

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



D4.4: WP4 Workshop Report

February 2022

Start date of project: December 27, 2019
30 months

Duration:

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WP4 co-leaders: D. Howlett (ESR), N. Jornet (ESTRO)

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Reviewed by all consortium members

For the attention of: European Commission, Directorate General for Energy, G.
Simeonov



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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 QuADRANT project is an important part of the SAMIRA initiative, forming part of the pillar dedicated to quality and safety. Three medical disciplines are represented within the QuADRANT project, namely radiology, radiotherapy, and nuclear medicine. These disciplines are represented by the European Society of Radiology ([ESR](#)), European Society for Radiotherapy and Oncology ([ESTRO](#)), and European Association of Nuclear Medicine ([EANM](#)).

The QuADRANT Work Package 4 (WP4) workshop was the second of two workshops held as part of the QuADRANT project. The first workshop was held as a series of webinars on 14th, 15th, and 16th December 2020 as the first of two workshops forming part of the QuADRANT project. A redacted version of the workshop report was published on the [QuADRANT website](#). The workshop slides, plus 3 posters submitted after the workshop, were also made available on the website. The outcomes of the first workshop informed the project's Main Survey, which was conducted between 25th March 2021 and 7th May 2021. The data collected during the Main Survey was analysed between June and August 2021, a literature review was conducted, and experts were provided with the data and, subsequently, interviewed.

The aim of the WP4 workshop was to present the results of the Main Survey to representatives from the EU27+4 and to discuss with representatives of Member States the need for further coordinated EU action on quality and safety of radiology, radiotherapy and nuclear medicine. The ultimate goal of this was to produce, by discussion and consensus, a detailed outline and guidance as to how clinical audit uptake and implementation across the EU27 (plus Iceland, Norway, Switzerland, and the UK) can be enhanced.

The planning of the workshop was the responsibility of the WP4 team, consisting of Prof F. Giammarile (EANM) as Work Package leader, Prof D Howlett (ESR) and Prof N. Jornet (ESTRO) as co-leads, with the support of ESR Office Staff (M. Hierath and J. Clark). This report details the workshop planning, content, and outcomes.



2 Workshop Programme

The workshop programme is also available as a PDF on the QuADRANT website:
<http://www.eurosafeimaging.org/wp/wp-content/uploads/2022/01/Final-QuADRANT-Workshop-Programme.pdf>



Second QuADRANT Workshop

Thursday 13th January 10:00-13:00 CET

Friday 14th January 10:00-13:00 CET

VENUE: Online only – zoom webinar software (registration link:
https://us02web.zoom.us/webinar/register/WN_0GYrK7jDR22LVgsxl0r4eg)

AIMS:

- Discussion of Findings and Conclusions from the Survey on Clinical Audit (plus Expert Interviews and Literature Review)
- Selection of Best Practice Examples
- Transfer of Knowledge to those Countries without (or with limited) Clinical Audit Implementation
- Towards the Development of General Recommendations (WP5)

TARGET GROUP:

- The target group of the workshop is representatives from relevant national and professional societies representing the key disciplines, radiation competent and health authorities and also the European Commission.



QUADRANT

DAY 1: Clinical Audit in the EU 27+ 4 – The Current Status

Thursday 13th January 10:00-13:00 CET

10:00 - 10:10	Session 1.1: Day 1 Opening	
	Welcome (M. Huebel)	5 mins
	Introduction – Meeting agenda (F. Giammarile)	5 mins
10:10 - 11:00	Session 1.2: Clinical Audit – Setting the Scene	
	Overview of project aims and structure: Context, background & definitions in use (D. Howlett)	10 mins
	Previous key work, overview of clinical audit related initiatives, clinical audit and the background to the BSSD (S. Ebdon-Jackson)	10 mins
	Summary of first QuADRANT workshop (W. Wadsak)	10 mins
	Q & A session (Moderator: M. Coffey)	20 mins
----- 11:00 - 11:10 Break -----		
11:10 - 12:05	Session 1.3: Status of Clinical Audit in the EU 27+4 – WP3 (Part 1) Rapporteur: N. Jornet	
	Overview of QuADRANT Work Package 3 - Main Survey, Expert Interviews, Literature Review (P. Strojan)	10 mins
	Clinical Audit Practice and Process (D. Paez)	15 mins
	Patient Involvement (E. Briers)	10 mins
	Q & A session (Moderator: A. Brady)	20 mins
12:05 - 12:55	Session 1.4: Clinical Audit, Regulatory Control and the BSSD Rapporteur: J. Clark	



Regulatory Control – Clinical Audit and the BSSD (key outcomes from WP3) (A. Schreiner)	15 mins
Roundtable Panel Discussion (Moderator: W. Wadsak)	30 mins
Panellists: H. Delis, C. Clark, W. Jaschke, A. Schreiner, R. Bly, N. Jornet	
Topics:	
<ul style="list-style-type: none">• Radiation Protection,• the role of clinical audit as outlined within the BSSD,• link to inspections,• issues raised within the survey,• how to improve uptake and compliance,• dosimetry quality management.	
Round up Day 1 (W. Wadsak)	5 mins
12:55 - 13:00	Session 1.5: Day 1 Close
Closing Statements (G. Simeonov & D. Howlett)	5 mins



QUADRANT

Day 2: Clinical Audit in the EU 27 +4 – Improving Uptake and Implementation

Friday 14th January 10:00-13:00 CET

10:00 - 10:15 **Session 2.1: Day 2 Opening**

Welcome (G. Simeonov)	5 mins
Summary Day 1 and Overview Day 2 (F. Giammarile)	10 mins

10:15 - 11:30 **Session 2.2: Status of Clinical Audit in the EU 27+4 – WP3 (part 2)** **Rapporteur: M-L. Ryan**

Barriers, Incentives, Accreditation (B. Brkljacic)	15 mins
Development of Infrastructure – the Role of the National Societies (N. Jornet)	15 mins
Educational Aspects (M-L. Ryan)	10 mins
Overview of Good Practices (A. Brady)	15 mins
Q & A Session (Moderator: M. Coffey)	20 mins

----- 11:30 - 11:40 Break -----

11:40 - 12:45 **Session 2.3: Enhancing European Clinical Audit Uptake and Implementation** **Rapporteur: M. Coffey**

Roundtable Panel Discussion (Moderators: A. Brady & W. Wadsak)	60 mins
Panellists: N. Reynders-Frederix, D. Keenan, C. Galli Marxer, H. Waltenburg, G. Simeonov, A. Schreiner, D. Paez, M. Perez, P. Papirnik, B. Brkljacic, W. Oyen, P. Strojjan	
<ul style="list-style-type: none"> Points for discussion to include: - 	



- Commonalities and differences in practice
- Sharing best practices
- Prioritisation and resourcing
- Barriers, incentives
- Accreditation/certification
- Improving patient involvement
- Clinical audit and the BSSD/inspection.
- How can EU co-operation and sharing of best practices be improved?

Round up Day 2
(M. Coffey)

5 mins

12:45 - 12:50 **Session 2.4: Day 2 Close**

Closing Statements
(G. Simeonov & D. Howlett)

5 mins



3 Workshop 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-4>

Additionally, it was agreed with the European Commission during the QuADRANT project Final Progress Meeting that this redacted version of the workshop report should be published on the QuADRANT website.

Webinar 1: Thursday 13th January 2022

Session 1.1: Day 1 Opening

D. Howlett (QuADRANT Project Leader, Chair of the European Society of Radiology (ESR) Audit and Standards Subcommittee) began the workshop and introduced himself and the theme of the workshop: to consider the current status of clinical audit in the EU27+4 and produce, by discussion and consensus, a detailed outline and guidance as to how clinical audit uptake and implementation across Europe can be enhanced.

F. Giammarile (QuADRANT Work Package 4 Lead, EANM Lead Expert - Nuclear Medicine Physician) also welcomed attendees and introduced the agenda for Day 1 of the workshop.

Session 1.2: Clinical Audit – Setting the Scene

Overview of project aims and structure: Context, background & definitions in use

D. Howlett set the scene by providing contextual background information on clinical audit as a well-established tool for quality assurance and a key component of effective clinical governance. Clinical audit sets out to improve not only patient care and related outcomes but also safety whilst, at the same time, enhancing the clinical experience. Clinical audits are mandated within the BSSD to be carried out “in accordance with national procedures”.

Looking at the development of clinical audits, previous work by the EC demonstrated the variable situation on the member state level regarding the implementation of clinical audits. In response to this finding, the EC published the Radiation Protection Series 159 Guidelines on Clinical Audit for Medical Radiological Practices. Despite these efforts, follow-up studies by the EC, as well as professional societies such as ESR, proved the continuing difficulties in clinical audit implementation. Consequently, in 2019 the EC put out the tender at hand (no. ENER/D3/2019-231-2) and the work on QuADRANT started in 2020 within a consortium of the three societies ESR (lead), EANM and ESTRO. Over the 30-month duration of the project, the consortium is guided by the EC and supported by both an Advisory Board and Steering Group. The work has been divided into 5 work packages (WP). The two envisaged face-to-face workshops (WP2 and WP4) had to be conducted online due to the COVID-19 pandemic. The first workshop, as well as the main project survey (WP3), feed into the second workshop (WP4). All findings will be brought together in the final guidance and recommendations paper (WP5) as part of the project completion in summer 2022.

D. Howlett emphasised the project objectives:

- a) review the status of implementation of clinical audits in the Member States;
- b) identify good practices in Member States and available guidance and resources for clinical audits, at national, European and international level;
- c) provide further guidance and recommendations on improving the implementation and integration of clinical audits into national healthcare systems;
- d) identify potential for further coordinated EU action on quality and safety of radiology, radiotherapy and nuclear medicine.



D. Howlett concluded his presentation by reminding the participants of the two definitions that are in use for clinical audit as well as other terminology used primarily in the WP3 Main Survey:

- Clinical audit is “a systematic examination or review of medical radiological procedures that seeks to improve the quality and outcome of patient care through structural review, whereby medical radiological practices, procedures and results are examined against agreed standards for medical radiological procedures, with modifications of practices, where appropriate and the application of new standards if necessary” [BSSD] – whereby this is applicable to all medical applications involving ionizing radiation
- Clinical audit is “improving the quality of patient care by looking at current practice and modifying where necessary”
- Self-assessment/evaluation: a step in preparation for internal clinical audit, the process being undertaken by a multi-disciplinary evaluation team consisting of members of the team being audited
- Internal audit: audit that occurs at local level (individual, departmental, hospital) on its own initiative and consistent with national requirements
- Internal audit with external direction: a system whereby guidance or direction is provided via an external body (e.g. national professional society), allowing co-ordination of audit potentially across multiple departments/hospitals
- External audit: an external audit team (ideally comprising relevant healthcare professionals) working across a number of centres/hospitals within a region or country
- Further terms used included *inspection* and *regulatory audit* and were used to clearly differentiate these concepts from clinical audit – see below

Previous key work, overview of clinical audit related initiatives, clinical audit and the background to the BSSD

S. Ebdon-Jackson (Health Policy Maker / Health Economist, UK) introduced the participants to the origins of the concept of clinical audits, outlined how it has developed since, and how it is related to current activities within the European Union (EU).

Starting in the late 1980s/early 1990s the first noteworthy publication is the UK White Paper published in 1989 and entitled “Working for Patients” which delivered an early definition of clinical audits. It served as basis for the practical manual by the UK’s Royal College of Radiologists (RCR) “Clinical Audit in Radiology. 100+ Recipes” (de Lacey, Godwin and Manhire). Further development on the concept came from Finland (“Implementing External Clinical Audits in Radiological Practices: the Experience in Finland”). A couple of years later, HERCA provided explanation of how the regulators saw clinical audits, while the ESR started to develop and evolve the understanding of clinical audits within the professional radiology community.

The key elements of clinical audit are:

- It is a process
- It is designed to improve patient care
- It requires systematic review against explicit criteria
- It requires the implementation change when necessary

All of which is part of an audit cycle, intended as ongoing process of observation that also does not stop when improvements were made. As outlined by **D. Howlett**, there are different forms of clinical audits:

- Internal audit
- External audit



- o Internal audit with external direction.

While the “internal audit” approach reflects the Finnish experience, external audits are where most member states started from. Internal audits with external direction can be understood as local audits that are conducted against criteria set forth e.g. by professional societies or as part of a national initiative.

Related to the EC Directives, the Medical Exposure Directive 97/43/Euratom was the first of its kind to include the concept of “medical audit”. In the BSSD the “medical” was replaced by “clinical” while the requirement to conduct the audits adhering to national procedures was preserved to be harmonised with other medical disciplines. Further guidance on the matter was provided by the EC in their Radiation Protection Series report No. 159. Since the EC recognised that the update of clinical audits was not fully exploited, it was decided to launch this study to promote the constant improvement in quality and safety in radiology, radiotherapy, and nuclear medicine through clinical audit.

S. Ebdon-Jackson mentioned the ESR’s ESPERANTO guide as a further successful piece of guidance for the professional community that keeps maturing (3rd Edition issued in December 2021).

HERCA as the regulator’s forum, established a working group on medical applications that published a position paper in 2019 on clinical audits in medical radiological practices in which they are set out as regulators’ expectations. These expectations are that: a) clinical audits are carried out; and, b) they are targeted to radiation protection principles.

S. Ebdon-Jackson clarified that clinical audit is neither a regulatory audit nor inspection, which is outlined by a comparative table in the HERCA report.

	Clinical audit	Regulatory audit	Inspection
Defined criteria	Good practice or standard	Regulations	Regulations
Expected level of achievement	Locally/nationally defined	100% compliance against self-assessment of regulatory requirements	100%
Aim	Promotes and develops clinical outcomes and quality of care	Demonstrates and may improve regulatory compliance	Checks the compliance with regulations and implement enforcement
Outcome and follow-up	Recommendations to be considered by the audited party	Recommendations to be considered by the audited party	Decision made by the competent authority
Organization	Undertaking/peer review system	Undertaking/peer review system	Competent authority
BSSD	Mandatory	Not applicable	Mandatory



In 2021, HERCA published an addendum to provide further clarity on the differences between clinical audit, regulatory audit and inspection to address confusions that still exist regarding these concepts.

S. Ebdon-Jackson concluded that:

- audit is part of modern clinical practice
- inspection is a BSSD requirement
- Clinical audit and inspection can be carried out in parallel
- Inspections shall determine whether clinical audits are taking place and are relevant to the radiation protection principles
- However, clinical audit, regulatory audit and inspection are different things, as outlined in the HERCA addendum
- Regulators and professionals want the same thing: high quality patient care and improvement
- The 364:1 rule shall be considered: while inspection happens once a year, clinical audit can be carried out all through the year as a continuous process – both are needed

Summary of first QuADRANT workshop

W. Wadsak (Associate Professor of Medicinal Radiochemistry, Certified Radiopharmacist, Radiation Safety Officer; Medical University of Vienna) reported that the first QuADRANT workshop, for WP2, was, due to the COVID-19 pandemic, conducted as a series of webinars on December 14th, 15th and 16th 2020. A total of 132 people registered for the workshop and attendance was good on all three days. 24 out of the 31 EU27+4 countries were represented by at least one health or radiation protection authority representative and other countries were represented by consortium members.

The aims of the first workshop were to understand the status quo of clinical audits in the member states, to arrive at a clearer definition and common understanding of the clinical audits across all three disciplines, to get a first direction for guidance for future EU actions, and to present best practices and examples of measures and outcomes in the member states.

Webinar day 1 focused on the basics of the projects and definitions, as previously outlined, to arrive at a common understanding based on the BSSD requirements. Insights were shared from HERCA, IAEA and WHO on their views on and experience of clinical audits.

Webinar day 2 focused on European and national experiences of clinical audit and separate views from radiology, nuclear medicine, and radiotherapy respectively. Representatives from Belgium, Finland and Switzerland presented their national cases and lessons learnt.

Webinar day 3 continued the national case studies with presentations by the United Kingdom, Luxembourg, Norway and Slovakia. Finally, the webinar series concluded by giving an introduction to the WP3 Main Survey and the next steps of the project for the upcoming work packages.

W. Wadsak summarised the key findings and learnings from the first workshop as follows:

- Clinical audits are a key part of the SAMIRA initiative dedicated to quality and safety improvement



- The need for and relevance of clinical audit was clearly acknowledged by all three disciplines
- The importance of clinical audit in quality improvement in health care was stressed, linking also legislation and clinical practice
- Clinical (and quality) audits should be performed in public and private institutions
- the current level of compliance with the BSSD rules is heterogenous in the member states
- it was also recognised that a widening of the scope of clinical audit is necessary, not only to include justification and optimization, but also to more broadly apply the rules and try to add value for patients, staff and the healthcare establishment.
- small local audits of practices were identified as adding significant value relating directly to patient outcome
- there is no “one size fits all” approach to clinical audit
- guidelines and guidance are available and easily accessible from various organisations from national and international organisations
- Still there is the need for development of clinical audit infrastructure on national levels; this would need to incorporate national, regional and local specifics to increase the effectiveness of successful implementation
- There is need for a clear differentiation between clinical audits, regulatory audits, and inspections – the differences in understandings of those concepts among the involved actors (regulators, practitioners) needs to be overcome
- Clinical audit needs to be embedded in all departments and shall form a core component in department accreditation in line with national practice and procedures
- The question of potential mandatory involvement of external bodies was raised – while it was agreed that this can be highly beneficial and shall be encouraged, it is not a pre-requisite

W. Wadsak outlined the identified key factors for the implementation and success of clinical audits:

- Involvement of patient as partners
- Transparency of clinical audits and openness in discussing and sharing the results
- Multi-disciplinarity to allow for optimal coverage of the entire patient pathway
- Collaboration between parties carrying out the clinical audits
- Definition of the profile of peer auditors
- Embedding of clinical audits in a more holistic culture of quality within the healthcare establishment
- Increase in the communication efforts and information campaigns around clinical audit
- A “One system fits all” approach is not recommended: even though there are common topics that need to be covered by each clinical audit, national particularities need to be considered
- Challenges on the national level that need to be addressed include e.g. financial or organizational resources, availability of a pool of experts for developing and conducting audits.

W. Wadsak concluded that the first QuADRANT workshop was highly successful and generated extremely useful information and insights, while helping all participants to work towards a common understanding of clinical audits, the status quo of their implementation and challenges encountered along the way. Learnings from the workshop have been used to inform the subsequent WPs (e.g. the content of the WP3 Main Survey) and, thereby, have contributed positively to the overall project outcomes.



Question & Answer Session

M. Coffey (ESTRO Expert – Radiation Therapy, School of Medicine, Trinity College Dublin, Ireland) asked the speakers to express their views on whether the confusion around clinical vs regulatory audits and inspections still exists and whether clinical audit – despite all explanatory efforts – is still perceived as regulatory or inspection.

F. Giammarile agreed that this difference in perception is still a challenge to be overcome despite the guidance documents and various definitions that are available. The fact that clinical audits are not an inspection needs to be clearly stressed.

M. Coffey noted that her experience with the IAEA clinical audit scheme QUATRO was that people had a variety of different reasons for looking for clinical audits.

G. Simeonov (Policy Officer, European Commission Directorate-General for Energy, Unit D.3 Radiation Protection and Nuclear Safety) added that the discussion is taking place within the framework of the EU legal system and EURATOM legislation mandates both clinical audits and inspection: they are clearly defined as different entities and processes. These differences are also reflected in the definitions provided, even though the BSSD does not specify who conducts clinical audits, whereas inspections are clearly conducted by regulators. Inspection is a tool for regulators to check on compliance with radiation protection principles. The scope of clinical audits is broader than those for inspection, the outcome is to improve patient care.

Within SAMIRA, a strong link shall be created between the radiation protection and the healthcare worlds. In this context, clinical audit is one of the first topics to focus on. The QuADRANT project shows that there seems to be a need to further educate member states to ensure broad understanding of the different concepts. On that note, a lot of effort has gone into defining what clinical audit is *not*, so it is now helpful to set out minimum standards for audits. This could present one of the major goals for the EC of the QuADRANT project. While peer-review is clear, the approach of topical vs comprehensive audit needs more nuance.

Additionally, the question of whether local audits can really be recognized needs to be raised, given that the BSSD clearly puts it into national (external?) context. This project shall help to reach an agreement on these matters, which can then be included in the future work under SAMIRA.

M. Coffey pointed towards the necessity for people to experience and understand the value of an audit, rather than looking at it only as tool for compliance with legislation.

W. Wadsak noted one of the major hurdles is the differences between the reality of how clinical audit is mandated in the BSSD and the perception of how it is or should be done. Since clinical audit might be perceived as “forced”, as it is required by the directive, it might still be perceived as something that should be done by the governmental bodies top-down. This difference needs to be addressed in the final guidance document.

S. Ebdon-Jackson referred to how the history and development of clinical audit across Europe has influenced the level of understanding and the perception around clinical audit. Member states which had already integrated clinical audit as part of their healthcare services prior to the publication of the Directive might have had an advantage in the overall comprehension of the concept and its added value. The link to the national context in the Directive was included with the aim of encouraging the member states to conduct clinical audits as part of improvement. It should also be underlined that the concept was in fact not new but was successfully implemented in some member states before the BSSD. A higher level of confusion and miscomprehension might have been created in those member states that were introduced to the concept of clinical audit through the Directive



only. Significant progress has been made in the past with all the involved partners and, through QuADRANT, a successful next step can be made in the process.

M. Coffey emphasized the comment by **D. Howlett** on the need for a multi-disciplinary team for conducting external audits, allowing all aspects of practice to be considered, bringing it closer to the clinical reality. Further, HERCA stated in their addendum that numerous member states have put a lot of efforts into check lists to assess compliance: the next step would be to embrace the real character and exploit the potential of clinical audits.

M. Coffey picked up on questions that were posted around financing of audits that will also be covered during the second day of the workshop.

D. Howlett agreed that resourcing of audits is a challenging topic and reiterated that this will be discussed on day 2 of the second QuADRANT workshop. Also, the topic of incentivizing will be brought up in the context of this funding discussion.

In the UK a well-developed infrastructure for clinical audit has been set up based on governmental funding for bodies active in clinical audits. Some responses in the QuADRANT survey stated incentives are not needed since clinical audits are a legal requirement; however, looking at the level of implementation of clinical audit, incentives could be a useful option.

N. Reynders Frederix (QuADRANT Steering Group, Belgian Federal Public Service for Public Health) stated that the clinical audits for radiology should also include MRI and ultrasound, even if the development of quality criteria for those applications might be challenging due to a lack of existing documents.

Upon question, **M. Coffey** confirmed that clinical audits must also be conducted in the private sector, since they are also treating patients. There might be member states where a considerable amount of healthcare services is delivered by private practices.

M. Coffey referred to discussions from the first QuADRANT workshop on how to deal with the differences across the three disciplines radiology, radiotherapy, and nuclear medicine under a global umbrella. This becomes increasingly difficult as the disciplines evolve and might lead to the discussion around separation of rules for the three specialties.

M. Coffey asked the panellists about their opinions on the question of whether clinical audit also includes the patients' satisfaction with the clinical services.

S. Ebdon-Jackson agreed that this can be a part of the clinical audit, but it is not formally required. One of the differences in the uptake of clinical audits is the way in which clinical audits have entered the national arena initially: either through the ministries and professional bodies, or through the regulators. In the latter case, there might be less understanding of the matter. It might be helpful if the ministries could be motivated to take this on as their responsibility, rather than leaving it solely to the regulators.

The session concluded.

Summary of key points from session 1.2

Previous studies demonstrated the variable situation on the member state level regarding the implementation of clinical audits. Consequently, QuADRANT started in 2020 within a consortium of the three societies ESR, EANM and ESTRO following the EC tender in 2019.

The first QuADRANT workshop was highly successful and generated extremely useful information and insights, while helping all participants to work towards a common



understanding of clinical audits, the status quo of their implementation and challenges encountered along the way. Learnings from the workshop have been used to inform the subsequent WPs (e.g. the content of the WP3 Main Survey) and, thereby, have contributed positively to the overall project outcomes.

Clinical audit is “a systematic examination or review of medical radiological procedures that seeks to improve the quality and outcome of patient care through structural review, whereby medical radiological practices, procedures and results are examined against agreed standards for medical radiological procedures, with modifications of practices, where appropriate and the application of new standards if necessary” [BSSD] – whereby this is applicable to all medical applications involving ionizing radiation.

While inspection is a BSSD requirement, audit is part of modern clinical practice. The key elements of clinical audit are the following: it is a process; it is designed to improve patient care; it requires systematic review against explicit criteria; and it requires the implementation change when necessary.

Session 1.3: Status of Clinical Audit in the EU 27+4 – WP3 (Part 1)

Overview of QuADRANT Work Package 3- Main Survey, Expert Interviews, Literature Review

P. Strojani (ESTRO Expert - Radiation Oncologist, Institute of Oncology & Medical Faculty Ljubljana, Slovenia) presented the methodology for developing the Main Survey and the Expert Interviews, which formed key parts of WP3. The Main Survey was developed after the first QuADRANT workshop by the WP3 team, led by D. Howlett. The questions to be included in the survey were discussed by email and on-line meetings were based on the results and lessons learned from WP2 workshop and were reviewed by the Steering Group, Advisory Board, consortium members, and the EC. A pilot version was sent to the Steering Group, Advisory Board, consortium members, and EC in February 2021 to test its functionality and to finalise the structure and content of the questions.

The Main Survey consisted of [28 questions](#) divided in two sections. The first section focused on clinical audit process and infrastructure as part of everyday clinical practice, the second section focused on processes of inspection and requirements for clinical audit as defined in the BSSD. In March 2021, the Main Survey was sent to a pre-agreed distribution list including national health authorities, national audit and radiation protection competent authority representatives, the HERCA working group for medical applications, and members of the societies in the consortium. The survey was closed the 7th May 2021.

Eighty-three responses were collected, covering all EU27+4 countries. However, not all countries provided answers to both sections of the main survey. Most answers were provided by national societies representatives and radiation protection authorities representatives. For 24 countries multiple responses were received. In such cases, careful analysis of conflicting and ambiguous answers was needed in order to obtain single coherent set of answers from each country.

WP3 complemented the Main Survey by interviewing a group of 9 clinical audit experts proposed by the Steering Group and Advisory Board and approved by the EC. The aim of these interviews was to provide additional context to the Main Survey. The experts were sent a list of 9 questions covering personal experience, their views on barriers for the implementation of clinical audits, suggestions for potential solutions, best practices and also view on the QUADRANT initiative and main survey and key messages that could be



extracted from the survey as the interviewees were provided with the main survey results. The written answers to the interviews were collected by July 2021.

The main messages extracted from the interviews were that:

1. The understanding of the concept of clinical audit is not uniform across Europe nor within countries.
2. There are big differences in the clinical audit infrastructure and level of implementation between countries. This is mainly due to differences in the prioritization at a national level and resources both financial and human allocated to clinical audits.
3. In order to overcome the barriers to successful implementation of clinical audits, the experts suggested improving cooperation between regulators and professional associations, stable funding, including training in clinical audits within national professional education and training programmes, increasing the involvement of patient organisations and providing guidelines and reference documents.
4. Private sector and departments using ionizing radiation apart from radiology, nuclear medicine, and radiotherapy should also undergo clinical audits.
5. At a European level, clinical audit should be a requirement for department accreditation programmes and also for healthcare professional registration to practice

The WP3 team also conducted a thorough literature review on clinical audit in the areas using ionizing radiation. This literature review was divided into four areas: the first on clinical audit as a legal requirement; the second on clinical audits in relation to radiation protection, mainly on justification and optimisation of practices; the third on clinical audits and quality assurance; and, a final area on other relevant literature not linked to any of the previous areas. A total of 93 references were included and discussed in five subchapters covering the legal basis of clinical audit, as well as the methodological aspects of implementing them as suggested by the EC in the review of the deliverable D3.4.

Clinical Audit Practice and Process

D. Paez (Nuclear Medicine Physician, Section Head - Nuclear Medicine and Diagnostic Imaging Section, Division of Human Health, Department of Nuclear Sciences and Applications, International Atomic Energy Agency) introduced the IAEA approach to clinical audits in radiology, nuclear medicine, and radiotherapy. Following the WHO definition, a quality health service is one which organises resources in the most effective way to meet the health needs of those most in need, for prevention and care, safely, without waste and within higher level requirements. The process of quality improvement aims at defining, measuring and setting quality standards and overcoming the associated challenges that include rising costs and skills shortages. When considering quality, the patient, professional and management views have to be taken into consideration: all the perspectives matter to achieve a quality health system even if sometimes they can be in conflict.

There are six areas or dimensions of quality improvement: effectiveness, efficiency, accessibility, acceptability (patient-centred), equitability, safety. The IAEA's statutory role includes establishing or adopting standards of safety for protection of health and minimization of danger to life and to provide for application of these standards. The IAEA has established an open and transparent process for gathering, integrating and sharing knowledge and experience gained from the use of technologies and from the application of the safety standards themselves. The safety standards have three parts, safety fundamentals, safety requirements and safety guides. As part of the safety fundamentals IAEA published the 'Radiation Protection and Safety of Radiation Sources: International



Basic Safety Standards' (first edition in 2003, revised in 2014). In these standards the IAEA outlines the need to audit medical radiation technology (diagnostic and therapy), which has been also highlighted and recommended by the EC 97/43/Euratom directive. Therefore, the IAEA developed and published methodology for comprehensive clinical audits in radiotherapy, nuclear medicine and diagnostic radiology.

The IAEA has also, together with the WHO, developed dose audit services (postal dose audits). Since 1969 more than 13,000 therapy beams have been checked. Since 1981, the IAEA dosimetry lab has also supported dosimetry audit networks and audit radiation protection standardisation in Secondary Standard Dosimetry Labs (SSDLs).

In addition to the postal audits, the IAEA has developed, published and conducted clinical audits in the area of nuclear medicine (QUANUM), radiotherapy (QUATRO) and diagnostic radiology (QUAADRIL). In 2005, the IAEA created QUATRO teams that provide independent quality audits through comprehensive review of clinical practice in radiotherapy. It focuses on peer review and quality assessment of all components of radiotherapy practice in cancer centres, with the view to improve quality. Since then, 96 audits have been conducted in 80 countries.

The second programme is QUANUM, introduced in 2007 and periodically updated. Version 3.0 was published in July 2021. To date, 76 audits have been conducted in 46 countries.

More recently, in 2010, QUAADRIL was introduced and 6 audits have been conducted.

The audit teams are multi-disciplinary and the IAEA has trained auditors in the three areas. Finally, **D. Paez** presented the audit cycle, stressing the importance of the clinical audits as a tool for continuous quality improvement. Some countries, such as Belgium, have adapted the tools developed by the IAEA for their clinical audits.

Patient Involvement

E. Briers (QuADRANT Advisory Board, ESR-Patients' Advisory Group (ESR-PAG) member) explained that the project objectives, constant improvement, quality, safety through audits, are important from the patient perspective. The patient expectation is a timely and accurate diagnosis, leading to a curative treatment or a treatment that controls the disease with optimal outcome and quality of life. From the patient perspective, quality includes having access to state-of-the-art equipment, dedicated and trained staff, a pleasant environment, and the best medical experts. If we consider radiation safety at a patient level, patients' priority is the diagnostic and the therapeutic results over a reduction in dose. The patient experience through the service should also be safe including in non-radiation issues, such as pain from manipulation, anxiety, delays, trust. Audits should be systematic and based on standards. Patients should be involved in contributing to the definition of the audit topics and also the standards of those aspects related to patient perception of quality. There should be different audit trails for different procedures.

Patients should not be involved in measuring radiation doses. However, the patient has to be aware that the specialist may decide not to perform an x-ray examination if it can be replaced by another type of examination (i.e. ultrasounds, physical exploration, etc). It is important to clearly explain such decisions to patients.

Patients can be involved in defining patient satisfaction questionnaires that could be part of the audit. The '[ECR2022 patient in focus: listen to your patients](#)' could provide material that should be considered.

The audit should monitor:



1. Patient information regarding radiation risks and safety
2. Other safety (comfort)-setting up of the audit, questionnaires, reporting
3. Quality-setting up the audit, reporting and end report
4. Patient should be part of the auditing team

E. Briers recommended having a patient advisory board (PAG) to assist in making the department patient-friendly. Additionally, the PAG should be involved in audits.

Question & Answer Session

J-C. Leclerc (Chairman of the French Standards Labeling Commission (Labelix)) was invited to present Labelix, a patient-oriented audit covering: patient welcome; patient information; patient consent; justification and optimisation; risk and safety management; hygiene; vigilance; radiation protection and magneto protection of workers and patients (EU directive 2013-59); management of medical incidents and accidents; organisation of teleradiology; GDPR compliance and quality policy; and, records management. After internal and external audits by independent companies, this label is awarded for a period of 4 years, with intermediate documentary review after two years. Labelix has been implemented in France since 2004. Today 15 medical imaging structures are committed to this voluntary auditing approach. Since last year, Labelix standards have become the official French standard: AFNOR NF S99-300:2021 standards. The next step they propose is the implementation of a European technical committee. AFNOR has sent a proposal for a European voluntary standard: quality in medical imaging along the patient pathway to go beyond the EU council directive, as it wants to include all aspects of the patient pathway as well as MR and ultrasound.

J-C. Leclerc outlined difficulties with the GDPR: allowing access to patient records for clinical audit requires special consent. Patients have to give permission to go through a specific procedure. At the same they should be asked consent to the use of their images for quality improvement. Following **Eric Briers'** view, **J-C. Leclerc** agreed that most patients would agree to that. The Importance of educating patients about clinical audit, so that they can understand how their data can be used to improve quality, was emphasized.

One of the major problems in quality is the failure to educate staff. This must be kept in mind when designing clinical audits.

There are similar projects to Labelix being developed for Nuclear Medicine.

The programmes implemented by the IAEA are cost free, but they can only be requested by countries that have a regional project with the IAEA. There are countries that have adopted the tools developed by the IAEA in their country. Regarding certification, the IAEA does not give certification as it is not the aim of their programmes. Their programmes focus on pointing towards areas of improvement for the centres being audited.

Summary of key points from session 1.3

The Main Survey was developed after the first QuADRANT workshop. It consisted of 28 questions divided in two sections. The first section focused on clinical audit process and infrastructure as part of everyday clinical practice, the second section focused on processes of inspection and requirements for clinical audit as defined in the BSSD. The survey was closed the 7th May 2021. Eighty-three responses were collected, covering all EU27+4 countries.



WP3 complemented the Main Survey by interviewing a group of 9 clinical audit experts proposed by the Steering Group and Advisory Board and approved by the EC. The aim of these interviews was to provide additional context to the Main Survey.

The main messages extracted from the interviews were that: the understanding of the concept of clinical audit is not uniform across Europe nor within countries; there are big differences in the clinical audit infrastructure and level of implementation between countries; the experts suggested improving cooperation between regulators and professional associations, stable funding, including training in clinical audits within national professional education and training programmes, increasing the involvement of patient organisations and providing guidelines and reference documents; private sector and departments using ionizing radiation apart from radiology, nuclear medicine, and radiotherapy should also undergo clinical audits; at a European level, clinical audit should be a requirement for department accreditation programmes and also for healthcare professional registration to practice.

The WP3 team also conducted a thorough literature review on clinical audit in the areas using ionizing radiation. This literature review was divided into four areas: legal requirement radiation protection; quality assurance; and other relevant literature not linked to any of the previous areas. A total of 93 references were included and discussed in five subchapters covering the legal basis of clinical audit, as well as the methodological aspects of implementing them.

Session 1.4: Clinical Audit, Regulatory Control and the BSSD

Regulatory Control – Clinical Audit and the BSSD (key outcomes from WP3)

A. Schreiner (QuADRANT Steering Group, Medical Physics Expert, Radiation Protection Dept., Ministry of Health, Luxembourg, Former-Chair (until Jan 2022) HERCA WGMA (working group medical applications)) explained that section two of the QuADRANT Main Survey was concerned with the requirement for clinical audit as set out in the Basic Safety Standards Directive (BSSD) and its enforcement through regulatory inspection. She would seek to present the key outcomes to this section of the Main Survey.

The first question of section two of the QuADRANT Main Survey asked: *“Is there awareness in your country of the requirement to undertake clinical audit of medical radiological practice mandated within the European Basic Safety Standards Directive?”*

Respondents were asked about awareness at each of the following levels “At individual/healthcare professional level”; “At hospital level (managerial)”; “At regional/state official level”; “At national professional society/professional body level”; and, “At senior governmental/ministerial level”. For each, they were required to select one answer from the following options: “Yes – broad awareness exists”; “Yes – but awareness is not widespread”; “No”; and, “Don’t know”.

Only four countries reported broad awareness at all levels and one country reported no awareness of the requirement at any level. In general, however, broad awareness was indicated, though levels of awareness varied and awareness was most common at national professional society level (n=17) and at senior governmental/ministerial level (n=16). Reported awareness was lower at state, hospital, and individual levels.

From the answers to Question 2.1 of the QuADRANT Main Survey, it could be concluded that actions must be taken to increase awareness at state, hospital, and individual levels. Furthermore, the importance of cooperation between regulators and professional



associations was highlighted: national healthcare professional educational/training programmes must include training in clinical audit, taking into account the multidisciplinary composition of clinical audit teams.

The second question of section two of the QuADRANT Main Survey asked: *"Is there an established process of hospital/departmental inspection by the relevant national competent authority in your country?"*

Respondents were asked to select one answer from the following options: "Yes – it was well established before the Basic Safety Standards Directive (Council Directive 2013/59/Euratom)"; "Yes – it has been established since the Basic Safety Standards Directive (Council Directive 2013/59/Euratom)"; "No – it is in development"; "No – not in development"; and, "Don't know".

Twenty-two countries reported that a process of hospital/departmental inspection by the relevant national competent authority was well established before the BSSD, with a further three countries reporting that it was established after the BSSD. An additional three countries reported that an inspection process was in development. Only one country reported that no inspection process existed nor was in development, although two countries provided no response to this question.

The third question of section two of the QuADRANT Main Survey asked: *Does the inspection process include assessment of clinical audit?* Due to logic employed in the programming of the Main Survey, this question was only asked if the response to the previous question was positive.

Respondents to Question 2.3 were asked to select one answer from the following options: "Yes, limited to audit practice/process"; "Yes, including audit outcomes"; "No"; "Don't know"; and, "Not applicable".

From the answers to Questions 2.2 and 2.3 of the QuADRANT Main Survey, eleven countries indicated an established process of inspection which was limited to audit practice/process, and a further seven reported an established process which included audit outcomes. In ten countries, clinical audit assessment was reported to not be part of inspection.

It may be concluded from this that clinical audit assessment should be included in inspection processes and that this will help increase awareness at the hospital and individual levels as well as helping in the implementation of clinical audit.

The fourth question of section two of the QuADRANT Main Survey asked: *What effects (if any) has the Basic Safety Standards Directive (Council Directive 2013/59/Euratom) had on related clinical audit activity in your country?*

Respondents were able to select multiple answers from the following options: "A system of clinical audit practice and process was established as a result of the Directive"; "Process of inspection by radiation protection/enforcement authority introduced to include assessment of clinical audit processes"; "Clinical audit guidelines/directives developed/in development"; "Clinical audit activity incorporated into national hospital accreditation programmes"; "Individual healthcare professional engagement in clinical audit mandated"; "Clinical audit findings/recommendations published in peer-reviewed journals/national guidance"; "No change, a well-established system of clinical audit was already in place"; "There has been introduction of new processes/technologies or changes in practice to improve audit outcomes (for example – the introduction of decision support software to improve justification and supporting audit processes. Please include examples in the 'other' box below)"; "Don't know"; and, "Other (Please specify)". An open text box was provided for respondents to provide additional information.



The answers to Question 2.4 revealed that a well-established system of clinical audit was considered to already be in place in nine countries. Clinical audit guidance had been developed or were in development in thirteen countries. Twelve countries have included the assessment of clinical audit in their inspections process. The BSSD was reported to be the impetus behind the development of a system of clinical audit practice in eight countries. Healthcare professional involvement was mandated in three countries. Clinical audit was incorporated into hospital inspections in two countries. Finally, the BSSD was reported to have led to new processes or technologies being introduced in three countries.

Another important item to note is that mandated involvement in clinical audit within departments using ionizing radiation procedures outside of radiology, radiotherapy, and nuclear medicine only occurs in sixteen countries (and in private practice providers of radiology, radiotherapy, and nuclear medicine providers in seventeen countries).

A. Schreiner proposed that, from the answers to Question 2.4 of the QuADRANT Main Survey, it could be concluded that the implementation of the BSSD has led to changes in the practice of clinical audit; however, there is no harmonized approach to implementation at the European level. The sharing of best practice and guidance, as well as participation in European and international clinical audit-related initiatives, could assist in the harmonization of clinical audit implementation.

Overall, **A. Schreiner** summarized the main conclusions to be taken from section two of the QuADRANT Main Survey: the BSSD provides the legal framework for mandating participation in clinical audit “in accordance with national procedures”; clinical audit assessment (including assessment of the outcomes of clinical audit) ought to be incorporated in the inspection process; and the private sector and all departments undertaking ionizing imaging procedures (urology, orthopaedic, theatres etc.) must also participate. Whilst the publication of the BSSD has improved clinical audit implementation, to improve the implementation of clinical audit further, awareness must be raised, especially at state, hospital, and individual levels, and education for all relevant professions be provided. The lack of a harmonized approach to clinical audit in Europe suggests the need to a common reference document and/or guidance.

Roundtable Panel Discussion

W. Wadsak thanked **A. Schreiner** for this summary of the results and conclusions of the second section of the QuADRANT Main Survey and introduced the panellists for the Panel Discussion:

- **H. Delis** (Medical Physicist Expert - Diagnostic Imaging, University of Patras, Greece),
- **S. Ebdon-Jackson** (Health Policy Maker/Radiation Protection Regulator (Retired), UK),
- **W. Jaschke** (Interventional Radiology Expert (CIRSE), Department of Radiology, Medical University Innsbruck (Emeritus)),
- **R. Bly** (QuADRANT Steering Group, Medical Physics Expert, Core Group Member of HERCA WG on Medical Applications, Chair of IAEA RASSC (Radiation Safety Standards Committee), the Radiation and Nuclear Safety Authority of Finland),
- **N. Jornet** (QuADRANT Work Package 4 co-Lead, ESTRO Lead Expert - Medical Physicist),
- **R. Ward** (QuADRANT Advisory Board, The Heads of the European Radiological Protection Competent Authorities (HERCA)).



W. Wadsak began the discussion by asking the panellists how they believed awareness of the requirement to conduct clinical audit can be raised at various levels.

R. Bly explained that, in Finland, many national discussions took place with professionals and, when clinical audits were first started, this helped inspectors and auditors distinguish responsibilities.

W. Wadsak asked who initiated these discussions.

R. Bly replied that it was the regulatory bodies.

N. Jornet stated that the inclusion of clinical audit in the meetings of scientific societies is important: such meetings tend to focus on practice and can overlook quality improvement. Leaders must be convinced of the importance of the topic. She called for 'quality champions' within departments to advocate for training, continuous professional development, and the availability of materials to assist with clinical audit (e.g. on the websites of professional societies). She added that regulator involvement is key at the start to ensure the distinction between inspection and audit is clear, but clinical audit should really 'come from the community' of those involved in practice at all levels.

S. Ebdon-Jackson commented that, to improve understanding of the need for clinical audit, both top-down and bottom-up approaches are required. Health Ministries etc. need to buy in to the idea that clinical audit is part of good medical practice and push this down to the providers. At the same time, the professional bodies need to push up to the providers and make it clear that they are willing to undertake clinical audit as a key part of improving outcomes for their patients. Regulators can facilitate these discussions by reminding both professionals and ministries of the legal requirement for clinical audit. Clinical audit in radiology, nuclear medicine, and radiotherapy must be seen as part of a broader clinical audit in medicine – it goes beyond radiation protection. Radiological services, especially imaging, interact with other clinical disciplines.

W. Wadsak summarized:

- In a bottom-up approach, patient involvement is key
- In a top-down approach, regulators must play their part

S. Ebdon-Jackson agreed that patients play a role, but we must be clear what they want. Returning to the regulatory requirements, the basis for regulators pushing both professionals and ministries is the BSSD. He related conducting inspections and asking questions such as:

- Are you doing clinical audit?
- What are the topics and can you provide evidence?
- How do the topics relate to the requirements of the BSSD and national regulations?

H. Delis emphasized the need for training: 'quality' and 'audit' should not be considered vague concepts – there are organized processes and clear methodologies that can be taught. All staff within departments can be engaged, especially in internal audits.

R. Ward agreed with **S. Ebdon-Jackson's** assessment and added that the process of clinical audit should not be over-complicated. It is mandatory – as an inspector in the UK, she stated that she had served numerous enforcement notices to private and NHS trusts for failure to adhere to the requirements of the BSSD. Clinical audit can be done cheaply and simply, including by undergraduate students and trainees – financial incentives in this context should be unnecessary.

W. Wadsak asked for clarification of whether **R. Ward** viewed clinical audit as a mandatory requirement within inspection practices, or could it be outside of regulatory inspections of radiation protection?



R. Ward replied that it is a fundamental part of inspection, but also, referring to **S. Ebdon-Jackson's** talk in session 1.2 and the '364:1 principle', clinical audit should be demonstrated during inspection, but it should be happening continuously.

W. Jaschke noted that, in Austria, investments have been made over recent years in improving radiation safety e.g. the introduction of dose management systems. But, prior to such investment, clinical pathways were optimized e.g. breast cancer treatment, and results/outcomes must be reported to, for example, insurance companies. In the clinical setting, feedback e.g. on high numbers of false reports, is also received via clinical conferences. In circumstances where such steps have already been taken, it can be difficult to see where clinical audit might fit into this broader environment of quality assurance methods.

W. Wadsak responded that it is important to ensure clinical audit is included in quality assurance regimes. He reemphasized **S. Ebdon-Jackson's** point about inclusion of patients and noted this is different to traditional quality control systems arising out of regulatory practices.

W. Wadsak asked the panel for their views on the different disciplines: whilst it was agreed that clinical audit is part of a broader picture in medicine as a whole, are there specific issues that pertain particularly to the use of ionizing radiation and the BSSD?

R. Bly referred to the financial aspects in the BSSD: the resources that should be allocated to clinical audit are related to the radiation risk. In the Finnish experience, multidisciplinary teams are important for clinical audit.

S. Ebdon-Jackson stated that the BSSD requirements can help drive good practice across disciplines. Using the example of justification, he noted it would be wrong to have differing justification procedures for ionizing and non-ionizing procedures. Regulations can be used to drive the spread of clinical audit and its value and to improve good practice.

W. Jaschke agreed that it would be wrong to focus only on procedures involving ionizing radiation, though high-dose procedures should certainly be a priority, especially in CT and IR, as improvements in these will have the biggest effects. Procedures should be optimized across disciplines.

N. Jornet also agreed that high-dose procedures merit focus, but noted that the BSSD also includes screening. In response to **W. Wadsak's** question, she suggested the answer depends on how comprehensive we want clinical audits to be: R. Ward's comments suggested that, from the perspective of inspectors, quality improvement initiatives within departments might be seen as fulfilling the requirements of clinical audit. However, **N. Jornet** suggested that, to really be considered as clinical audit all the staff should be involved and, potentially, there ought to be external direction or peer review by other professionals. Different guidelines are required for different settings.

W. Wadsak concluded the discussion and thanked the panellists. He provided a brief round up:

- The 364:1 rule is very helpful – clinical audit must be continuously practiced
- Training and education is vital, including training for the trainers (e.g. from the IAEA).
- Patient involvement is vital, though how this should best be done remains a subject for discussion.

Summary of key points from session 1.4



According to the survey, the BSSD provides the legal framework for mandating participation in clinical audit “in accordance with national procedures”; clinical audit assessment (including assessment of the outcomes of clinical audit) ought to be incorporated in the inspection process; and the private sector and all departments undertaking ionizing imaging procedures (urology, orthopaedic, theatres etc.) must also participate. Whilst the publication of the BSSD has improved clinical audit implementation, to improve the implementation of clinical audit further, awareness must be raised, especially at state, hospital, and individual levels, and education for all relevant professions be provided. The lack of a harmonized approach to clinical audit in Europe suggests the need to a common reference document and/or guidance.

Session 1.5: Day 1 Close

D. Howlett thanked the Day 1 session moderators, **M. Coffey**, **A. Brady** (QuADRANT Project Co-Manager; ESR 1st Vice President (Incoming ESR President from July 2022); Radiologist, Mercy University Hospital, Cork and University College Cork, Ireland), and **W. Wadsak**, noting that a lot of interesting points were raised and a lot of further topics remain to be covered in Day 2. He also thanked the speakers, **S. Ebdon-Jackson**, **P. Strojan**, **D. Paez**, **E. Briers**, and **A. Schreiner** and panel members. Furthermore, he thanked other contributors to Day 1 and the QuADRANT project as a whole, especially **M. Huebel** (Head of Unit – Radiation Protection and Nuclear Safety, European Commission Directorate-General for Energy), **G. Simeonov** and **S. Paultre** (Policy Officer - Seconded National Expert, European Commission Directorate-General for Energy, Unit D.3 Radiation Protection and Nuclear Safety) from the European Commission, and the ESR, EANM, and ESTRO Office Staff.

In particular, some key considerations that were brought up in Day 1 included:

- How can patients be more involved in clinical audit?
- How can clinical audit be embedded in education/training in a more structure manner?

Looking forward to Day 2, the following items remain to be discussed:

- Infrastructure, particularly at the national level
- The roll of the national professional societies
- Barriers to clinical audit and incentives
- Accreditation and certification
- Good practice examples from around Europe

D. Howlett and **G. Simeonov** both encouraged participants to join Day 2 and closed the workshop.



Webinar 2: Friday 14th January 2022

Session 2.1: Day 2 Opening

G. Simeonov opened the workshop and welcomed the participants. He emphasised the importance of the QuADRANT project as it feeds into the SAMIRA project.

F. Giammarile provided a brief recap of the contents of Day 1 of the workshop:

- Session 1.2:
 - D. Howlett:** Overview of project aims and structure
 - Answer to an EU tender (2019); 30-month project, 5 WP
 - S. Ebdon-Jackson:** Previous key work
 - Clinical audit and the background to the BSSD
 - W. Wadsak:** Summary of first QuADRANT workshop (December 2020)
 - Understanding the concept of clinical audit; cooperation between regulators and professionals; patient organizations
- Session 1.3:
 - P. Strojan:** Overview of QuADRANT Work Package 3
 - Main Survey, Expert Interviews, Literature Review
 - D. Paez:** Clinical Audit Practice and Process
 - IAEA institutional role; IBSS; guidelines; QM projects (QUATRO, QUAADRIL; QUANUM)
 - E. Briers:** Patient Involvement
 - Patient perspective (quality of life, safety, reduction of pain and anxiety); participation
- Session 1.4:
 - A. Karoussou-Schreiner:** Regulatory Control
 - Clinical Audit and the BSSD (key outcomes from WP3)
 - Roundtable Panel Discussion Panellists: **H. Delis, C. Clark, W. Jaschke, R. Bly, N. Jornet, R. Ward**
 - Topics: Radiation Protection, the role of clinical audit as outlined within the BSSD, link to inspections, issues raised within the survey, how to improve uptake and compliance, dosimetry quality management.

There were 100 attendees in addition to the 25 speakers, moderators, and panellists in Day 1.

F. Giammarile introduced the agenda for Day 2 of the workshop.

Session 2.2: Status of Clinical Audit in the EU 27+4 – WP3 (part 2)

M. Coffey welcomed everyone to the session.

Barriers, Incentives & Accreditation (B. Brkljajic)

B. Brkljajic (Secretary General of the ISR; ESR Past-President; Diagnostic Radiologist University of Zagreb, School of Medicine) reviewed the aims of the QuADRANT Main Survey, which took place between March and May 2020, focusing on barriers, incentives and accreditation in clinical audit.

Two questions in the survey focused on barriers and incentives.

The first sought opinions of respondents on potential barriers to clinical audit uptake and activity.



The **key barriers** included (in descending order of frequency): insufficient funding at national level; low national priority; insufficient staffing/personnel; insufficient funding at hospital level; lack of time; low departmental/hospital priority; insufficient local expertise; insufficient national expertise; insufficient funding at individual level. Few respondents noted no barriers.

Improved prioritization of and improved resource allocation to clinical audit infrastructure development were identified as **key changes** required to overcome the barriers and enhance national professional societal involvement in external direction of clinical audit.

The second question sought the opinion of respondents as to potential incentives for encouraging or facilitating clinical audit participation. 18 countries reported that because clinical audit activity is a legal requirement, incentives were not required; however, five of these countries indicated the use of incentive. Only a minority of countries indicated the uptake of incentives.

Example incentives included (in descending order of frequency): an enhanced hospital accreditation system; direct remuneration; indirect remuneration; improved access to staff/equipment; exemption from clinical work.

Funding

B. Brkljacic reported on responses regarding **funding** for clinical audit. The majority of respondents noted no funding is provided. Where funding is provided, examples were diverse and included one-off funding or regular funding for specific projects at regional/state, hospital and departmental level.

Accreditation

With regard to accreditation, 11 countries noted that evidence of participation in clinical audit was required by the hospital for accreditation, 13 countries reported that it was not required. Four countries noted no system of accreditation to be in place; however, the survey did not ask specifically if accreditation was voluntary or mandatory in nature.

Registration to Practice

Regarding evidence of clinical audit as a requirement for registration to practice, nine countries noted that this was the case in some or all professions. This was not the case in 17 countries. Thus, the responses suggest that whilst a system of accreditation exists in many countries, it would appear that the majority do not require evidence of clinical audit.

B. Brkljacic noted that as part of the analysis of the QuADRANT Main Survey results, a panel of 9 experts, selected due to their competency in clinical audit, was interviewed.

The experts were asked for their opinions on the main barriers at local and national level for successful implementation of clinical audit. They responded:

- A fundamental lack of understanding, together with a lack of trained professionals and willingness to engage in clinical audits due to lack of remuneration, time, availability and conflict of interest;
- A paucity of leadership and a lack of quality-culture; cooperation between professional groups is required;
- Lack of financial incentives and dedicated funding;
- Lack of knowledge on how to increase compliance for clinical audit in particular when they are not mandatory;
- Lack of regular review with updates of auditing guidelines and incomplete quality assurance programmes.



The experts considered the main barriers at European level for uptake and implementation of clinical audit to be the same as barriers at national level. In addition, it was noted that:

- There is fragmentation of field regulation between different government departments and agencies;
- Clinical audits are not producing directly measurable results;
- Implementation of accreditation displaces interest in clinical audit;
- There is poor planning of clinical audit.

The expert group suggested potential solutions to achieve implementation of clinical audit programmes. These included:

- Training of auditors;
- The initiation of an educational campaign for medical professionals to develop a common understanding of what clinical audit is;
- Ensure adequate funding and availability of reference material;
- Nationwide organization of the auditing system together with a 'leading hospital' working as an example;
- Participation in a national order plan should be a legal requirement, funded from the health system and research programmes;
- Certificates of participation in clinical audit should be a prerequisite for incentive;
- Involvement and support of different national societies, radiation protection authorities and government bodies should be implemented, ideally with an independent national body or institution responsible for the process;
- A two-stage approach was recommended- first, self-evaluation followed by internal clinical audit by another department in the same institution. Secondly external orders could be introduced as a valuable upgrade;
- Optimization of the balance between workload and audit activities in institutions by alteration between full audits and limited audits.

B. Brkljatic concluded by noting that, in Europe, understanding of clinical audit is not uniform and is often related to inspections by regulatory authorities. Subsequently, the difference between regulatory inspection, external audit by peers, and hospital accreditation is misunderstood. Furthermore, there are big differences between countries in Europe in the way clinical audit is organized and implemented. A common reference document is required to guide countries in organizing and implementing audit.

Good cooperation between regulators and professional associations; stable funding; and the inclusion of audit in national healthcare professional education and training programmes, taking into account the multidisciplinary composition of clinical audit teams, is required. It would be prudent to work with patient organizations to organize clinical audit and the private sector and departments undertaking ionizing procedures outside of radiology, radiotherapy, and nuclear medicine must be included.

Finally, **B. Brkljatic** noted that reflection is required on several aspects of clinical audit programmes including audit as a requirement for hospital accreditation, audit as a requirement for healthcare professional registration, regulatory clinical audit and the availability of results of clinical audit to the public.

Overall, the most significant barrier is insufficient priority at national level and financial and human resources.

M. Coffey noted **B. Brkljatic's** presentation was a very interesting and informative overview and will generate a great deal of discussion in the question and answer session.

The role of National Societies in Clinical Audits. Development of Infrastructure.



N. Jornet began by highlighting a statement from the ESR Guide to Clinical Audit¹, which stated that a key component in effective clinical audit is a functional infrastructure at both departmental and national level, allowing external direction and guidance of departmental internal audit, with the potential for wider collaborations with hub organisations such as the European societies and organisations.

N. Jornet noted her presentation would focus on the role of national societies in clinical audits, with a particular focus on development of infrastructure. By means of introduction, she noted that an ESR survey in 2019² reported that few national societies have administrative structure dedicated to clinical audits (only 22% in place); national societies have no clear channel of communication with different hospital departments (72% in place) likely to be because they are member societies and few national societies are in permanent communication with hospital departments (only 36% in place).

N. Jornet noted that when we talk about what infrastructure includes, the following should be considered: administrative support, IT, clinical leadership / quality champions, trained professionals, engagement, managerial support, equipment and financial support.

N. Jornet described challenges that are prevalent in developing clinical infrastructure, such as constrained financial, human and infrastructure resources and problems in managing change in people and organizations. Ways to overcome these challenges include leadership, regulation, financial resource allocation and the availability of data. It was noted that change management is difficult, yet highly important for success in quality improvement and requires focus on staff motivation, behavior modification and a shift in culture. Performance feedback on audits, a blame free leadership and staff support is required, public involvement for focusing on change through consultation and transparency and the commitment of resources for clinical audit and quality improvement.

N. Jornet recapped on the respondent types from the QuADRANT Main Survey, which were predominantly on behalf of a national society and national radiation protection authorities (total = 46 respondents).

- Most countries have a set of quality indicators for use in clinical audits. **N. Jornet** noted that national societies should be involved in setting relevant, evidence-based quality indicators;
- Clinical audit guidelines were available in 17 countries in at least 1 specialty, with 11 countries having no manual/guidelines;
- In 22 countries, national societies are responsible for providing national standards for clinical audit and 20 countries have multidisciplinary cooperation, which was very interesting to see and is a key factor in effective clinical audit;
- There is a lack of training in clinical audit in healthcare professional education and training programmes and there is a potential for development of courses and CPD.

N. Jornet repeated **B. Brkljacic's** summary that there are a number of barriers to effective clinical audit to be overcome. Examples of how this can happen include: lobbying at national level, training, fund raising, provide expertise through the network of professionals and leadership, for example quality champions to drive the process.

- It was noted in the expert interviews that there is a lack of understanding between inspections, regulatory audits and clinical audits. To address this, there is a role for

¹ European Society of Radiology (2020). The Current Status of Radiological Clinical Audit and Feedback on the ESR Guide to Clinical Audit in Radiology and the ESR Clinical Audit Tool (Esperanto) - an ESR Survey of European Radiology Departments. *Insights Imaging*. 2020;11(1):37. Published 2020 Feb 26. <https://doi.org/10.1186/s13244-020-00843-0>

² European Society of Radiology (2019) The Current Status of Radiological Clinical Audit – an ESR Survey of European National Radiological Societies, *Insights into Imaging*, <https://doi.org/10.1186/s13244-019-0736-4>



national societies to increase understanding through dedicated courses, symposia during annual meetings, e-learning material and guideline development.

- Dr Jornet echoed that there is a lack of trained professionals willing to conduct clinical audits and there is a role for the National societies to provide training, select auditors and create a bridge between different societies to create audit teams to address this barrier.
- The survey shows there is a need for good communication between professional and scientific societies and regulators. Dr Jornet suggests there is a role for the national societies to set up channels for communication with clinical departments and act as a consultant for governmental bodies and regulator organisations.

N. Jornet presented the Swiss experience as a positive example, which has just established infrastructure for clinical audit. The roles of the national societies include a steering committee (8 stakeholders), strategy of implementation, provision of experts to perform the audit, expert commissions (for guidelines and quality indicators) and auditor training. Support is from the Federal Office of Public Health (FOPH) and audited hospitals pay a fee.

N. Jornet presented a template for best practice for implementation which includes the sharing of information and infrastructure such as equipment, with key roles of national and international societies.

M. Coffey thanked **N. Jornet** for raising interesting issues around the role of National Societies and commented on varying roles and strengths of national societies across Europe and whether the role should lie with professional societies.

Educational Aspects

M-L. Ryan (Radiographer - Diagnostic Imaging, University College Dublin, Ireland) began by highlighting the clinical audit cycle and that education and clinical audit are often discussed in tandem. Education can be appreciated and recommended in many ways in the clinical audit cycle, such as the process of audit being educational in itself.

M-L. Ryan noted that there are a number of key documents on carrying out clinical audit, however there is a lack of literature that focuses specifically on education in clinical audit. For example, what information should be included, in particular for different professions, at what point in one's career should clinical audit be taught and an understanding of the key benefits of educating clinical professionals in this topic.

With regard to education, the QuADRANT survey asked participants the level of incorporation of training in clinical audit into national healthcare professional education and training programmes. Only 3 countries reported clinical audit training to be widely incorporated, 4 indicated limited incorporation for some healthcare professions, 4 responded "in development" and in 17 countries no incorporation was present or planned. Some examples were given. However, it was evident that training in clinical audit is both lacking and inconsistent based on the results of the survey.

Regarding the results of the expert interviews, it was felt that there is a:

- Fundamental lack of understanding of what clinical audit is: it is frequently mistaken for inspection or regulation and perceived as a threat rather than a way to improve.
- Lack of trained professionals and/or willingness to take over the task due to insufficiency of remuneration to cover the costs, lack of time and availability (clinical work is taking priority over audit), conflict of interest.



- No firm leadership commitment to assure optimal involvement of all auditors in the audit (from preparation to implementation) and low “culture” of good/close cooperation across different professional groups and between professionals and regulatory authorities could increase this problem. Both of these could be aided by appropriate education.

It was agreed by the experts that the QuADRANT Main Survey has shown that there is no clear understanding of what clinical audits are, which is one of the main reasons for implementation problems. Appropriate training of auditors and initiation of the educational campaign for medical professionals to develop a common understanding of what clinical audit is was noted as imperative.

When participants were asked about key barriers to clinical audit implementation, the results showed a key barrier is the lack of national/local expertise and trained staff/personnel. Again, this raises the issue of a lack of education and training and indeed relates to the issue of leadership and expertise.

M-L. Ryan noted the European Federation of Radiographers- Statement on Clinical Audit, where it is stated that

- Education in clinical audit, and the need for participation in clinical audit, should be encompassed in undergraduate / entry level programmes.
- Regular updates and participation in clinical audit should be part of a radiographers continuing professional development (CPD) profile.

M-L. Ryan also gave the example in her home institution in University College Dublin where clinical audit is taught and assessed in the diagnostic radiographer degree.

She finished by highlighting potential actions including development of a suggested curriculum at European level, definition of roles and responsibilities in clinical audit, a clear recommendation at what point should appropriate training take place and cooperation between regulators, clinical bodies and academic programmes.

M. Coffey commented that **M-L. Ryan** noted that health professionals may identify areas for clinical audit, however commented that not all healthcare professionals may be educated to the standard to identify these issues.

Overview of Good Practices:

A. Brady began by reiterating the fact that the QuADRANT Main Survey asked a number of questions on clinical audit but that question 2.5 focused on the participants giving examples of clinical audit guidance/directives and any national clinical audits recently presented or published.

Whilst all 27 EU member states, plus Iceland Norway Switzerland and the UK responded to the main survey, not all had examples or documents for this question.

Belgium

Belgium responded in great detail at the previous [QuADRANT workshop](#) on their audit structures. **N. Reynders-Frederix** described the publication of the B-QUAADRIL handbook for diagnostic radiology in Belgium by BELIMP. Clinical audit has been made mandatory for all departments using X ray since September 2019 and encompasses self-assessment (with internal and external clinical audit currently on a voluntary basis). **M. Vandecapelle** (Coordinator Nuclear Medicine, Federal Agency for Nuclear Control (FANC), Belgium) noted similar for nuclear medicine which use the B-QUANUM manual adapted from the ICRP. Self-assessment and internal audit are in place with external audits yet to start. **A. Vaandering** (Quality Assurance Specialist, University Clinic Saint-Luc, Brussels) reported on the IAEA



adapted B-QUATRO document for radiotherapy. All 25 departments in the country are on a rolling audit cycle with audits conducted by a trained pool of auditors. All this is coordinated by multi-professional collaboration.

In the QuADRANT Main Survey, a 2020 paper investigating the feasibility and impact of national peer reviewed clinical audits in radiotherapy departments, was reported³.

Croatia

Croatia noted a poster presented as part of the Eurosafe session, which audited image provision for children across the country. Issues arising from imaging children in adult facilities included environment, justification, appropriate protocols and paediatric specific DRLs⁴. A re-audit was planned.

Estonia

Estonia provided a link to a summary of clinical audits recently coordinated by the Estonian health insurance fund⁵.

Finland

Finland has a very well-established clinical audit structure which was presented at the first QuADRANT workshop.

All radiological practices are audited at least every 5 years and all practices have now been audited several times. Audits run for 0.5-4 days, with a total cost of approximately €2500 per day for 2 auditors. In 2001, stakeholders established Finnish Advisory Committee for Clinical Audit to develop and provide support for clinical audit which is funded. Audit criteria are derived from legislative requirements and existing recommendations for good clinical practices, with an average of 4-7 recommendations to improve practice issued per healthcare unit. **A. Brady** made reference to a paper describing the Finnish system⁶.

Germany

The German participants directed QuADRANT to a 2019 paper, describing comparisons between implementation of the new radiation protection framework in Germany and other European countries⁷.

Ireland

In Ireland in 2011 a document was jointly produced by the overseeing Healthcare body (HSE) and the Faculty of Radiology called Requirement for Clinical Audit Radiological Practices (Diagnostic Radiology, Radiotherapy and Nuclear Medicine). In 2013, the HSE published a Practical Guide to Clinical Audit which was updated in 2017⁸. All medical doctors

³ Vaandering A, Lievens Y, Scalliet P; Belgian College for Physicians in Radiation Oncology. Feasibility and impact of national peer reviewed clinical audits in radiotherapy departments. *Radiother Oncol.* 2020;144:218-223. <https://doi.org/10.1016/j.radonc.2020.01.012>

⁴ Kralik, I., Brkljacic, B., Roic, G., Stimac, D., Vavro, H., Turk, T., Gotovac, N., Popic, J., Beck, N., Insight into imaging of children in Croatia - first results, EuroSafe Imaging Poster Exhibition 2020, <https://dx.doi.org/10.26044/esi2020/ESI-07747>

⁵ <https://www.haigekassa.ee/partnerile/tervishoiuteenuste-kvaliteet/kliinilised-auditid> (in Estonian)

⁶ Soimakallio S. Implementing External Clinical Audits in Radiological Practices: The Experience in Finland. *HealthManagement.* 2009;9(4). <https://healthmanagement.org/c/imaging/issuearticle/implementing-external-clinical-audits-in-radiological-practices-the-experience-in-finland>

⁷ Loose, R., Wucherer, M., Walz, M., Adamus, R. (2020) The new radiation protection framework since 2019 – Implementation in Germany and comparison of some aspects in seven European countries <http://dx.doi.org/10.1055/a-1137-0096>

⁸ Quality and Patient Safety Directorate, Health Service Executive, Ireland. 2017, A Practical Guide to Clinical Audit, <https://www.phecit.ie/Images/PHECC/Clinical%20Practice%20Guidelines/CPG%20Approved%20Orgs/STN019%20Practical%20Guide%20to%20Clinical%20Audit.pdf>



in Ireland are required to complete one clinical audit per year, which is policed by the registration body, the Medical Council. Financial or administration support is not available. There was a national review of clinical audit in 2019 by the HSE which noted that there should be protected time for audit, templates, data analysis support. **A. Brady** noted that these improvements were beginning to happen.

Luxembourg

A Karoussou-Schreiner presented the Luxembourg experience in the [first QuADRANT workshop](#). The Medical Imaging Technical group was created involving all stakeholders to implement the new legislation on radiation protection. Internal audits are done in every department once per year and external audit information is fed up to their Ministry of Health.

In the main survey, the QuADRANT project was guided to a paper published in 2019 on a National Audit of appropriateness of CT and MRI examinations in Luxembourg⁹. This paper audited all departments in Luxembourg and found that 39% of CT requests and 21% of MRI requests were inappropriate.

Norway

I. Heikkila (Norwegian Radiation Nuclear Safety Programme) presented at the first QuADRANT workshop. The presentation noted the national radiotherapy Quality Assurance programme which has been in place for over 20 years. This is funded by the national budget and dedicated time is made available for health professionals. External peer review site visit audits are conducted on a regular basis across all nine radiotherapy sites and provide local and national reports.

Slovakia

Slovakia also presented at the first QuADRANT workshop (**M Horvathova** (Department of Laboratory Examination Methods in Healthcare, Faculty of Health and Social Work, Trnava University, Slovakia) & **D Nikodemova** (Faculty of Public Health, Slovak Medical University, Bratislava, Slovakia)). They reported on a 2018 audit on screening mammography units. This audit defined standards and identified centres meeting them, to qualify for the mammography screening network. Based on the audit, the Ministry of Health established a permanent working group to take responsibility for national clinical audit.

Spain

Spain referred the QuADRANT group to a document from the Basque Region Department of Health (2015)¹⁰ which is a manual of evaluation and certification of QA programmes for radiology services.

Switzerland

C. Galli Marxer (QuADRANT Steering Group, Swiss Federal Office of Public Health) reported in the first QuADRANT workshop on the audit process which began in 2008. Third party audits of ionizing radiation departments occur every 5 years and self-evaluation is

⁹ Bouëtté, A., Karoussou-Schreiner, A., Ducou Le Pointe, H. *et al.* National audit on the appropriateness of CT and MRI examinations in Luxembourg. *Insights Imaging* **10**, 54 (2019).

<https://insightsimaging.springeropen.com/articles/10.1186/s13244-019-0731-9>

¹⁰ Cáceres Cáceres, C., Vázquez Castro, E., Muñiz Saitua, J., Arteagoitia González, M.L., (2015) *Manual de evaluación y certificación de programas de garantía de calidad de Unidades Asistenciales de Radiodiagnóstico*, Administración de la Comunidad del País Vasco, Departamento de Salud. www.ogasun.ejgv.euskadi.eus/r51-catpub/es/k75aWebPublicacionesWar/k75aObtenerPublicacionDigitalServlet?R01HNoPortal=true&N_LIBR=051730&N_EDIC=0001&C_IDIOM=es&FORMATO=.pdf



required once per year. Mandatory audits were scheduled for 2020 but were postponed by 1 year due to the pandemic.

UK

R. Greenhalgh (Chair of the RCR Clinical Radiology Audit & Quality Improvement Committee) and **D. Keenan** (QuADRANT Steering Group, Medical Director of the Healthcare Quality Improvement Partnership (HQIP)) presented at the first QuADRANT workshop.

HQIP is an independent national organization that manages a national clinical audit programme. It manages more than 30 national audits for NHS England, and provides benchmarked reports of compliance and performance to participating hospitals.

The National Quality Improvement and Clinical Audit Network (NQICAN) combines 15 regional clinical audit networks in England and provides practical guidance and assistance in implementing national audits.

The Royal College of Radiologists (RCR) Clinical Audit and Quality Improvement Committee are dedicated to the development and support of national clinical audit of radiological practices and procedures. It provides open access audit templates and examples using their Auditlive website. It supports local and national audit through local audit leads and online resources and have an annual audit forum and a network of over 200 clinical audit leads across UK departments. They aim to complete up to four national audits per year, examples include imaging provision in severely injured patients and radiology practice in cancer multidisciplinary teams.

HQIP¹¹, NICE¹², and the RCR¹³ have produced key documents focusing on Clinical Audit.

A. Brady described an example of an audit run by the RCR committee focusing on accuracy of interpretation of emergency abdominal CT for non-traumatic abdominal pain¹⁴.

European Society of Radiology

ESR is a leader in clinical audit and noted the third edition of *Esperanto* will be launched at ESR 2022.

It contains a substantially expanded explanation of clinical audit process, description of QuADRANT project and a substantial expansion of clinical audit topics and regulatory audit topics.

Eurosafe Imaging is the ESR flagship organization for radiation protection and is engaged in many European wide projects encompassing audit¹⁵.

¹¹ Healthcare Quality Improvement Partnership (HQIP) UK (2020) Best Practice in Clinical Audit <https://www.hqip.org.uk/resource/best-practice-in-clinical-audit/>

¹² National Institute for Clinical Excellence, NICE, UK.2021. Audit and Service Improvement, Into Practice. <https://www.nice.org.uk/about/what-we-do/into-practice/audit-and-service-improvement>

¹³ The Royal College of Radiologists, UK. Auditlive. <http://www.rcr.ac.uk/clinicalradiology/audit-and-qi/auditlive>

¹⁴ Howlett, D.C., Drinkwater, K., Frost, C., Higginson, A., Ball, C., Maskell, G. (2016) The accuracy of interpretation of emergency abdominal CT in adult patients who present with non-traumatic abdominal pain: results of a UK national audit, *Clinical Radiology*, DOI: [10.1016/j.crad.2016.10.008](https://doi.org/10.1016/j.crad.2016.10.008)

¹⁵ Frija, G., Hoeschen, C., Granata, C. *et al.* ESR EuroSafe Imaging and its role in promoting radiation protection – 6 years of success. *Insights Imaging* **12**, 3 (2021). <https://doi.org/10.1186/s13244-020-00949-5>



IAEA

A. Brady noted documents that were noted during the first QuADRANT workshop specific to clinical audit for diagnostic radiology, radiotherapy and nuclear medicine^{16 17 18}.

WHO

Finally, **A. Brady** noted the value of the WHO document 'Using audit and feedback to health professionals to improve the quality and safety of health care'¹⁹.

Q&A Session (Moderator: M.Coffey)

M. Coffey began by raising the repeating issue of how we get professionals to understand the fundamental difference between quality audit and regulatory practice or inspection. **M. Coffey** noted that we continue to use terminology such as reporting and measurability. In some countries where clinical audit is in development, the terminology makes it difficult. We need to be sensitive to challenges and difficulties. Those who are doing audit for the first time may likely see audit as inspection even if auditors are coming from a quality improvement perspective. How can we consolidate that difference in understanding between quality improvement audit and regulatory inspection?

R. Bly began by stating that, in the beginning in Finland, people were afraid of colleagues assessing of what we are doing. Emphasis had to be put on the fact that clinical audit is a good opportunity to have discussions between colleagues to better practice. Whilst clinical audit can be done digitally, discussions and observations of practice are very important- thus a hybrid approach would likely be optimal. **M. Coffey** agreed that it is really important to go and observe practice and noted that it gives a secondary message that it is a team approach and each member has a specific and important role.

R. Bly noted that the Finnish regulations were updated in 2018. They now have self-assessment required, internal audits every 4 years (except dental) and external audits 6 yearly for high risk settings and 8 yearly for low risk settings.

A. Brady raised the issue that we need to move conversation away from Radiation Protection and Regulatory requirements. Clinical audit can be about anything that improves patient outcomes. **A. Brady** noted a published study regarding UK regarding detection of osteoporotic fractures on CTs. If you are aware of an issue then you are more likely to change your practice based on it. He further gave the local example audit of the use of PFAs in the emergency department. The results were presented in house as an educational endeavor, and inappropriate referrals were reduced, hence the value of audit for professional education, team approach and improvement for patients.

¹⁶ International Atomic Energy Agency (2007) Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement. Quality Assurance Team for Radiation Oncology (QUATRO). <https://www.iaea.org/publications/7680/comprehensive-audits-of-radiotherapy-practices-a-tool-for-quality-improvement>

¹⁷ International Atomic Energy Agency (2010) Comprehensive Clinical Audits of Diagnostic Radiology Practices: a Tool for Quality Improvement. Quality Assurance Audit for Diagnostic Radiology Improvement and Learning (QUADRIL). Vienna: International Atomic Energy Agency. <https://www-pub.iaea.org/books/IAEABooks/8187/Comprehensive-Clinical-Audits-of-Diagnostic-Radiology-Practises-A-Tool-for-Quality-Improvement>

¹⁸ International Atomic Energy Agency (2015) Quality Management Audits in Nuclear Medicine Practices Second Edition IAEA Human Health Series No. 33. Vienna. International Atomic Energy Agency <https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1683Web-68161172.pdf>

¹⁹ World Health Organisation, WHO (2010) Using Audit and Feedback to Health Professionals to Improve the Quality and Safety of Healthcare <https://www.euro.who.int/en/data-and-evidence/evidence-informed-policy-making/publications/2010/using-audit-and-feedback-to-health-professionals-to-improve-the-quality-and-safety-of-health-care>



M. Coffey noted that the ICRP is preparing a document on Ethics in Radiation Protection which is challenging because it is to do with the ethics of clinical practice not necessarily radiation dose.

D. Paez noted that it can depend on who you are talking to and who will be conducting the evaluation for example hospital administrators versus clinical staff versus patients. Each have different perspectives and expectations. In the case of the IAEA, it is a patient centered peer review process and should include all the processes from the patient referral to report including patient surveys, administration. Self-assessment and findings of experts must then be compared. Quality Management includes all aspects and clinical audit forms just part of this.

M. Coffey noted QUATRO experience was very positive and highlighted the importance of establishing team support initially. She raised an interesting challenge regarding how, in the process of doing audit, do auditors or professionals manage very bad or dangerous practice when you are completing the audit in a supportive or developmental capacity.

M-L. Ryan noted that the whole clinical audit cycle is an educational process. UCD completed a study recently on near miss reporting and key feedback from radiographers was that there would be a blame culture. **M-L. Ryan** noted that feedback and actioning can be challenging resource wise but is key to focus on this area.

M. Coffey again noted the use of 'reporting' as terminology and in Radiotherapy, that documenting an issue is seen as a tool so you can learn from it.

N. Jornet noted that there are a lot of examples on justification however there are very few audits reported on optimization in diagnostic radiology and nuclear medicine, however there are somewhat more in radiotherapy. An example of patient opinion on Image Guided Therapy was discussed.

N. Jornet also raised the issue of internal audit within a hospital - how can other departments make a commentary and audit another department where they are not an expert.

M. Coffey reiterated the point of a broader context of clinical audit outside of radiation protection.

D. Keenan noted that the whole system of clinical audit is dictated by radiation safety. Everywhere else in medicine looks at gold standards that are not regulatory. He suggested that aspects of radiation that focuses on inspection should be kept separate and noted that, in Wales, they use quality improvement rather than clinical audit. The most missed point is implementing change: that is where the focus should be on quality improvement.

S.Ebdon-Jackson noted that **A. Brady** gave a perfect example of clinical audit and what can be done. This is the approach that regulators want to see- something that is based on clinical understanding, improve patient outcomes and service improvement. The regulator would be satisfied with this.

A. Rockall (Clinical Chair of Radiology, Imperial College London, UK) raised the issue on how we should prioritise important issues for clinical audit and whether it should be a discussion between societies. **D. Howlett** felt that prioritization should be decided by engagement between societies, staff, managers and patient groups, together with BSSD mandated topics. Furthermore, **D. Howlett** noted that patient involvement should occur at all levels (for example societal level and hospital level).

N. Jornet noted that it would be challenging to conduct internal audit between 2 departments who have different levels of expertise. Auditing teams within departments or from similar institutions were suggested. **N. Reynders-Frederix** suggested that



sometimes talking to colleagues from a different department about issues can potentially be helpful to identify areas for improvement.

N. Reynders-Frederix and **G. O'Reilly** (Chief Physicist and Head of the Medical Physics and Bioengineering Department (MPBE), St James's Hospital, Dublin, Ireland) echoed the issue in the questions and answers session regarding the confusion between inspection and clinical audit. **E. Briers, A. Brady** and **G. O'Reilly** reiterated the point that clinical audit expands beyond radiation dose issues.

M. Coffey thanked all the speakers and contributors for their input and stimulating discussion and closed the session.

Summary of key points from session 2.2

According to the survey, the key barriers to clinical audit uptake and activity included (in descending order of frequency): insufficient funding at national level; low national priority; insufficient staffing/personnel; insufficient funding at hospital level; lack of time; low departmental/hospital priority; insufficient local expertise; insufficient national expertise; insufficient funding at individual level. Few respondents noted no barriers.

Improved prioritization of and improved resource allocation to clinical audit infrastructure development were identified as key changes required to overcome the barriers and enhance national professional societal involvement in external direction of clinical audit.

Potential incentives for encouraging or facilitating clinical audit participation might not be required, because clinical audit activity is a legal requirement. Only a minority of countries indicated the uptake of incentives. Example incentives included (in descending order of frequency): an enhanced hospital accreditation system; direct remuneration; indirect remuneration; improved access to staff/equipment; exemption from clinical work.

Session 2.3: Enhancing European Clinical Audit Uptake and Implementation

The session was moderated by **A. Brady** and **W. Wadsak**.

The panellists were:

- **N. Reynders-Frederix** (QuADRANT Steering Group, Belgian Federal Public Service for Public Health)
- **D. Keenan** (QuADRANT Steering Group, Medical Director of the Healthcare Quality Improvement Partnership, UK)
- **C. Galli Marxer** (QuADRANT Steering Group, Swiss Federal Office of Public Health)
- **H. Waltenburg** (QuADRANT Steering Group, Deputy Director, Danish Health Authority, Radiation Protection)
- **G. Simeonov** (Policy Officer, European Commission Directorate-General for Energy, Unit D.3 Radiation Protection and Nuclear Safety)
- **A. Karoussou-Schreiner** (QuADRANT Steering Group, Medical Physics Expert, Radiation Protection Dept., Ministry of Health, Luxembourg, Chair HERCA WGMA (working group medical applications))
- **D. Paez** (Nuclear Medicine Physician, Section Head - Nuclear Medicine and Diagnostic Imaging Section, Division of Human Health, Department of Nuclear Sciences and Applications, International Atomic Energy Agency (IAEA))
- **M. Perez** (QuADRANT Advisory Board, Scientist, Radiation and Health Unit, Department of Environment, Climate Change and Health (ECH), Division of Healthier Populations (HEP), World Health Organization (WHO))
- **P. Papirnik** (QuADRANT Steering Group, Czech State Office for Nuclear Safety)



- **B. Brkjacic** (Secretary General of the ISR; ESR Past-President; Diagnostic Radiologist University of Zagreb, School of Medicine)
- **W. Oyen** (QuADRANT Advisory Board, European Cancer Organisation (E.C.O.))
- **P. Strojan** (ESTRO Expert - Radiation Oncologist, Chair of Oncology, Medical Faculty University of Ljubljana, Slovenia)
- **E. Briers** (ESR-Patients' Advisory Group (ESR-PAG))

A. Brady introduced the session by stating that the session was intended to bring together the previous day's discussions and put what has been discussed into a practical context. In particular, the goal was to consider what should be done to make clinical audit a reality in all countries and in all specialities.

One thing that has become clear is that the perspective that, if something is mandatory, it will happen is not necessarily true unless time and support are given to enable it. Being mandatory also does not mean that clinical audit will be carried out in a useful manner or on useful topic. Regulatory enforcement is a last resort and may create resistance within the healthcare professionals: what is required is to help healthcare professional who actually want to improve their practice.

A. Brady asked what practical things can be done to translate mandatory audit or voluntary audit into reality and in a way that staff will embrace it.

Suggestions for what incentives are necessary or would be helpful:

- We need an overarching national body/ies responsible for clinical audit practice and infrastructure and it is important that clinical audits are seen as practical and useful to patients and that locally staff are enthusiastic about audit and willing to engage with it.
- National handbooks and guidelines
- Shared data collection techniques amongst countries with both quantitative and qualitative methodologies to establish benchmarks for data against which units can measure their own activity/ies.
- Encourage participation in European and national audits
- How to prioritise the issues for clinical audits
- National Societies suggest the important issues for national audits with the different subspecialities

Questions to panellists

1. What are the most pressing actions that could be taken immediately at the national level and by professional societies (ESR, EANM, ESTRO) to make all of this happen?

N. Reynders-Frederix explained that different countries have included clinical audit in the framework of regulation but agreed that the regulatory component is maybe the least important. What matters is the added value/benefits that clinical audits can bring and getting the healthcare sector on board. He asked how the healthcare sector can be helped to promote clinical audit and a culture of safety that enables this.

He noted that a handbook is really useful, but it must be user-friendly and as clear and meaningful as possible on the quality criteria. They should be developed by all the healthcare professionals involved in practice and not only by the national authorities; furthermore, they should also include the patient perspective. If the patient is not involved in the initial development of a handbook, they should, at the very least, be involved in the review process.

The handbook should contain quality criteria specific to the patient perspective and criteria on how feedback from patients is collected, and used, in order to identify room for



improvement. Handbooks should make a distinction between minimum criteria and the different levels of desirable criteria. In this way, centres/hospitals can start with the minimum criteria, which is often actually being met, and can learn the process of clinical audit and begin to grow to not see clinical audit as a threat, but for it to become a habit. It may also be useful to have a distinction between clinical audit criteria for small centres and for large university hospitals, for instance.

It is also important to have a division between the different phases of clinical audit –

- self-evaluation/assessment as a starting point with professionals from the department acting as a multidisciplinary team looking at how they work compared to the quality criteria;
- then internal audit by colleagues within the same hospital but another department – where they might not have full understanding of your area it can help just to talk about how you work and you can then identify areas that can improve but this is very much dependent on the criteria which should be as clear as possible;
- External audit has a lot of potential but is also the most challenging.

It is important then to link back to the underlying needs and to remember that the healthcare professional is already motivated to work in a qualitative and safe way but that in daily practice this isn't straightforward. The daily workload in the healthcare sector is high and quality and patient safety does not happen by accident but requires constant attention. There are very important barriers but also elements that can contribute in creating a culture of quality and patient safety. It is important to facilitate and to support the healthcare professional.

C. Galli Marxer stated that practice is important: you cannot only rely on theory. It must be accepted by the community and all the stakeholders in order to achieve a result. The experience in Switzerland was that it helped to visit Finland and see how clinical audit was arranged there. The culture is different in the two countries, the legal system, the culture in the hospital etc.; however, information may be obtained from other countries. Nevertheless, it is important to ensure that what is imported is in line with the culture of the country in question. A list of countries that have implemented systems would be very useful to facilitate learning from others. To learn from each other is a first step: another extremely important point is that some organisation must take the lead in order to implement clinical audit, otherwise people will talk about it but not implement it.

A. Brady noted that this is what this workshop is about (at least in part) – learning from each other.

M. Perez added that, from the WHO perspective, the most important factors are:

- The BSSD is a very strong legal instrument that calls on member states in Article 57 to ensure clinical audit in place. This is unique for medical procedures using ionising radiation which is its strength.
- The BSSD's weakness is that, so far, it has been driven by the regulatory sector. One way to change this is to engage the health authorities as there is another reality, not leading to any legally binding rule, but which is very strong, and that is commitment at the governmental level to universal health coverage, which is a priority of health ministries all over the world, and also a component of the sustainable goals of the United Nations. All member states are committed to sustainable goals and refer to access to quality and essential health services.
- Clinical audit must be integrated into the picture of the national quality strategies: silence must be broken and bridges created to integrate clinical audit into the concept of quality care, risk not to know the boundaries between justification optimisation and outcomes of patient care but not really a risk if we integrate.



Top-down (ministries of health regulatory bodies, professional bodies) and bottom-up approaches must be combined.

M. Perez underscored the importance of engaging the health workers and the patients, who are a priority. Health workers may be engaged through education and a culture of respect for ethical values for radiation protection and clinical audit. Patient involvement is really an ethical duty and their engagement is a powerful tool to improve quality and increase uptake of clinical audit.

In the education of health professionals, patients, and families, we need to be more creative and take innovative approaches: for instance, not only to train auditors but to train health professionals to be audited and to contribute, to use problem solving, championship and mentorship. In this area the national and regional societies can help. Given that one barrier is funding, which can be solved by political commitment by governments, one way to get their involvement is making the business case – to convince them with numbers by introducing the component of health economy and to demonstrate that investment in clinical audit and improving quality will have benefits. They should look at opportunity costs in terms of public health and effective use of resources.

D. Paez added that, to put the points into steps, the following things have to be done:

- Quality audits require a holistic approach, nobody must be left behind all the elements, regulators must be considered as part of the process;
- To create a culture of quality, which means we have to include the three main dimensions of quality: the patients, the health professionals, and the management;
- To establish the process or the elements that will be used. The IAEA has the three tools which can be adopted or adapted by a country. The three tools have integrated checklists for all the elements necessary and compare to international standards;
- Once the process has been completed, the centres must be able to implement the recommendations that have been made: what issues have been identified and how can they be addressed?

A. Brady asked how it should be demonstrated to health authorities that there is value to be generated for health care provision by engaging in clinical audit: that clinical audits can be used to demonstrate that the value of what we do can be increased and that clinical audit could be a useful tool.

P. Papirnik responded that in some countries the attitude tends to be that nobody does anything unless it is their duty. However, there is a duty to do clinical audit and this duty extends not just to undertaking clinical audit, but to how the external clinical audit should look. When defined in law, the external clinical audits are carried out very well. When internal clinical audit is not written in law, it has become something of poor value and not well carried out. This culture dominates possibly in Eastern European countries, where integration into law means audits are done and carried out correctly.

D. Keenan added that the UK has leadership: it is a 'hearts and minds' matter and leadership should be employed to show how to offer a better service to patients. He asked how departments can know they are delivering high quality care? Asking such questions can stimulate some people to start using simple audits, and that can grow and develop. Templates to make the process easier and using the digital medium to give access to quick data also leads to quality improvement. How the leaders bring everyone with them is key. The groups are spanning Europe and are also international which is a very positive factor.

G. Simeonov explained that the most important thing that he has understood from the discussion is integration.

Clinical audit is, of course, mandated at EU and at national level. This might discourage some people but it is a reality; however, what we have seen is that the mandate is not



enough and this is a waste of an excellent tool. The tool is wasted if it only focuses on dose and core radiation protection issues. In the broader context, he expressed a desire to see how radiation protection issues and the regulatory mandated clinical audit can be integrated into the national systems.

He suggested that he sees two cases for this: the first, where you have a national system of clinical audit, which is a general system working for improving quality of services, what you have to do very practically is, from the authority perspective:

- to make sure that the issues that are important for protection of patients and radiation safety are part of the system;
- identify processes that are already in the system where you have to integrate these issues

The other case is a country where (from the EU perspective) there is no national system or system for quality improvement, then the regulations are a good starting point.

He suggested radiotherapy, radiology, nuclear medicine could be leaders for other clinical specialities, and would stop the waste of this very valuable tool by maintaining a narrow focus on dose and other issues of this kind. In relation to justification and optimisation, he asked if they are really only specific to radiation protection or whether they are issues that take place in any medical practice: is your practice justified and optimised? They may come from the radiation protection world but they should be seen as good quality clinical practice – an integrated approach.

From the Commission perspective, where the regulatory authorities have done an excellent job, we need to take this to the health authorities and health ministries who need to take it on board.

G. Simeonov talked about the establishment of SAMIRA, the quality and safety group that is being created as a more permanent body, discussed bringing all this to the health authorities to convince them that: there is something in it for them, that they have a responsibility and a role to play, and to ensure that all the players are brought together to ensure cooperation in the country – the ‘top-down’ approach from the European perspective.

In addition, through SAMIRA, the quality and safety stream is another level of integration where we have all the different policies (the policies for healthcare but also the digital agenda) and see what are the appropriate instruments that already exist and where the elements of addressing these barriers and ensuring support in all the different systems can be integrated. He proposed starting with the integration of radiation protection into the broader quality system and going to the authorities and integrating there also.

G. Simeonov also proposed taking these elements from the workshops and trying to help implement clinical audit through the support from societies and professionals – the ‘bottom-up’ approach.

The BSSD does not state that the issues to be audited are only radiation protection dose, justification or optimisation but allows for a much broader concept of audit.

W. Oyen added that one important aspect for increasing uptake of clinical audit is that on a national level the whole array of audits, inspections is harmonised. There is an increasing pressure on departments and specialists from all sides and you have someone looking into your practice continually with a different view etc. and that is time consuming especially in a small practice. He advocates for National Societies to appreciate the framework of external audit in the broadest sense and then bring this into the system to work



synergistically with what is already there, joint audit where same people are doing a slightly different task – e.g. training programme, quality audit of the national societies require a slightly different focus and is a challenge for staff. To make clinical audit a tool to improve quality then frame it in what is already in a country. Share information across audits so the process only has to be done once.

W. Wadsak summarised the discussion to date: for countries that have little or nothing in place, people should start going and ask themselves and their colleagues what they do and what they should be doing to provide high quality for patients because they may be a patient in the same department or in another department and would also rely on getting the best quality treatment. This can be a starting point.

On the other hand, some countries have already established a very good culture in clinical audit, so they can help the other countries - bilateral communication could be very helpful in a mentor-mentee relationship. The QuADRANT consortium, with the final report, together with the EC will try to set a framework and the rules and give good guidance. Of course, it is important to embed it in a whole quality framework so as not to overwhelm everybody.

Q. What are the barriers/hurdles, what do we need to overcome both from the regulator and department side. Where do you see the barriers and why does it not happen in a way you want to do it?

N. Reynders-Frederix explained that important barriers are the lack of resources and the adherence to habits. In healthcare, there is a high workload and limited resources. It's important to keep critically examining habits and reflect on how you work. That is where clinical audit can help as it makes people think about whether they do the right things and do them in the correct manner. The viewpoints of colleagues / peers in this reflection are very interesting. A pitfall can be that, if the hospitals do not have the resources and clinical audit is enforced, it will become something administrative with one person behind a desk checking everything.

Clinical audit must be performed by a multidisciplinary team and there are ways to make the workload of clinical audit a bit smaller. One possibility is to alternate between an audit where you look at all criteria from a certain level within your handbook, and an audit where you look at specific domains.

Some countries already have a long history of clinical audit, such as Finland for example; but, for other countries, it would be useful to integrate clinical audit into education – then new healthcare professionals who have already learned about the importance of clinical audit graduate every year and are hopefully inclined to continue what they have learned about clinical auditing when they enter the field. A clear international statement of recommendation on the need for education on clinical audit is needed.

Performing clinical audit could be integrated as a requirement for the voluntary hospital accreditation. If a hospital has gone through a voluntary accreditation process they can be reluctant to introduce the concept of clinical audit as they will feel they already have done the accreditation process even though they are not really the same. It could be made a requirement of the voluntary hospital accreditation that clinical audits are carried out regularly.

Given the constraints on resources, the management needs to recognise the importance of multidisciplinary clinical audit and support this.

P. Papirnik identified the greatest tool, in his view, for successful clinical audit: national radiological standards or guidelines. It is key to have written national agreement on what the radiological procedures should look like, what the minimum requirements are and what



constitutes good practice. This should be written in detail in long documents in the three specialities.

P. Papirnik also identified the biggest issue or problem, in his view, of the whole system: the resources are not there to create these standards or to keep them updated in smaller/poorer countries and therefore there are not many peers who would be able to write and agree the standards and standard practice at the national professional bodies or at a national level. The peers who could write the standards have such a heavy workload that keeping any such document current is a problem. His suggestion is that the EC could create a platform of peers that could create and keep current a set of standards in radiological practice, or identify which of the national standards in each country could become the European standards so that the individual countries do not have to create these standards from the beginning – they could translate and select the appropriate ones for their country. This would be less time consuming and save resources.

The lack of resources, from a different perspective, could present an opportunity for the professional societies – they are already using it to some extent, but from a legal perspective standards would need to come from the EC.

M. Perez supported this big picture on standards as it is the first step, the notion of clinical audit is assessing whether health care is provided to a set standard so there should be some criteria otherwise some countries will not be in a position to do it. It is necessary to have clear guidance on the standards of clinical care using radiation but also guidance conducting the audits or it will be difficult to implement the requirements of the BSSD where it states implementing national guidelines according with national procedures. Standards are definitely necessary, but not enough. Additional actions such as training, supervision monitoring, and feedback to the healthcare providers are needed.

Regarding education and training, she supported multidisciplinary and multi-professional education, which are different but both very helpful and complementary, although they can also be problematic. One of the barriers that she sees to audits is that, where they should be carried out by a multidisciplinary and multi-professional team, one professional may consider being audited or questioned by a different profession a threat. For certain professions, such as physicians, they can quite often feel uncomfortable if a radiographer/RTT is part of the team assessing the quality of care. This can be avoided if a culture of teamwork is created in which everyone is important. Breaking false hierarchies by multi-professional education as of healthcare providers and involving the patients also is one way to overcome this issue.

D. Keenan noted that many barriers are local and national. An example of a local barrier is having poor levels of experience and doing clinical audit badly: e.g. not collecting the right information and not being multidisciplinary, being a small group looking at something with no multidisciplinary team implementing change. Many people have such a bad experience that they never repeat the audit. On a national level it is a different problem that has already been touched on: the burden of collecting the information must be reduced. Conversely, the feedback must be prompt to be meaningful and not out of date when it is of no value. It is not necessary to strive for the optimum: going for the 'low hanging fruit' can have a quicker impact.

Q. Regarding patient involvement: it is not easy to address if there is no patient organisation, for example as might be the case in a small country. How can patients to be involved be identified?

E. Briers noted that in this situation, a patient organisation might not be necessary: patients go through your care every day, so talk to them! There are different kinds of patients, those who come only once and those that come regularly for monitoring of disease etc. Patients who are willing to talk to you about your service can be found in this group;



but you should not wait for them to contact you – you should proactively approach the patients and invite them to be involved. Create a patient group, with an open invitation to join, within your service and ask them for collaboration. You do not need the national authority to identify patients for you. The importance is the local patients auditing the local system.

Summary of day 2:

M. Coffey noted that several issues had been raised: the idea of establishing a culture of quality and patient safety that integrates clinical audit and radiation safety, the whole idea of a holistic approach which is really key and has been mentioned consistently over the full QuADRANT project. This topic may take it a step later looking at governments and health authorities being involved, at regulatory level, the role of hospital management and we have just heard about the involvement of patients at a local level and the issues that are important for them in that department and learning from that in the broader context. That led to the discussion of a top down and bottom up where you are capturing the views or the perspectives of everybody.

One really important thing that has come out is the idea of openness and transparency and how countries or centres can actually share experiences but share them in a very non-judgemental way that is involves learning from others. **M. Coffey** suggested that it is not just learning from where it has been successful but also learning from where things went wrong, why it went wrong, why it didn't work that is also a really valuable learning experience for people and maybe this could be promoted a little bit more the sharing of the totality of experiences. The importance of education built on a good basic undergraduate education and part of lifelong learning taught in a multi-professional way where you don't have hierarchical issues arising where people speak the same language giving a greater understanding of the process of clinical audit which is important but why you do it to improve the quality of your practice effectively.

In terms of practical help, the idea of handbooks has been raised consistently and handbooks to assist and to help people actually start and that can include people carrying out simple audits. You do not really need to reinvent the wheel: there are a lot of guidelines already available but it is looking at your actual context, how do you use them best and how do you integrate them into your practice. She thinks this leads to the concept that, if you can start with a simple audit of a single component of practice people learn about the process of clinical audit, they learn about being a member of a team if this is a good experience it can lead to a larger more comprehensive audit, so taking the small steps an developing them and evolving from them. It is clear that we need the actual health authorities to be involved and not only the regulatory bodies.

She ended on the idea that, what is really key, is that clinical audit is actually part of the role of health care professionals because they are responsible for patient outcomes either directly or indirectly. This is what they impact on when they are involved in diagnostic imaging, nuclear medicine or radiotherapy and of course that requires resources and there has been a lot of discussion on the need for resources but it is that you need to integrate into your own personal psyche that you are delivering care to patients and that should be optimum and that you are constantly aware of how you practice and how you can practice better.

Session 2.4: Day 2 Close

G. Simeonov reiterated his thanks to all of the speakers and moderators, especially **M. Coffey** for her summary. He also thanked the WP4 team, for planning the workshop, **D. Howlett**, as project lead, and the ESR/EANM/ESTO staff. He noted the attendance over



the two days of the workshop was over 100 people on both days and that this was a sign of the importance of the subject and level of interest in it. He reminded participant that the European Commission hopes to publish the final report from the QuADRANT project and that this will feed into the SAMIRA project.

D. Howlett added his thanks to the QuADRANT consortium and to the workshop participants, also noting the good attendance at the workshop as well as the success in making progress towards recommendations and guidance on clinical audit.

The workshop closed.



4 Workshop summary and conclusions

The QuADRANT project is an important part of the SAMIRA initiative, forming part of the pillar dedicated to quality and safety. Three medical disciplines are represented within the QuADRANT project, namely radiology, radiotherapy, and nuclear medicine. These disciplines are represented by the European Society of Radiology ([ESR](#)), European Society for Radiotherapy and Oncology ([ESTRO](#)), and European Association of Nuclear Medicine ([EANM](#)).

QuADRANT aims to provide an overview and roadmap of clinical audit uptake and implementation across Europe, identifying good practices, available resources and guidances. The QuADRANT Work Package 4 (WP4) [online workshop](#), focused on the need for and relevance of clinical audit, was the second of two workshops held as part of the QuADRANT project, the [first QuADRANT workshop](#) having been held in December 2020.

Targeted at representatives from national and professional societies, radiation competent and health authorities as well as the representatives from the EU27+4 (i.e. the 27 EU member states plus Iceland, Norway, Switzerland, and the UK), the WP4 workshop presented the findings from [Main Survey under WP3](#) on the status of clinical audits and paying particular attention to the responses received to the Main Survey, as well as expert interviews on the status of clinical audits. The need for further coordinated EU action on quality and safety of radiology, radiotherapy and nuclear medicine was discussed with the representatives from Member States. The attendance over the two days of the workshop was over 100 people on both days and this may be taken as a demonstration of the importance of the subject and level of interest in it.

The Main Survey results were divided into the same 8 sections used in the WP3 analysis. Specific round table expert panel discussions were also a key feature of the WP4 workshop. During the first day, discussion was focused on clinical audit and the BSSD, with a more extended panel discussion taking place on day 2 covering clinical audit uptake more generally and incorporating the survey and expert interview results.

Looking at the development of clinical audits, previous work by the European Commission (EC) demonstrated heterogeneous levels of implementation of clinical audit at the member state level. It is important to recognize that the different European countries have different strengths and weaknesses and will thus face different challenges in establishing or developing an effective clinical audit infrastructure. Moreover, the COVID-19 pandemic has a significant impact on healthcare systems; in particular, affecting healthcare resources.

The ultimate goal of this workshop was to produce, by discussion, knowledge transfer, and consensus, a detailed outline and guidance as to how clinical audit uptake and implementation across the EU27 can be enhanced.

Participants and speakers in the workshop agreed on the importance of clinical audit in quality improvement in health care, particularly because it links legislation with practice. It was agreed that quality and clinical audits should be performed both in public hospitals and private practice. Clinical audits are the basis of good clinical governance and key components of quality improvement. Establishing a national body with responsibility for clinical audit (and quality improvement) was seen as an important step in the development of a successful national audit programme.

Some of the key questions and responses to them that were brought up and generated by the workshop were:

- **What is the relation between Clinical Audit and the BSSD?**



BSSD provides the legal framework mandating participation in clinical audit in support of radiation protection BSSD requirements “in accordance with national procedures”.

- **What is the role of infrastructure, particularly at the national level?**
A key component in effective clinical audit is a functional infrastructure at both local (departmental/hospital) and national level. WP3/WP4 revealed only a minority of national professional societies have a dedicated clinical audit administrative infrastructure or the ability to communicate effectively with hospital departments or memberships.
- **What are the barriers to clinical audit and what incentives might promote improved clinical audit?**
Lack of resources was considered a major barrier to national professional society involvement in clinical audit. Governmental/health authority affiliation may facilitate access to funding and allow more effective influence upon national clinical audit policy.
- **How can accreditation and certification be performed at national and international level?**
Accreditation of hospital service provision can provide a marker of quality for external use and for patients. An established system of accreditation does exist in many European countries, but the schemes are often voluntary and do not usually require evidence of participation in clinical audit as part of the accreditation process. Evidence of involvement in clinical audit should form part of the certification process for healthcare professionals.
- **How can clinical audit be embedded in education/training in a more structure manner?**
A successful programme of clinical audit requires effective engagement of participants, in healthcare. Education in clinical audit and the need for active participation in clinical audit should be encompassed within both undergraduate and postgraduate educational programmes. Certification of individuals and may have a role in promoting engagement.
- **How can patients be more involved in clinical audit?**
As part of the workshop presentation by the ESR Patient Advisory Group representative it was highlighted that patients are often very willing to become involved in clinical audit at all levels within the healthcare system, whether in local projects or in strategic planning at national professional society or healthcare administrative levels. Active patient involvement at local hospital / departmental and national professional levels should be both encouraged and formalised where possible. Patients can input effectively into development of guidance documents or into clinical audits directly, helping identify and prioritise key areas for audit from the patient perspective. Patient involvement can take several forms, including direct representation on relevant working parties or committees, or direct or indirect involvement in the clinical audit itself.
- **Good practice examples:**
A key outcome of QuADRANT is the identification of good practices, available guidance and resources in clinical audit at national, European and international



levels, with a view to sharing practices and guidance between European countries. Different approaches will suit differing countries depending upon resources and infrastructure available and it is hoped that the examples of good practice included can provide templates going forwards.

In summary, clinical audit is “a systematic examination or review of medical radiological procedures that seeks to improve the quality and outcome of patient care through structural review, whereby medical radiological practices, procedures and results are examined against agreed standards for medical radiological procedures, with modifications of practices, where appropriate and the application of new standards if necessary” [BSSD] – whereby this is applicable to all medical applications involving ionizing radiation. While inspection is a BSSD requirement, audit is part of modern clinical practice. The key elements of clinical audit are the following: it is a process; it is designed to improve patient care; it requires systematic review against explicit criteria; and it requires the implementation change when necessary. Self-assessment/evaluation is a step-in preparation for internal clinical audit, the process being undertaken by a multi-disciplinary evaluation team consisting of members of the team being audited. Internal audit is an audit that occurs at local level (individual, departmental, hospital) on its own initiative and consistent with national requirements, while in external audits the team (ideally comprising relevant healthcare professionals) is working across a number of centres/hospitals within a region or country.

The key barriers to clinical audit uptake and activity included firstly a general lack of resources: insufficient funding; insufficient staffing/personnel; insufficient funding at hospital level; lack of time; insufficient expertise. Other barriers to uptake included lack of understanding of the process of clinical audit and the difference from inspection; lack of prioritisation at national/regional/hospital level; poorly developed culture of quality and safety; lack of education and training. Conversely, improved prioritization of and improved resource allocation to clinical audit infrastructure development were identified as key changes required to overcome the barriers and enhance national professional societal involvement in external direction of clinical audit. Potential incentives for encouraging or facilitating clinical audit participation might not be required, because clinical audit activity is a legal requirement. However, the key factors of a successful audit have been identified in the development of a culture of safety, the absence of a blame environment, the necessity of a multidisciplinary and multi-professional team, and the patient’s involvement.

The output and conclusions from the WP4 workshop, both presentations and panel discussions, combined with the findings from the previous WPs, in particular WP3, form the basis of the final conclusions/recommendations document in WP5.