicine centres, and applies good clinical practices by identifying areas of improvement
  - Over 12 years, has run 76 audits in 36 countries, and 24 workshops (for 540 trainees)
  - 14 teams of auditors have been trained, each comprising a NM physician, a medical physicist, a radiographer and a radiopharmacist
  - 24 workshops have been organised for 540 trainees on use of QUANUM tool
- Quality Assurance Audit for Diagnostic Radiology Improvement and Learning (QUAADRIL) = IAEA Clinical Audit tool and programme for diagnostic radiology practices, developed in 2010
  - Very similar to QUANUM process.
  - 6 QUAADRIL audits have been implemented in 6 countries (Bosnia and Herzegovina, Belgium, Israel, Thailand, Malaysia & UAE)
- Achievements of QUAADRIL, QUANUM & QUATRO projects
  - Establishment of quality management culture
  - Provision of training in quality management in radiology, radiotherapy and nuclear medicine
  - Provision of training of multidisciplinary audit teams
  - High impact worldwide and in audited centres
  - Countries can adopt methodologies of these 3 projects as part of the national comprehensive quality system, or can perform self-audits at departmental level

16:25 World Health Organization Experience of Clinical Audit

Shams Syed (Coordinator, Quality of Care Unit, World Health Organization (WHO)) explained the WHO perspective on clinical audit, the actions it takes to promote quality health care, and its understanding of the potential of clinical audit to benefit patients worldwide.

- 2018 – 3 seminal publications appeared globally
  - Delivering quality health services – WHO/World Bank & OECD report
  - Lancet Global Health Commission report
  - Crossing the Global Quality Chasm from the US National Academies of Sciences, Engineering, and Medicine
- Lancet Global Health Commission report estimated number of deaths due to poor quality of care
  - 8.6 million deaths per year due to inadequate access to quality care

        - 3.6 million are people who did not access the health system
        - 5.0 million sought care but received poor quality care
    - COVID 19 has highlighted these issues of access and quality
- Thinking through quality – 6 domains of quality health care
    - Effectiveness
    - Safety
    - People-centeredness
    - Timeliness
    - Equity
    - Efficiency & Integration
- Dr. Tedros Adhanom Ghebreyesus (WHO Director General) wrote in response to 2018 publications
    - "Quality is not a given. It takes vision, planning, investment, compassion, meticulous execution, and rigorous monitoring, from the national level to the smallest, remotest clinic"
- World Bank / OECD report – high-level actions suggested:
    - All governments encouraged to:
        - focus on national strategic direction on quality
        - close gap between actual and achievable quality
- WHO has published Handbook for National Quality Policy and Strategy. Building quality into foundations of health systems requires holistic attention to
    - Health care workers that are motivated & supported to provide quality care
    - Accessible and well-equipped health care facilities
    - Medicines, devices and technologies that are safe in design and use
    - Information systems that continuously monitor and drive better care
    - Financing mechanisms that enable and encourage quality care
- Establishing standards for care is important, but is of limited value alone. Additional actions are needed to focus on a culture of quality (training and supervision, monitoring for compliance and feedback to health care providers)
- Quality Improvement can be thought of as "the action of every person working to implement iterative measurable changes to make health services more effective, safe and people-centred". We can consider clinical audit as one of the pathways to quality improvement
- Within WHO/OECD/World Bank report, 4 inter-dependent blocks of quality interventions were highlighted
    - Systems environment, including performance-based financing and contracting, external evaluation and accreditation
    - Improvement in clinical care, including clinical audit and feedback
    - Reducing harm, including safety checklists
    - Patient, family and community engagement and empowerment
- Radiation safety is embedded in health care quality and therefore needs to be integrated into quality improvement strategies (including use of clinical audits)
- Radiation safety – unintended and accidental exposures. UNSCEAR in 2008 reported on radiation accidents over 60 years (1945-2007). A large number of fatalities (46) and a high number of acute injuries (623) were due to accidents occurring during the use of radiation in health care. This can be examined and tackled thorough the use of clinical audit
- In 2008, WHO reported (Radiotherapy Risk Profile) on 3125 patients affected by radiotherapy incidents between 1976 and 2007. About 1% (38) of affected patients died due to radiation toxicity (overdose). More than 4500 near-misses reported in literature between 1992 and 2007.
- The power of clinical audit and feedback as a quality improvement tool resides in the human interactions between those developing their thinking around a

subject area and designing an intervention with clear identification on feedback and identifying areas that need improvement
- Implementation of the BSS requirement to perform clinical audits needs concurrence/coordination between the radiation protection regulator (i.e. radiation safety) and the health authority (clinical governance, good medical practice)

16:40 Round Table Discussion & Q&A-forum

- **Michael Brada** (ESTRO) asked Georgi Simeonov to what extent the EC feels that audits should be comprehensive (to the standards suggested by the IAEA and WHO), or are they happy with smaller, piecemeal audits?
    - **G. Simeonov** answered that the EC is looking for comprehensive audits, and that this is what is required under the BSSD. Audit related to practice governed by the BSS is what is of most interest to the EC. Smaller, local, less comprehensive audits are legitimate ("you have to start somewhere"), but not sufficient. Some central coordination and support is still needed.
    - **M. Brada** said it is up to national bodies to organise and support such comprehensive audits, which may come from smaller local audits
    - **D. Howlett** said that smaller audits can change practice locally, and that such changes can be expanded nationally by national coordination of audits
- **Diana Paez** (IAEA) outlined the advantages of the IAEA programmes as checklist tools and the peer review process. Audits in these programmes are done by trained peers in each specialty. She emphasised the importance of generating a quality culture among physicians, and commented that the IAEA tools are freely available, and any member state can use them.
- **Steve Ebdon-Jackson** (UK, ex HERCA) said that although auditing aspects of clinical practice such as patient waiting times is important, this type of audit is not what is required by the BSSD, which looks at medical radiological practices involving ionising exposure. The basic requirements of the Directive are optimisation and justification. Inspectors will be looking for audits that specifically relate to major principles of the Directive. Inspectors will be looking for clinical audits being performed, and particularly that audits that relate to major principles of the BSSD are being performed. Audits of waiting times, for example, would not be acceptable to a regulatory inspector as a satisfactory implementation of the regulations, or the intentions of the Directive. Audits should look comprehensively at radiological practice as a whole rather than just focusing on the radiation elements or exposure factors.
    - **A. Brady** responded that one can learn a lot about one's practice and can improve processes for patients by doing relatively simple audits. The reason for focusing on simple audits in his talk was to educate beginners on the simplicity of the audit processes, and on how to begin doing more basic audits before engaging in more-complicated studies. He emphasised that he was not suggesting that auditing something like waiting times fulfils a BSSD requirement. Esperanto is designed to assist departments begin the process very simply, and then move on to fulfilling legislative and regulatory requirements.
    - **S. Ebdon-Jackson** agreed that it is helpful to start simple and then move on to more complicated things. As a patient, he would be very interested in simple audits such as one about patient waiting times, but as an inspector under the regulations, he would be looking for audits specifically relating to BSSD requirements. We need to ensure that

people understand they cannot stop with simple audits alone, but must move on to more complicated audits, to fulfil BSSD requirements.

- **Catherine Clark** (ESTRO) asked if clinical audit always has to take place on site, to be comprehensive.
    - **Diana Paez** answered "Yes". While much of the self-assessment can be done locally, (and **Francesco Giammarile** [EANM] added that online meetings can manage much of the activity), it is necessary to visit the site to complete the process, for a comprehensive external audit.
    - **Mary Coffey** said that supplied documentation can often be found to be quite different from actual practices on site, and that specific issues and difficulties can best be appreciated by on-site visits.
    - **Petr Papirnik** (Czech state office for nuclear safety) said that if done remotely, such an activity cannot be called a clinical audit.
- **Dominique Carrié** (radiologist, France) asked if we know how many countries in Europe are involved with mandatory clinical audit
    - **David Howlett** answered that we will know a lot more about this at the end of the project, with information from the Main Survey (WP3).
- **Nuria Jornet** said that her understanding is that audit must have peer-to-peer competence, and that she believes a clear distinction must be made between quality management and audit.
    - **D Howlett** answered that there is no clear distinction between self-assessment and clinical audit, but that there is a spectrum of activity. Having peers looking at your work can add value but is not an absolute requirement. How you manage the way you audit others' practices is important, to avoid audit being used as a tool for confrontation. Audit has to be done for positive reasons, in a non-threatening way.
- **M. Brada** said that, as audit is done to change clinical practice, the standards within an audit must be of sufficient quality. If there is a quantitative component, it must be statistically sound. Otherwise, there is a danger of practice being changed incorrectly on the basis of flawed statistics.
- **Marleen Vandercapelle** (Belgian Federal Agency for Nuclear Control) asked about external auditors looking at patients' medical dossiers if they are not involved in treating the patient. She said that in Belgium they would not be allowed such access
    - **David Howlett** said that the relevant regulations vary from country to country. In the UK, an auditor engaged on an official external audit would be entitled to access to patient information.
    - **F. Giammarile** said that one solution would be to anonymize the patient's name.
- **Shams Syed** again emphasised the importance of encouraging a culture of quality within departments and ensuring integration within institutions. Proper planning of this integration can enhance the power of a department to capitalise on improvements within its own and other areas of the service as a whole.
- **Amparo Garcia-Burillo** (Nuclear Medicine, Spain) agrees that clinical audits must be done by knowledgeable physicians, radiologists or physicists, and that national and governmental participants must provide legal backup and the standards against which to compare local results. These partners perform inspections but not clinical audits.
- **S. Ebdon-Jackson** referred to the statement in A. Brady's talk that "clinical audit should not be threatening". He agreed that it is very important when embarking on an audit process that everyone involved agrees the goals, parameters, and methods, with a common goal of improving the lot of patients as a whole. The process loses value once objections and obstructions begin to be raised.

- **M. Brada** said that one of the main issues that has been successful in radiotherapy in improving quality is the introduction of no-fault error reporting
- **G. Simeonov** wrapped up by stating that the topics and questions discussed had been very pertinent, and that they will inform the Main Survey (WP3) and the discussion in the second workshop (WP4).

Summary of the 'take away' outcomes from the webinar.

Participants and speakers agreed on the importance of clinical audit in quality improvement in health care. Many organisations have produced guides on performance of clinical audit, which are freely available. The different types of audit were explained. There were some differences in understanding of clinical audit between those engaged in regulation/inspection and practitioners. Some participants believe that an audit does not really constitute clinical audit unless some external person/body is involved. Others accorded more value to the self-assessment aspect of audit. There was a productive dialogue led by the speakers with clarification of the above issues.

The use of clinical audit "in accordance with national procedures" in support of the requirements of the BSSD is rightly considered a matter of high priority by the European Commission and regulatory bodies and professionals. While audit of BSSD requirements (optimisation and justification) is of particular importance to regulators, in the context of fulfilling legal responsibilities, it is important to acknowledge that clinical audit is a much-broader topic, with broader application outside of the field of radiation protection with potential for significant added value for patient outcomes. There is significant potential benefit for patients and services to be gained from small, local audits of clinical practices relating directly to patient experiences, while also maintaining constant auditing of key BSSD requirements relating to optimisation and justification. Focussing time and resources in establishing an effective clinical audit infrastructure at local level will have benefits across the board for patients, staff, and hospitals.

There was a useful discussion around key definitions and clarification of differing terms and terminologies. The definition of clinical audit as is referenced in the BSSD is an important baseline concept, understanding the application of core requirements around optimisation and justification and then auditing their actual effect on clinical practice and patient outcomes. Understanding the differences from regulatory type audit and also inspection is fundamental and was discussed at some length.

It was very useful for the audience to appreciate also the experiences of larger international organisations, the IAEA, and WHO, in the field of clinical audit and to appreciate the potential of clinical audit to change practice on a wider scale.

Webinar 2: Tuesday 15th December 2020

14:30 Welcome & Summary of Webinar 1

W. Wadsak (Work Package Co-Leader and representative of the European Association of Nuclear Medicine, EANM) welcomed the participants. Webinar 1 introduced the participants to the background of the QuADRANT project as well as the underlying expectations by the European Commission. QuADRANT's interrelations to the SAMIRA (Strategic Agenda for Medical Ionising Radiation Applications) initiative as well as the planned European Initiative on Quality and Safety (EIQS) were outlined. A precise definition of clinical audit was delivered and various international organisations (IAEA, WHO, HERCA) gave their views on the topic. During the discussion rounds the need for involvement of patients as partners, as well as a need for transparency in clinical audit processes, was raised. A clear definition of the profile of the peer auditors is considered key to success. Further, embedding clinical audits in a holistic culture of quality within the respective establishment was agreed to be one of the corner stones of a successful implementation.

W. Wadsak introduced the aims of Webinar 2: it is dedicated to the viewpoints and particularities of the three specialities (radiology, radiotherapy and nuclear medicine) related to clinical audits, its aims and benefits. Moreover, a first look will be taken at national experiences in the setting up of clinical audit processes in member states across disciplines.

14:40 Aims and Benefits of Audit by Specialty: Radiology

B. Brkljacic (Chairman of the European Society of Radiology Board of Directors) introduced the participants to the work of the ESR Quality and Safety Committee and its sub-committees, which provides guidance on clinical audits, in close collaboration with other health stakeholders and regulators, and is also engaging in various dedicated European projects. As such, all aspects regarding the implementation and promotion of clinical audits in radiology in Europe are covered by this Committee. The ESR Clinical Audit booklet ESPERANTO (latest update 2019) facilitates the improvements in patient experience, care, and outcomes and shall help departments to comply with the BSSD. ESPERANTO includes guidance on regulatory and clinical audits, provides templates of the main audit questions, and also addresses differences in internal and external clinical audit processes.

- Despite the holistic approach of ESPERANTO and the efforts of the Committee, a survey conducted by the ESR amongst its member societies (02/2020) still showed a significant lack of compliance with the BSSD and proved the need for further coordinated actions.
- While the vast majority of respondents acknowledge the importance of clinical audit, they also highlighted shortfalls in resources and infrastructure which are hindering implementation. A follow-up survey is planned for early 2021.
- These activities show the role that the European professional societies have in providing guidance and best practice examples towards their member societies, which in turn will need to support implementation on national level.

14:50 Aims and Benefits of Audit by Specialty: Nuclear Medicine

W. Oyen (President of the European Association of Nuclear Medicine) highlighted the multidisciplinary nature of nuclear medicine, in which radioisotopes are used both for diagnostic as well as therapeutic purposes. These applications are supported by a diverse range of technologies and used for benign as well as malignant diseases. As well as this diversity in scope, application and technology, the practice of nuclear

medicine is challenged by the half-lives of the radioactive sources it uses that are produced on-site in the hospitals. The innovative nature impacts nuclear medicine procedures and processes as the local infrastructures as well as a creating a challenge in generating evidence due to the high level of personalized treatment (hence smaller patient samples). The EANM has more than seven decades of experience in combining diagnostics and treatment ("theranostics") in a holistic way for e.g., thyroid cancer patients, with the concept now being expanded to other diseases.

- As set forth in the BSSD, justification as well as optimization are taken very seriously by the nuclear medicine community and are supported by the use of modern devises, innovative applications, and optimized procedures and protocols, as well as an overall decrease in radiation burden by applying doses that are as low as possible.
- All particularities as outlined above must be considered when designing and implementing clinical audit processes in nuclear medicine establishments.
- Clinical audits are regarded as a highly beneficial measure of learning and improving the holistic service that nuclear medicine has on offer.
- The level and pace of innovation in the field, however, is partly slowed down by the old standards that need to be adapted in order to convert novelties in research into clinical applications. Hence, clinical audits would need to be designed carefully and with a certain level of flexibility and with room for adaptation to be implementable.

15:00 Aims and Benefits of Audit by Specialty: Radiotherapy

P. Strojan (QuADRANT project team, representative of the European SocieTy of Radiation Oncology) highlighted the importance of internal control given that radiotherapy treatments are a multi-step process involving a multitude of different professionals. The specialty is challenged by heterogeneous good practices throughout the European member states, greatly influenced by the availability of resources. Within the radiotherapy community, the QUATRO project by the International Atomic Energy Agency (IAEA) is well recognized and has been developed with the support and input from experts in the field. It has proven to be suitable for a multitude of countries within various cultural as well as socio-economic settings. The approach to clinical audit aims at a dynamic improvement of quality in the service delivery of the specialty.

- While the components and clinical steps for radiotherapy are comparable, a successful clinical audit needs to be conducted by an audit team that reflects the multi-disciplinarity of the professionals involved in the radiotherapy processes.
- The independence as well as the skills of the audit team members need to be ensured and the entire process shall be audited.
- The exit meeting at the end of the process has shown to play a significant role.
- Furthermore, the end report should not only feature a summary but, more importantly, a list of actions to be taken and should outline the barriers as well as provide recommendations to overcome them. Clinical audit should offer help and advice, especially in those areas where difficulties are exposed.

15:10 Round Table Discussion & Q&A-forum

- Upon question, **A. Brady** confirmed that the practice of clinical audits in radiology throughout Europe is rather diverse and not widely dispersed; ESR is trying to raise awareness of the need for clinical audits amongst its members

while encouraging the awareness and use of ESPERANTO by its promotion among members.

- **W. Wadsak** asked whether the diversity of nuclear medicine practice could ever be covered in one clinical audit setting.
    - **W. Oyen** agreed that it is vital to clearly pre-define the baseline as well as the aim of the audit depending on the establishment at hand (e.g., highly specialised expert centres versus general hospitals without specialisation)
- **W. Wadsak** asked whether the mentioned subspecialisation in radiotherapy makes it necessary to adapt clinical audit processes that were mentioned?
    - **P. Strojan** specified that this would depend on the services that the centre is delivering. For comprehensive clinical audits, the processes for radiotherapy are similar, so the audit structure could be the same. However, if the aim is to audit only specific parts of the process, there would and should be differences in the audit process.
- **W. Wadsak** asks the speakers to identify specific activities that the professional societies have or are undertaking to facilitate clinical audits.
    - **EANM: W. Oyen** replied that EANM has set up a standardisation programme to harmonise the diversity in standards set by the equipment vendors, that made comparing of patient images very difficult. Given the mobility of patients nowadays, the EARL accreditation and standardisation process has improved patient care. Discussions on how to expand this are ongoing
    - **ESTRO: P. Strojan** pointed towards the collaboration with the IAEA QUATRO project that was led by an active decision by ESTRO to join forces with the IAEA in order to not to multiply efforts in the development of the audit programme. The specific knowledge of radiotherapy experts in the development of the programme was one of the major success factors. ESTRO is also offering educational activities in the area of quality improvement and has a dedicated group for quality standards, not specifically related to clinical audits, however.
    - **ESR: B. Brkljacic** added that in addition to the ESPERANTO initiatives, the topic of justification was picked up by the ESR through the iGuide tool, which targets the reduction of unnecessary exposure and reducing unnecessary radiological scans, and which is an indirect element of clinical audit and could also be of interest for nuclear medicine
        - **W. Oyen** agreed that the topic of justification is relevant for both specialties, with the EANM having picked this up through its Clinical Decision Support tool (Nuclear Medicine CDS), that is currently under second revision. These manuals are considered as fundamental documents for justification and interaction with the clinicians.
- **F. Giammarile** pointed out that with the mention of justification, the panel has reached the most delicate part of the discussion, namely that it is not only about quality improvement, but also legal requirements set forth by the BSSD that lack compliance in member states.
- **D. Howlett** and **W. Oyen** agreed on the challenges put forward by the rapid advancement in technologies for radiology and nuclear medicine as well as the novel treatment applications in nuclear medicine, which makes the definition of standards to compare against challenging. While acknowledging this challenge, the inequalities throughout Europe also need to be addressed.
- **W. Wadsak** summarized that there are clearly different activities by the societies to addressing quality improvement; however, there is only one clear guide that is focused on Clinical Audits, namely the ESPERANTO initiative. One of the main questions is whether and how ESPERANTO could be transposed.

G. Simeonov (Policy Officer, Radiation Protection and Nuclear Safety in DG ENER, European Commission) appreciated the interactivity of the panelists as well as participants. The discussions show that there is potential for mutual learning based on the different approaches to the issues at hand, also including cooperation on the international level through e.g., IAEA.

He reiterated that the BSSD clearly puts the fulfilment of the requirement for clinical audits within the remit of the national authorities. However, it is clear that the national professional societies have a potentially key role to play in both national as well as European clinical audit. The SAMIRA initiative is one of the approaches to foster these types of collaboration, also involving DG Energy and DG Sante. Clinical audits were chosen to be the best topics to start off with, hence QuADRANT is only the first step in a longer process.

15:30 National Experience of Clinical Audit: The Belgian Experience

N. Reynders-Frederix (Belgian Federal Public Service for Public Health) introduced the Belgian clinical audit process for radiology. In Belgium, a handbook for clinical audits in radiology has been established by a multidisciplinary group of experts within BELMIP (Belgian Medical Imaging Platform). This handbook (referred to as B-QUAADRIL) was published in 2019 and is based on the QUAADRIL handbook of the IAEA and input from the experts in BELMIP.

The B-QUAADRIL handbook differentiates between three levels of quality criteria for clinical audits:
A – clearly by law defined, or considered essential
B – desirable, not mandatory; but should be achievable by all establishments
C – additional, not essential; concern educational/scientific research centres

The B-QUAADRIL handbook not only gives practical examples and guidance for the clinical audit process, but also addresses particularities of the national legislation. Since September 2019, clinical audits have been mandatory for all departments in Belgium using X-rays (including operating theatres) and consist of three phases:

- Self-assessment (done by staff of department, on departmental level)
- Internal clinical audit (done by auditors from other departments, on hospital level)
- External clinical audit (done by auditors from other institutions/hospitals, on national level)

Challenges to the implementation of clinical audits identified by Belgian authorities are:

- Significant increase in workload, especially external audits
- Lack of centralized information to authorities, whether audits were carried out and what their impact is on quality of care
- Clinical audit is inward looking, not comparable to accreditation
- Challenge to promote a culture of quality improvement to be fostered
- Update of B-QUAADRIL is still challenging due to workload for BELMIP volunteers

N. Reynders-Frederix concluded the Belgian experiences for B-QUAADRIL as follows:

- Clinical audits should be user-friendly
- Self-assessment is a good means of familiarizing establishments with the concept of clinical audit

- To overcome resistance focus should be put on the added value of clinical audits
- Multi-disciplinarity is key for success and quality of clinical audit processes
- Co-creation and involvement of experts is essential

M. Vandecapelle (Belgian Federal Agency for Nuclear Control) introduced the Belgian clinical audit process for nuclear medicine. Despite legal obligations introduced in 2001, the level of non-compliance was rather high. Various guidance documents on the international level (IAEA, EANM, European Commission) were consulted to co-create the Belgian clinical audit process for nuclear medicine, involving a multitude of federal as well as non-governmental bodies (e.g., professional society).

- The national manual was based upon the international QUANUM handbook by IAEA (2008) with principles, methodology and checklist questions being checked against national relevance in a pilot study (2010-2011) and adopted to create the B-QUANUM manual.
- Additional supporting documents were created when identified as necessary during the pilot
- Practical guidelines were written on how to start with the implementation of clinical audits.
- A thorough information and communication campaign was launched.

The checklists are the core of the manual, including classification of the quality component (A/B/C as per above) as well as level of compliance. If full compliance is not reached, an explanation as well as action plan are provided. A graphical summary of the achieved results is an effective means of communication within the establishment.

M. Vandecapelle concluded by summarizing the status quo:

- The self-assessment (07/2011) and internal clinical audit processes (07/2012) were started on time and have been taken up well. They are now also specifically mentioned in national legislation (2019-2020)
- External clinical audits (planned 07/2013) however, have not been started due to lack of financing as well as the absence of any definition of responsible organising entity
- B-QUANUM update to be started in 2021, as IAEA QUANUM was updated, and radiation protection legislation has changed

M. Vandecapelle identified the following key success factors for implementation of clinical audits:

- Tailoring the process to national particularities
- Addressing the need for information sessions should not be under-estimated

A. Vaandering (Department of Radiation Oncology, Cliniques Universitaires St Luc) introduced the Belgian clinical audit process for radiotherapy. The legal basis was set in 2001, with implementation of clinical audit being accelerated through the first federal cancer plan in 2010, which made clinical audits a pre-condition for financing of quality improvement initiatives in radiotherapy (e.g., hiring of quality managers). It was decided that these audits would be developed by the Belgian College for Physicians in Radiation Oncology, composed of Radiation Oncologists appointed by the Ministry of Health, supported by external experts.

Also, for radiotherapy clinical audits the methodological basis was the IAEA QUATRO manual which foresees a multidisciplinary peer review clinical audit process. A pool of 14 auditors was set up in 2010, considering various profiles (different languages,

university vs non-university backgrounds) and undergoing training by the QUATRO experts. Auditors conduct audits on a voluntary basis, with costs arising during the audit being covered. Between 2011 and 2015 all 25 radiotherapy departments were audited (hence 5 departments per year).

Feedback was collected after the first cycle of audits on the perceived relevance and impact of audit recommendations. The majority of respondents considered audits moderately to very useful and recommendations to be very relevant. However, the impact of the recommendations was scored lower, as a good proportion of the recommendations are not within the scope of influence of the actual department.

Based on the pilot study it was decided to maintain the clinical audit processes and to adapt the QUATRO manual to national needs, like B-QUANUM and B-QUADRIL, and to add aspects of more recent developments, while adding an entire chapter on quality management and reviewing the set of checklists and scoring systems. A second cycle of audits was started in 2017 based on B-QUATRO audits now also including the satellite sites.

A. Vaandering summarized the key success factors for clinical audits in radiotherapy:

- Access to existing material (QUATRO) and experts who developed this
- Existing high level of quality and safety culture in radiotherapy
- Number of departments to be audited is rather limited, compared to radiology or nuclear medicine
- Multidisciplinarity and good level of cooperation between professional groups involved in delivering radiotherapy procedures

A. Vaandering addressed the main challenges:

- Maintaining of experts in the audit team and therewith the expertise
- Need for regular updates of B-QUATRO manual
- With arrival of hospital accreditations, need for clear definition and separation of clinical audits
- Financial resources, lack of

15:54 National Experience of Clinical Audit: The Finnish Experience

R. Seuri (Helsinki University Hospital) explained that external clinical audits in Finland are performed in all institutions every 5 years to comply with national regulations. Clinical audits are coordinated by the Finnish Advisory Committee for Clinical Audit (KLIARY) composed of representatives from the ministry, radiation protection authorities as well as professional societies. The clinical audits are performed by an independent organisation with the audit team being set up as multi-professional group along pre-defined rules. Auditors are specifically trained but are also professionals in the field that they are auditing.

In the early days of auditing, the process resembled the IAEA QUAADRIL process, with review of documents (upfront and onsite) as well as interviews and observation of practices for 1-2 days. The first five years were dedicated to establishing, organising, and documenting the quality systems in the establishments. Once the basics around the quality systems were set, different priorities were defined for each of the 5-year audit cycles to review specific aspects or modalities in more detail.

As of 2017, all establishments have been audited several times and have proper systems in place, the clinical audit process has entered an advanced stage that does not always include an onsite visit by the auditors. More emphasis is put on departments' own quality assurance measures like self-assessments or internal audits

as well as documentation and auditing of predefined procedures against specific nationwide criteria. Various national recommendations and guidelines were issued by KLIARY in cooperation with the professional societies.

The first national clinical audit survey (2006) revealed improvements in the following areas

- Referral and justification practices
- Quality assurance programmes
- Distribution of responsibilities
- Inter-profession communication, also across departments

The follow-up survey (2012) highlighted the concern of the administration about the costs of clinical audits in general, while benefits were clearly acknowledged for the radiological professionals, impacting positively on the everyday practice.

R. Seuri summarized the key success factors:

- Auditors need to be professionals/experts in the field to ensure that also relevant advice and meaningful recommendations can be given
- Educational nature of first round(s) of clinical audits shall not be underestimated
- Need for providing good practice guidance on national and/or international level

16:07 National Experience of Clinical Audit: The Swiss Experience

C. Galli Marxer (Swiss Federal Office of Public Health) informed attendees that the Swiss process started in 2008 and the implementation into national legislation was accelerated by a meeting dedicated to clinical audits in 2010. Multi-professional expert working groups for all three disciplines were set up to define how to implement clinical audit in their field. All people were trained in auditing processes and the first pilot audits were used as a feasibility study. Basic agreements on where and how to conduct the clinical audits included:

- Only those establishments with high dose range will be audited
- Audit cycle is 5 years and to be carried out by third parties/auditors
- Quality manual was required from institutions
- Performance of self-evaluation once per year

A centralised governance structure was set up for strategic considerations, ensuring links between the federal office, the professional groups and various expert commissions. A large pool of auditors was set up. Auditors work in clinical environments and volunteered for the job, while the ministry is paying for their services. General timelines were agreed, and an IT platform was set up to exchange information and prepare for the audits. After the set-up phase, mandatory audits were scheduled to start in 2020/01 but since the COVID pandemic hit, the activities have been postponed by one year.

Lessons learned by the Swiss authorities:

- The national authority decides and supports as well as steers the project so that position on audits and necessary budgets are clearly defined
- It is crucial to consider national peculiarities and adapt accordingly
- Communication is key, a multi-channel approach is needed to:
    - foster understanding for the need of clinical audits
    - overcome resistance in affected services
    - explain the difference between clinical audit and regulatory inspection (recommendations vs measures)
- Main stakeholders have to be involved as early in the process as possible

- The time needed for the design, testing and final implementation of clinical audit processes on national level must not be underestimated

16:20 Round Table Discussion & Q&A-forum

- **C. Engel** (Denmark, national health care accreditation institute) noticed a focus on safety and patient experiences in the ESPERANTO manual. Which leaves the question of how to deal with clinical effectiveness as another important aspect of quality.
    - **B. Brkljacic** agreed with the need for assessing and improving the clinical effectiveness, however, this would be covered by referral guidelines and with tools such as the iGuide for radiological procedures that aim at improving quality, e.g., by reducing unjustified radiological procedures.
- **A. Gimelli** raised the question of whether there is a need for reporting dosimetry as indicator of the quality for the examination.
    - **B. Brkljacic** confirmed that, within radiology, structured reporting is promoted by ESR as well as their American counterpart, RSNA, to achieve improvements globally.
    - **W. Oyen** agreed that the increasing level of consciousness about delivered doses is a positive development. If deviating from protocol (i.e., delivering a much higher or lower dose) for good clinical reasons, detailed reporting is necessary. When staying within the limits of the protocol a standard sentence indicating at least the delivered range can be considered sufficient.
    - **P. Strojan** adds that beam dosimetry is a part of the QUATRO audit and was found useful. As such it should be part of each comprehensive assessment/audit in radiotherapy departments. This could be altered on national level.
    - **A. Vaandering** confirms that in Belgium, equipment dosimetry is carried out by a separate institution and therefore not part of B-QUATRO, while the way how dosimetry to patients is recorded is covered in the B-QUATRO audit.

- **F. Giammarile** asked how European recommendations shall be formulated to facilitate national adaption and implementation (broad-range vs specific)?
    - **N. Reynders-Frederix** replied that the recommendations need to leave a certain degree of freedom to modify and determine not only the practical approach but also the actual quality criteria. There is no way that this national exercise can be avoided. Again, user-friendliness should be the focus to foster understanding and ease application.
    - **M. Vandecapelle** added that the main focus for European/international bodies should be on stressing the added value of clinical audits while explaining the principles of auditing (peer view, internal/external) and the difference between clinical audits, inspections, regulatory audits. All these elements are the same throughout members states, while the development of quality criteria has to be carried out on national level.

- **W. Wadsak** picked up a comment by a participant, asking whether it would be an option to substitute national necessities by local/departmental procedures and protocols, especially in cases when there is no national guidance and standards are available.
    - **C. Galli Marxer** explained that in Switzerland there are no national guidelines available, therefore the experts had to turn to the various international guidelines to decide what and how shall be implemented. If

starting bottom-up from the departmental level, it might be highly challenging to get a real overview of national developments as the criteria might be too specific for the individual departments.

- **W. Wadsak** asked about opinions on who should start driving the process nationally (bottom-up vs. top-down approach; authorities, professional societies, joint ventures etc.).
    - **C. Galli Marxer** replied that the way of implementation highly depends on the culture of the country. In Switzerland, the national authority had to start the process, pushing all actors to collaborate while e.g., Finland is different in their culture and therefore also in their approach to implement clinical audits. Taking over the Finnish approach for Switzerland would have surely resulted in a higher level of resistance and, thus, would have slowed down the implementation of the clinical audit processes.

- **A. Placinska** enquired about the languages in which B-QUANUM is available.
    - **M. Vandecapelle**: confirmed that B-QUANUM is available in Dutch, French, German while the IAEA QUANUM is available in English.
    - **M. Coffey** confirmed that the various IAEA checklists for all specialties are available in English and downloadable for free, so they could be adapted to national needs/language.
      [*The IAEA checklists can be found here:*
      https://humanhealth.iaea.org/HHW/NuclearMedicine/QUANUM_2.0_Excel_Tool_and_QNUMED/index.html
      https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1297_web.pdf

      https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1425_web.pdf]

- **M. Del Rosario Perez** (WHO) backed the call of G. Simeonov for the need for collaboration between all stakeholders at European/international, as well as national level, in order to successfully implement clinical audit practice in the member states. The best practice examples presented in this webinar clearly showed that the route to success is based on multi-disciplinarity and transparent cooperation between various regulatory bodies, radiation protection, quality assurance as well as health authorities, professional societies etc. The BSSD can be regarded as powerful tool to bring all of these stakeholders together while engaging the health authorities.

- **S. Ebdon-Jackson** pointed towards the need for a high level of acceptability for other disciplines in the health care sector apart from radiation. Building on existing procedures will increase the acceptability as well as the value of those procedures. Clinical audits are about continuous improvement, which is also the essence of QuADRANT, which will help to define how this process can be continued.

W. Wadsak thanked all of the contributors and invites **G. Simeonov** to share final comments from the European Commission.

G. Simeonov highlighted three aspects from the presentations:

- Local vs national approach to clinical audits: from a legal perspective it is clear that the responsibility is at the national level; the best practice examples proved the role of national authorities' leadership

- There are many resources available on the national as well as international level (with national adaptations), so the aim should be to share these resources to equip countries with sufficient tools for implementation.
- The question of how clinical audit is embedded in broader quality aspects was only touched upon shortly so far. This topic will be addressed in more detail in the WP3 main survey and the WP4 conference.

Summary of the 'take away' outcomes from webinar 2:

The need for and relevance of clinical audit is clearly acknowledged by all three disciplines represented within the QuADRANT project (radiology, radiotherapy and nuclear medicine). However, the level of compliance with this aspect of the BSSD shows room for improvement throughout member states. Good practice examples clearly indicate that multi-disciplinarity as well as transparency and inclusion are key to successful design and implementation of clinical audits on national level. While the availability of international guidelines, guidance documents, and recommendations is highly valued and drawn upon, it was clearly proven that approaches to, and quality criteria for, clinical audits have to be developed on a national level, incorporating national or even regional specifics to increase the likelihood of implementation.

A certain lack of awareness around the concept of clinical audit, as compared to regulatory audits or inspections, was identified as another hindrance for successful implementation. As a consequence, emphasis needs to be put on communication efforts and information campaigns. European and international institutions are seen as assets when it comes to these educational aspects. The European societies representing the independent specialities using ionizing radiation (i.e. EANM, ESR and ESTRO) could and should play an important role in education. Further challenges for successful implementation that need to be addressed on national level include the need for financial and organisational resources, as well as the availability of a pool of experts with different background in terms of education and training for developing and conducting audits.

Webinar 3: Wednesday 16th December 2020 – Session 1

14:30 Welcome & Summary of Webinar 2

M. Coffey (ESTRO) welcomed the attendees to Webinar 3 and summarised Webinar 2. The first part of Webinar 2 consisted of presentations by representatives of the three professional organisations, focussing on the perspectives of the professional bodies on clinical audit and their approach to supporting clinical audit within their organisation. The second part consisted of presentations from Belgium, Finland, and Switzerland on their experience of introducing clinical audit at a national level in their respective countries. Webinar 2 was closed by Georgi Simeonov outlining three key points:

1. Clinical Audit should be promoted at national level to comply with the BSSD legislation
2. Many resources are already available through organisations such as the IAEA and the professional societies and these should be accessed and used in preparing national programmes
3. It is important to integrate clinical audit into quality of health care programmes of Member States (plus Iceland, Norway, Switzerland, and the UK); this will be the focus of the next workshop.

14:40 National Experience of Clinical Audit: The United Kingdom Experience

- In the United Kingdom there are a number of organisations supporting clinical audit. The Royal College of Radiologists (RCR) is a national professional society, the RCR Clinical Radiology Audit and Quality Improvement Committee (CRAQIC) is dedicated to the development and support of national clinical audit of radiological practices and procedures in the United Kingdom.
- The Healthcare Quality Improvement Partnership (HQIP) is an independent national organisation that manages a national clinical audit programme. The two organisations liaise with each other as appropriate.
- CRAQIC provides an open access and comprehensive series of audit templates and examples to assist auditors in the preparation and management of clinical audit – Auditlive.
- HQIP facilitates benchmarking for departments to support ongoing quality improvement and clinical effectiveness.

R. Greenhalgh (Chair of the RCR Clinical Radiology Audit and Quality Improvement Committee (CRAQIC)) presented the national clinical audit infrastructure in the UK, focusing on clinical radiology.

- The RCR is committed to robust audit to improve patient management
- This is done via a programme of national audit through CRAQIC
- CRAQIC supports local audit through local audit leads and online resources
- The RCR supports national audits working with other Colleges and Societies

The CRAQIC is the RCR committee dedicated to national audits. It provides advice to the RCR and has an annual programme of planned audits and quality improvement. They aim for up to four national audits per year conducted by local leads who are members of the RCR. The audits seek to raise awareness of new standards, facilitate benchmarking across Trusts and through repeat audits measure improvements over time.

Examples of national audits were presented. These included an audit on osteoporotic fragility fractures on CT studies (a collaboration between the RCR and the Royal Osteoporosis Society), which will be repeated to evaluate the impact of newly published guidelines. A second example concerned the provision of imaging in severely injured patients. It showed that larger centres are more compliant with guidelines, while smaller centres encounter more difficulties in reaching the standards. This audit is used by Trusts to look at how their services are configured and to improve them. The third example demonstrated a high standard of radiology practice in cancer multidisciplinary team meetings (MDT) but also demonstrated areas for improvement including the sharing of the correct imaging datasets in the right location and at the right time during MDT discussions.

CRAQIC also provides a range of services to support local leads and assist local trusts in providing a framework for carrying out audits.

- Audit templates covering over 100 radiology topics available on the website
- An Annual Audit Forum: this is a conference where both national and local audits are presented, promoting good practices on audits and quality improvement.

The RCR also worked with the Society of Radiographers in the UK to set up the QSI (Quality Standards for Imaging) which sets national quality criteria for imaging services which can lead to accreditation. The criteria are aligned with those of the Care Quality Commission.

D. Keenan, Medical Director of the Healthcare Quality Improvement Partnership (HQIP), presented the work of the HQIP and its collaboration with RCR.

- HQIP is committed to support those who commission, deliver and receive healthcare to measure and improve services
- HQIP's work programme is based on clinical effectiveness, looking into quality assurance and quality improvement
- HQIP works in partnership with healthcare professionals and currently has 36 national audits running
- HQIP empowers healthcare professionals with data and indication for improvements

HQIP is an independent organisation whose aim is to manage a National Clinical Audit Programme. A national programme is fundamental to identifying if healthcare is being provided according to standards, to facilitating benchmarking, and to identifying where improvements are possible.

The focus of HQIP audits is clinical effectiveness, with quality assurance and quality improvement. Standards are defined using the NICE guidelines and other published standards. Clinicians, through the Royal Colleges, are the driving force of the audits. Examples were provided of improvements as a result of audit related to practice in intensive care particularly with respect to COVID 19 and diabetes.

Sharing data and improving services are HQIP's guiding principles and HQIP provides access to graphs and data showing how the various services are doing and pinpointing areas for improvement. Additionally, HQIP publishes an annual report. All information and resources, such as workshops and infographics, are available publicly on their website.

Looking at the next steps in national clinical audit, data collection and especially real time data collection still remains key, and it is important in the future to reduce the burden of collecting data.

15:00 National Experience of Clinical Audit: The Luxembourg Experience

- The implementation of clinical audits in Luxembourg is guided by the EU directives transposed into national legislation
- In 2015 the Medical Imaging Technical Group was established with representation from all relevant stakeholders, continuing the work of improving the implementation of clinical audits
- Guidance for clinical audits, based on international published guidelines, is provided to all interested stakeholders

A. Karoussou-Schreiner (Radiation Protection Division) presented the national experience of clinical audits in Luxembourg.

The implementation of clinical audits started in 2001, with the transposition of the Euratom Directive 97/43 into legislation. The audit process is based on various publications: the 1996 RCR book "Clinical Audit in Radiology. 100+ recipes"; the 2009 "Radiation Protection" Report 159, European Commission Guidelines on clinical audit for medical and radiological practice, covering radiology, radiotherapy and nuclear medicine and covering both internal and external clinical audits. Ms Karoussou-Schreiner presented the results of the national 2016 audit on Adequate Completion of Radiology Requests Forms, stressing the importance of the audit as a tool for improvement.

In 2015 the Medical Imaging Technical Group was established with representatives of decision makers, social security, healthcare professionals, hospitals, and the radiation protection authority. Its aim is to work on the implementation of the new legislation on radiation protection.

With the 2019 transposition of the 2013 Euratom BSS directive into legislation, the requirements for internal and external clinical audits were further specified. Based on the legislation, their guidelines were updated to include practical examples and reference papers and were then provided to all stakeholders. Internal clinical audits with a clear objective should be carried out once a year and improvement actions put in place. External clinical audit information must now also be provided to the Ministry of Health.

Ms Karoussou-Schreiner listed a number of audits that have been carried out and presented the findings of the national external audit on adequate completion of radiology requests carried out in 2016. They found a wide variation in the level of completion of forms across specialities and the results were further analysed with respect to different typology and practices of departments, according to the specialty of the referrer or the imaging modality. A new form will be developed and an awareness campaign on the importance of accurate documentation will be implemented. A re-audit will then be carried out to assess the impact of these measures.

15:12 National Experience of Clinical Audit: The Norwegian Experience

- The national quality assurance programme in Norway established a national system for external peer review clinical audits in radiotherapy

- The key for success of clinical audits lay in the support of all stakeholders, as well as the willingness to change practice and national clinical guidelines, if necessary, as a result of the audit

I. B. Heikkila (representative of the Norwegian Radiation and Nuclear Safety Authority) presented the Norwegian experience in clinical audits in radiation oncology.

A national quality assurance programme in radiotherapy was established under the Norwegian Radiation Protection and Nuclear Safety Authority in 2000, within the frame of the plan for radiotherapy capacity expansion in the country. It was funded by a national budget and looked at organisational, clinical and physical aspects of radiotherapy. Clinical audits in radiotherapy are carried out as a team effort comprising clinical oncologists, medical physicists and Radiation Therapists (RTTs).

One specific quality assurance project was devoted to establishing a national system for external peer review clinical audits in radiotherapy. The work started in 2005, and the 2002 NICE Principles for Best Practice in Clinical Audits was used as a point of reference. The pillars of clinical audits were identified as patients, clinical guidelines and clinical practice and willingness to change practice when necessary. The process was described in the context of external, peer-reviewed site visit audits carried out by the multidisciplinary team. A set of audit parameters were defined and a group of 20 auditors were appointed to carry out 9 audits incorporating all the radiotherapy departments in Norway. As part of the 2.5-day onsite visit, the scope of the audit was explained again and a confidentiality clause signed. The results were presented and discussed with staff with challenges and possible solutions outlined. The final report was sent to the hospital within a few weeks and on completion of all nine audits a final national report was compiled which included analysis of the data and recommendations.

The example of one national audit was then described and related to radiotherapy for breast cancer. Results from a national workshop in 2008 had demonstrated some deviation between national guidelines and clinical practice. The delineation of treatment volumes was not homogeneous. Audit standards were the guidelines for diagnostic, treatment and follow up of breast cancer approved by the Norwegian Directorate of Health. Audit criteria were the indication to treat, prescription, delineation and dose distribution to treatment volumes and organs at risk (OARs). 180 patients' files (about 10% of all patients treated with RT for breast cancer) were analysed across approximately 100 audit criteria. Results showed that standards were achieved for the indication of radiotherapy, the dose levels and treatment technique. A lower level of compliance was shown for delineation, dose distribution and dose constraints. For 87% of the patients, clinical audit targets were achieved. For 77% of the patients, dose planning audit criteria were achieved. In conclusion, audit standards were achieved for the majority of the criteria. The results also emphasized the importance of using both qualitative and quantitative indicators during an audit, as well as multidisciplinary discussions. As a follow up of this audit, it was agreed that there was a need to improve delineation guidelines, definition of criteria for balancing the dose, and improved technique to reduce dose to OARs, as well as repeating the same audit to check for improvement, adding also waiting time and patient positioning.

Clinical audits were funded through the national budget and were very well received by the Norwegian radiotherapy community. They key for success is that they are well supported by both the hospital management and by the healthcare professionals involved, ensuring that dedicated time is provided. There must be the willingness to change practice as well as national clinical guidelines if necessary, as a result of the

audit. Clinical audits can also be internal, performed by hospital themselves, using national guidelines as standards.

15:24 National Experience of Clinical Audit: The Slovakian Experience

- This audit process was based on the Slovakian Screening Mammography network
- Results of their audit demonstrated that audit was an important tool for improvement and quality of care

M Horvathova and D Nikodemova (representatives of the Faculty of Health Care and Social Work of Trnava University and the Faculty of Public Health of the Slovak Medical University in Bratislava, respectively) presented the Slovakian experience in implementing and performing clinical audits for mammography screening.

Clinical audits are mandatory in order to comply with Slovak healthcare legislation and are considered a key component of effective practice. Consequently, a comprehensive quality assurance scheme for mammography was established, looking at equipment, training, accreditation, and outcomes.

Participation in the Slovak screening mammography network is confined to units dedicated to mammography, with a digital device not older than 8 years, performing at least 3000 examinations per year. In 2018, of the 43 units in Slovakia, 29 were tested according to these newly adopted standards. Of these, 16 were recommended for inclusion in the mammography screening network. The evaluation was carried out by experts representing the Ministry of Health and included a radiologist, a radiographer, an expert in radiation protection. Sonographic examinations, core biopsy and digital breast tomography were also evaluated. The audit considered both process management control and the control of performance indicators consistent with the defined basic indicators defined in the legislation. The results found areas of non-compliance where improvement could be made and confirmed that audit was an important tool for improvement of quality and patient care. Based on this experience the Slovak Ministry of Health has established a permanent working group to take responsibility for national clinical audit.

15:36 The clinical audit experience of European Union of Medical Specialists/European Board of Nuclear Medicine

- The UEMS/EBNM aims to promote the highest standards for nuclear medicine education, training and practice throughout the EU
- A dedicated committee is responsible for accreditation both for practice and as a training centre
- Accreditation of Nuclear Medicine departments has been implemented and ensures improvement and standardisation of quality and practice. It also ensures that the UEMS/EBNM syllabus is followed.

Prof. J Prior (Member of the Executive Board of UEMS/EBNM and chairman of the EBNM committee for accreditation of nuclear medicine departments and nuclear medicine training centres) presented the clinical audit experience of UEMS (European Union of Medical Specialists) and of EBNM (European Board for Nuclear Medicine).

UEMS was founded in 1958 and represents medical specialties in Europe. Its role is to promote and harmonize training for medical specialties. Nuclear medicine was recognized as a specialty in 1989 and became a section of the UEMS in 1990. In 1993,

the Board of Nuclear Medicine was founded. The two bodies – the NM section in UEMS and the EBNM – finally merged into UEMS/EBNM in 2003.

The UEMS/EBNM has 4 committees, dedicated to: education and syllabus; accreditation of departments and training centres; accreditation of continuing medical education; and Fellowship examination. The UEMS/EBNM education and syllabus committee works closely with the EANM (European Association for Nuclear Medicine) to ensure that the progress of the discipline is reflected and the highest standards maintained.

The committee on accreditation implements an accreditation system across Europe, granting a certification valid for 5 years. The accreditation is based on clinical audits. Since 2004, more than 70 departments have been accredited by UEMS/EBNM. Accreditation ensures correct daily practice and quality, but also enhances the credibility of the specialty. Clinical audits, by comparing practice with national and international standards, ensure consistent and safe practice of Nuclear Medicine.

A prerequisite of accreditation is certification (either the ISO certification, or an alternative such as the IAEA QUANUM or one or the national societies clinical audits). Afterwards, an accreditation application online should be completed which includes the certification of staff; list of services and protocols; the 5 most frequent protocols and 5 additional protocols randomly chosen. On site visits are exceptional, for budgetary reasons. A decision is given regarding deficiencies to be corrected, before receiving accreditation. As of today, in 2020, there are 23 accredited departments.

The additional accreditation as a Nuclear Medicine training centre is given based on the UEMS/EBNM criteria defined by the education and syllabus committee. There are now 14 accredited departments as training centres. The renewal of accreditation can be done online, and it is a 5-year cycle. The fees to apply for accreditation are quite modest. In summary, accreditation of NM departments is implemented since the 2000's and is beneficial in improvement and standardization of quality.

15:46 Round Table Discussion & Q&A-forum, Call for Posters

Key topics summarised from the presentations included:

- The important role of collaboration between bodies carrying out clinical audits: collaboration can cross-fertilize initiatives
- The key importance of transparency, and openness in discussing and sharing clinical audit results, leading to improvement and positive change
- Quality and clinical audits are crucial irrespective of the kind of establishment and should be performed both in public hospitals and private practice.
- Site visits remain an important component of clinical audits, allowing for better internal awareness and for future internal audit follow up.
- It is essential to have a multidisciplinary team leading audits to allow for optimal coverage of the patient pathway
- Accreditation and audits are different concepts. Clinical audits should be embedded in every department, potentially leading to accreditation.
- 'One system fits all' is not recommended in clinical audits: while there must be common themes, the specificities of each country should be considered.

M. Coffey asked **D. Keenan** and **R. Greenhalgh** about the collaboration relationship between RCR and HQIP and whether there was cross-fertilization between the two organisations.

- **D. Keenan** confirmed that there is continuous collaboration. The examples of the laparotomy audit, the stroke audit and the trauma audit were mentioned: the elements relating to diagnostics involved the RCR. He pointed out that radiology is involved in a large number of national audits and in most of the HQIP audits.
- **R. Greenhalgh** noted that while there are only a few specific national audits on radiology outside of the RCR, radiology is indeed included in many others with RCR representatives. Also, there is the willingness not to repeat the same work, so collaboration is key. The collaboration is fruitful because national audits can really drive change and support the creation of guidelines that can then be circulated to RCR members, targeting the whole country.

F. Giammarile (EANM) commented that D. Keenan raised a very important point regarding whether audit results should be public or not. Audits are fundamental to improving daily practice, and it can be useful to see the results from other institutions and countries.

- **D. Keenan** pointed out that since the 2000's, in the UK, the transparency agenda is particularly important in all sectors, including in the healthcare sector. Transparency is necessary, patients are advocates for this, and the more we make the results public, the better it is for all stakeholders. For example, the transparency of the process of reconfiguring the strokes units in various cities led to many improvements. Audits can drive improvement only if the results are known.

G. Frija (ESR) observed that many imaging examinations are now performed in private practice centres, and this raises the question whether there should be a different approach to audits between public hospitals or private centres? Is there a difference in terms of feasibility?

- **M. Coffey** supported the view that anybody using radiation in any form should be subject to audit. She highlighted the importance of quality, irrespective of the status of the hospital, for the benefit of the patients.
- **A. Karoussou-Schreiner** confirmed that this is the approach followed in Luxembourg, where the legislation is very clear that it applies to all establishments carrying out medical radiological procedures, referring to both public and private hospitals.
- **R. Greenhalgh** commented that, currently, the RCR only sends out audits to NHS hospitals; private hospitals are not included primarily because the majority of radiologists work in NHS hospitals, therefore it is felt that the practice is covered in this way. But of course, the principle is that every establishment should be treated in the same way. However, the private centres do not come under the auspices of the RCR.
- **J. Prior** pointed out that some private centres are applying for the UEMS/EBNM accreditation. It was noted however that, for some small private practices, it might be more challenging getting all the prerequisite to access the accreditation. Now with the push to make this mandatory, they hope to see a change in the future.
- **I. B. Heikkila** reiterated the point that under Norwegian legislation on radiation protection there is no distinction between private and public establishments.

G. Simeonov asked **R. Greenhalgh** if audits also include site visits?

- **R. Greenhalgh** commented that the RCR audits are very much voluntary, with the main goal of the staff being the desire to improve their department. There are some site visits, but not led by the RCR. The RCR does not do site visits *per se*.

M. Coffey, referring to the example of Norway, with the review of breast cancer practice, highlighted that it is interesting to note that positioning is now being added to the audit. It is particularly interesting, as positioning is often not properly considered and yet has a very significant role in accurate practice.

- **I. B. Heikkila** confirmed that it is a necessary step to be considered, and it has been added thanks to the Radiation Therapists (RTTs) being included in the audit teams. Even if the dose is correct, with incorrect positioning, the whole process is undermined. The addition of such step is the proof that working in a multidisciplinary fashion is extremely beneficial.
- **M. Coffey** also highlighted that checking these processes is quite important in relation to the discussion about having site visits during audits, actually seeing what people are doing on the ground and how they are implementing the guidelines.

A. Karoussou–Schreiner commented that we have been talking a lot about external clinical audits but wanted to highlight the importance of internal clinical audits also. While it is extremely beneficial to have external people to check and discuss practice, it is also beneficial to do internal clinical audits, with people from the department that participate and are actively involved in the external audits and in the site visits, then carrying out their own internal audits, learning while doing, and increasing awareness.

- **M. Coffey** agreed and added that the importance of site visits is that it offers an opportunity and the possibility to openly discuss issues, to debate the improvement of the system, and to boost the confidence of the group to carry out the audits again.

M. Coffey asked **J. Prior** to clarify if accreditation is linked directly to audit, in the UEMS/EBNM system. By doing so, does audit remain a voluntary process linked to improvement, as opposed to an obligatory regulatory step?

- **J. Prior** clarified that the accreditation is indeed a two-tier system. To ask for an accreditation, the first prerequisite is to acquire certification – such as the ISO one, or through the IAEA or national certification audits. That can be quite a time-consuming process and is probably linked to the feeling of undergoing stringent checks. But once this is done the matter is more to discuss the practice, beyond the strict rules of certification, checking the state-of-the-art practice. Once this is ascertained, the next step, if wished, is to be accredited as a training centre, proving that the centre is training the future professionals in Nuclear Medicine to the highest standard.
- **M. Coffey** praised the concept of accreditation of training centres, highlighting that in the IAEA QUATRO process centres that are recognized as centres of excellence are those that can then train other professionals.

D. Howlett asked for clarification from **D. Keenan** regarding the budget allocation of HQIP.

- **D. Keenan** gave an outline of the main budget items of HQIP, namely the management of the society and the bodies running the audits: funding is necessary and the budget is mostly dedicated to supporting the workforce, both to perform the audits and to collect and manage data and IT systems. It can be a rather expensive process, but as COVID-19 showed, it is extremely important to invest in health care services to have an impactful return on

investment. If looked at in perspective, audits do provide value for the money invested.

G. Simeonov expressed his appreciation for the lively discussion and agreed fully with the need to invest in audits to improve the systems and make them more efficient. This is a perspective that managers should consider. Additionally, he asked whether there should be clarification of the many labels applied to these processes – be it accreditation or audit – as well as clarity on their mandatory nature. There is a legal system where it is required to do clinical audits, so this is the action that should be performed, rather than additional non-mandatory stamps.

- **M. Coffey** shared her view that, ideally, accreditation should be possible only if you are actively involved in clinical audits. Clinical audits can help you to improve. It is crucial not to perceive the audits as something threatening and mandatory, as you might lose the opportunity of seeing it as a tool for improvement, as opposed to an obligation that is not beneficial.
- **R. Greenhalgh** agreed that clinical audits should be embedded in every department, because it shows the willingness to improve. Accreditation should be the additional step, the icing on the cake. Agreement that audit must be on the path towards accreditation.
- **J. Prior** stated that in Nuclear Medicine the accreditation system started about 20 years ago, before clinical audits were mandatory, and at the time ISO certification was a large piece of work and time consuming. The certification is the aspect encountering resistance from the community, not the accreditation. This said, clinical audits are for sure a necessary step towards reaching accreditation.

M. Brada asked, specifically concerning the UK, how the HQIP process is related to CQC (Care Quality Commission) and what the link was between them?

- **D. Keenan** explained that CQC is a regulatory body, existing only in England. CQC and HQIP work closely together. CQC has full access to the data that HQIP collects and can use those data. A practical example is the use of published HQIP data to contact hospitals that are outliers in some procedures, to understand the reasons and then to put a plan in place to help improvement. There is also collaboration at a methodological level.

R. Bly asks if a one-fit-for-all system is applicable and recommended in clinical audits across Europe or if countries should adapt the process to reflect their specific situation?

- **D. Keenan** replied that looking at the UK, where there are 4 countries, it is already difficult working across systems and populations, so the standardized approach would not work and probably result in a heavy bureaucratic machine. Comparing directly across Europe the exact same risks algorithms will probably miss out important aspects. However, what it is recommended is working together on the big picture and defining quality in a common manner.
- **M. Coffey** commented that there is a certain level of commonality that everybody should adhere to, but then the culture and the situation in each country should be considered. There is a large variation in the level of equipment, knowledge and practice that must be taken into account.
- **M. Coffey** stressed the role of clinical audit as a tool that allows learning and improvements. She asked how it could be checked whether or not the recommendations and improvement measures were implemented and stressed that the follow up audit is central in the process.

J. Clark (ESR) reminded the audience that during the workshops there had been several national presentations and the consortium was very pleased with the sharing of such a wealth of practices. He stated that they would encourage further sharing of other national experiences. He informed the attendees that they would welcome the submission of posters detailing other national experiences of clinical audit. These would be hosted on the QUADRANT webpage (within the Eurosafe imaging website).

- **D. Howlett** added that sharing national work can be extremely beneficial to the consortium and to the community at large.

Webinar 3: Wednesday 16th December 2020 – Session 2

16:25 Introduction of QuADRANT Work Package 3 Survey & Next Steps in the QuADRANT project

- The main deliverable of Work Package 3 is a survey on the implementation of clinical audits in the 27 EU member states (plus Iceland, Norway, Switzerland, and the UK). A pre-survey had already taken place to identify the main national players. Dedicated interviews will follow, and a literature review is ongoing
- The full survey will encompass many aspects of clinical audit and will be structured in two main parts: clinical audits and infrastructure with a section dedicated to clinical audit requirements and the EU-BSS.
- The discussions during this Work Package 2 workshop will feed into the survey and allow for additional topics to be added.

D. Howlett explained the process of QUADRANT and introduced Work Package 3.

QUADRANT is a 30-month project which commenced in the first quarter of 2020 and is composed of five work packages. WP1 covers the management of the project. WP2, which is now coming to an end, was focussed on this first workshop covering the essential of clinical audits and providing a baseline of national experiences. WP2 will inform WP3. All work packages will feed into WP4, with a meeting to present the findings, thoughts, and conclusions. WP5 will conclude the project, summarising existing guidance and providing a set of recommendations for consideration and use by the European Commission.

WP3 will consist of a survey on the implementation of clinical audit in 27 EU member states (plus Iceland, Norway, Switzerland, and the UK). It has four components: a pre survey, a set of expert interviews, a literature review, and the final survey: The pre-survey was carried out in the first quarter of 2020 and this also provided an opportunity to identify key players in the EU, particularly at national and administrative levels with respect to clinical audit. Their engagement in the next steps, especially in the Main Survey, will be of paramount importance. Their continued engagement with the project is anticipated. The expert interviews will cover the various disciplines and the on-going literature review will look at the key publications relating to clinical audit.

The Main Survey relates to the requirement of the EU tender, with respect to the identification and reporting of best practice, providing guidance documents, and identifying available resources for clinical audits, with the ultimate goal of creating an audit roadmap across Europe.

The proposed distribution of the survey is to target three groups: national audit administrators and healthcare representatives, HERCA/radiation protection national

contacts, and national society representatives for the three disciplines: radiology, radiotherapy and nuclear medicine. The replies will be anonymized. The survey will explore the types of audits carried out and the role of the national societies and international bodies. Licencing and accreditation will also be addressed together with administration, governance, and policy development. Education and training on clinical audit will also be considered together with incentives and barriers to participation in clinical audits. The impact of the BSSD will be discussed and there will be space for free text to enable sharing of national practices, additional comments and any recommended resources or publications of value.

Based on the discussions during WP2, additional topics have been identified and will be added to the survey. These include:

- detail of the central agencies responsible for clinical audits,
- the role of patients,
- peer review,
- quantitative as opposed to qualitative audits,
- the role of decision support software,
- further exploration of incentives that may facilitate audit participation,
- the role of national quality indicators,
- guidance and national initiatives,
- the concept of one-size-fits-all as opposed to empowering the countries and the stakeholders,
- the benefits of audits and collaboration across the various factors involved,
- the important role of professional societies to lead the process and liaise with the external partners, and whether this role should be pursued further.

D. Howlett concluded by thanking the European Commission, the lead of Work Package 2, M. Brada, and all collaborators in WP2, with the ESR office and the workshop moderators. A thank you was given to all speakers and to the audience. It was acknowledged that the workshop had a good turnout and lively discussion.

16:35 Q&A-forum on QuADRANT project Next Steps

- The next steps in the project having already been outlined, an opportunity was given for additional questions on the process.

- **C. Clark** commented on the large body of work currently ongoing on quality assurance in clinical trials. Her suggestion was for the survey to also capture this kind of activity.
    - **M. Coffey** agreed that clinical trials are a very important aspect to consider and stated that it also reflected the discussion about onsite visits, allowing for discussion on the actual practice, in all domains. Although in this specific case it might be a difficult aspect to capture.

- **M. Coffey** thanked all speakers and attendees for an excellent session followed by an excellent discussion.

- **J. Clark** reminded the attendees of the approximate timeline of the survey of WP3. It should be implemented in first half of 2021, with analysis taking place in summer 2021. Following this it is proposed that the workshop of WP4, which will present the results of the survey, will be scheduled for December 2021.

16:50 Conclusions

It was agreed that this had been a very positive workshop with high level presentations and lively discussion. G. Simeonov was then asked to make the concluding remarks and to close the session.

G. Simeonov concluded the workshop reminding the attendees that this project is an important part of the SAMIRA initiative, on the pillar dedicated to quality and safety. The clinical audit topic is very relevant because it links legislation with practice. The workshop participation and the lively discussion – which were both excellent – showed the importance of the topic.

He thanked all partners and the three professional societies – ESR, EANM and ESTRO – who took up this challenge.

Summary of the 'take away' outcomes from the webinar

It was clear from the workshop that there is a high level of interest in understanding clinical audit and learning more about the process and how it should be implemented and supported going forward. The results of the survey will provide greater clarity on the level of national implementation and will provide an opportunity to reflect the discussion of this workshop in both the questions and the final recommendations.

5 Workshop summary and conclusion

The QuADRANT project is an important part of the SAMIRA initiative, on the pillar dedicated to quality and safety. The need for and relevance of clinical audit is clearly acknowledged by all three disciplines represented within the QuADRANT project (radiology, radiotherapy and nuclear medicine). Participants and speakers in the workshop also agreed on the importance of clinical audit in quality improvement in health care, particularly because it links legislation with practice. Quality and clinical audits should be performed both in public hospitals and private practice.

The level of compliance with the BSSD shows room for improvement throughout member states. Additionally, whilst there is an understandable focus in audit in relation to the BSSD requirements (optimisation and justification), it is important that clinical audit is acknowledged as a more far-reaching topic, with broader application and value for patient outcomes, staff and hospitals. There is much value to be gained from small, local audits of practices relating directly to patient experiences, while maintaining constant auditing of key issues such as optimisation and justification.

The different types of audit were explained in webinar 1. Many organisations have produced guides on performance of clinical audit, which are freely available. Nevertheless, a clinical audit infrastructure needs to be developed on a national level, incorporating national, regional and local specifics to increase the effectiveness of successful and constructive implementation.

A certain lack of awareness of the concept of clinical audits, as compared to regulatory audits or inspections, was identified as a potential hindrance for successful implementation: there are some differences in understanding of clinical audit between those engaged in regulation/inspection and practitioners. The allocation of financial resources as well as the need for national bodies to take national leadership could also be potential sticking points. There was valuable discussion on these areas with consensus reached. Accreditation and audit are different concepts. Clinical audits should be embedded in every department, potentially then forming a core component of department accreditation depending on national practice and procedure (although it should be noted that this is not a requirement under the BSSD).

Some participants suggested that an audit does not really constitute clinical audit unless an external person/body is involved: site visits are an important component of clinical audits, allowing for better internal awareness and for future internal audit follow up. It was agreed that external audit, ideally peer-led, and also external direction of internal audit are both important, but implementation of effective internal processes of clinical audit and self-assessment are also to be strongly recommended and are good practice.

The following were considered key factors for the implementation and success of clinical audit:

- involvement of patients as partners
- transparency in clinical audit processes and openness in discussing and sharing clinical audit results
- multi-disciplinarity to allow for optimal coverage of the patient pathway
- collaboration between bodies carrying out clinical audits and that collaboration can cross-fertilize initiatives
- a clear definition of the profile of the peer auditors is considered key to success. Further, embedding clinical audits in a holistic culture of quality within

the respective establishment was agreed to be one of the corner stones of a successful implementation.

- communication efforts and information campaigns. The European societies representing the independent specialities using ionizing radiation (e.g. EANM, ESR and ESTRO) should look to play an important role in this
- A 'one system fits all' model is not recommended in clinical audits: while there must be common themes, the specificities of each country should be considered. Challenges for successful implementation that need to be addressed on national level include the need for financial and organisational resources, as well as the availability of a pool of experts with different background in terms of education and training for developing and conducting audits.

The workshop generated highly useful information that will support the collection of best practice information in the field of clinical audit and will influence the content of the Main Survey carried out as part of Work Package 3 (WP3), form the background to the second workshop (WP4), as well as provide valuable content for consideration in the final report and recommendations (WP5).

6 Appendices

Appendix 1: List of invitees, registrations, and attendees to the workshop

For reasons of privacy, the list of attendees and their contact details has been removed from the report submitted to the European Commission before publication on the QuADRANT webpage.

In total, 155 contacts were invited to attend the workshop, 131 contacts registered to attend, and 119 attended for at least one of the workshops.

Appendix 2: Steering Group and Advisory Board Feedback on workshop programme

On grounds of confidentiality, internal discussions between the project consortium and its Steering Group and Advisory Board been removed from the report submitted to the European Commission for publication on the QuADRANT webpage.

Appendix 3: Workshop programme

The workshop programme is also available as a PDF on the QuADRANT website: http://www.eurosafeimaging.org/wp/wp-content/uploads/2020/11/QuADRANT-Workshop-programme-v2-1.pdf

QuADRANT

QuADRANT Workshop
Monday 14th December 14:30 – 17:00 CET

Webinar 1: QuADRANT, Clinical Audit and Radiation Protection - An Overview

Moderator: D. Howlett; Rapporteur: A. Brady

14:30	Welcome & Introduction from the European Commission and Project Leadership Team Michael Hübel (Head of Unit Radiation Protection and Nuclear Safety in DG ENER, European Commission) David Howlett (Project Leader, radiologist, Chair of the European Society of Radiology (ESR) Audit and Standards Subcommittee) Adrian Brady (Project Co-Leader, radiologist, ESR 2nd Vice President)
14:40	Setting the Scene Georgi Simeonov (Policy Officer, Radiation Protection and Nuclear Safety in DG ENER, European Commission)
14:50	An Introduction to the QuADRANT Project David Howlett (Project Leader, Chair of the ESR Audit and Standards Subcommittee and former-chair of the UK Royal College of Radiologists (RCR) Clinical Audit and Quality Improvement Committee)
15:00	Clinical Audit as Defined in the *European* Basic Safety Standards Directive Alexandra Karoussou-Schreiner (Chair of HERCA Working Group – Medical Applications)
15:20	Clinical Audit & Quality Improvement Adrian Brady (Project Co-Leader, ESR 2nd Vice President)
15:40	Round Table Discussion & Q&A-forum
16:10	International Atomic Energy Agency Experience of Clinical Audit: QUAADRIL, QUANUM and QUATRO projects Diana Paez (Section Head, Nuclear Medicine and Diagnostic Imaging Section, Division of Human Health, Department of Nuclear Sciences and Applications, International Atomic Energy Agency)
16:25	World Health Organization Experience of Clinical Audit **Shamsuzzoha Babar Syed** (Coordinator, Quality of Care Unit, World Health Organization)
16:40	Round Table Discussion & Q&A-forum
17:00	Close

QuADRANT Workshop

Tuesday 15th December 14:30 – 17:00 CET

Webinar 2: Clinical Audit, Improving Patient Safety and Outcomes - The European and National Experiences

Moderator: Wolfgang Wadsak; Rapporteur: Sonja Niederkofler

14:30	Welcome &Summary of Webinar 1 Wolfgang Wadsak (project team, European Association of Nuclear Medicine, Head of Medicinal Radiochemistry and Biomarker Development, Department of Biomedical Imaging and Image-guided Therapy, Vienna)
14:40	Aims and Benefits of Audit by Specialty: Radiology Boris Brkljacic (Chairman of the European Society of Radiology Board of Directors)
14:50	Aims and Benefits of Audit by Specialty: Nuclear Medicine Wim Oyen (President of the European Association of Nuclear Medicine)
15:00	Aims and Benefits of Audit by Specialty: Radiotherapy Primoz Strojan (project team, Institute of Oncology Ljubljana, Slovenia)
15:10	Round Table Discussion & Q&A-forum
15:30	National Experience of Clinical Audit: The Belgian Experience Nils Reynders-Frederix (Belgian Federal Public Service for Public Health) Marleen Vandecapelle (Belgian Federal Agency for Nuclear Control) Aude Vaandering (Department of Radiation Oncology, Cliniques Universitaires St Luc, Brussels)
15:54	National Experience of Clinical Audit: The Finnish Experience Raija Seuri (Helsinki University Hospital)
16:07	National Experience of Clinical Audit: The Swiss Experience Carine Galli Marxer (Swiss Federal Office of Public Health)
16:20	Round Table Discussion & Q&A-forum
17:00	Close

QuADRANT Workshop
Wednesday 16th December 14:30 – 17:00 CET

Webinar 3: Further European and National Experiences&QuADRANT Next Steps and the Way Forward

Moderator: Mary Coffey; Rapporteur: Chiara Gasparotto

Session 1: Further European and National Experiences

14:30 Welcome &Summary of Webinar 2
Mary Coffey (ESTRO, Adjunct Associate Professor, Division of Radiotherapy, University of Dublin)

14:40 National Experience of Clinical Audit: The United Kingdom's Experience
Danny Keenan (Medical Director of the Health and Quality Improvement Partnership) Rebecca Greenhalgh (Chair of the Royal College of Radiologists' Audit and Quality Improvement Committee)

15:00 National Experience of Clinical Audit: The Luxembourg Experience
Alexandra Karoussou-Schreiner (Medical Physics Expert, Luxembourg Ministry of Health)

15:12 National Experience of Clinical Audit: The Norwegian Experience
Ingrid Bjørseth Heikkilä (Head of Section, Medical Applications, The Norwegian Radiation and Nuclear Safety Authority)

15:24 National Experience of Clinical Audit: The Slovakian Experience
Denisa Nikodemová (Faculty of Public Health, Slovak Medical University, Bratislava)
Martina Horváthová (Faculty of Health Care and Social Work, Trnava University)

15:36 The clinical audit experience of European Union of Medical Specialists/European Board of Nuclear Medicine
John Prior (Chair, European Union of Medical Specialists/European Board of Nuclear MedicineAccreditation of Nuclear Medicine Departments and Nuclear Medicine Training Centres)

15:46 Round Table Discussion & Q&A-forum, Call for Posters

Session 2: QuADRANT Next Steps and the Way Forward

16:25 Introduction of QuADRANT Work Package 3 Survey &Next Steps in the QuADRANT project
David Howlett (Project Leader, Chair of the ESR Audit and Standards Subcommittee)

16:35 Q&A-forum on QuADRANT project Next Steps

16:50 Conclusions
Georgi Simeonov (Policy Officer, Radiation Protection and Nuclear Safety in DG ENER, European Commission)

17:00 Close

Appendix 4: Workshop presentations

The slides from the workshop presentations are available on the QuADRANT website: http://www.eurosafeimaging.org/clinical-audit/quadrant/wp-2