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EDITORIAL

The QuADRANT study: current status and recommendations for improving uptake and implementation of clinical audit of medical radiological procedures in Europe—the nuclear medicine perspective

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Introduction

TheEuropean Council published the Basic Safety Standards Directive (BSSD) in 2014, allowing Member States four years (until 2018) to implement the laws, regulations, and administrative provisions required to meet the minimal standards set by the BSSD [1]. Based on the BSSD, inside the European Union, it is required by law to perform clinical audits following national procedures. Clinical audit is defined by the BSSD as a systematic analysis of medical radiological procedures seeking to ameliorate the quality and outcome of patient care, in which medical radiological practices, procedures, and results are examined against agreed standards for good medical radiological procedures, aiming at the modification of practices, where appropriate, and the application of new standards if necessary [1–3]. The term medical radiological procedures includes all medical applications that utilise ionising radiation, including radiology, nuclear medicine, and radiotherapy.

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One of the cornerstones of high-quality patient care is the practice of clinical audit. The European Commission, recognising the need to ensure Member States correctly perform clinical audits, dedicated efforts in this regard. In 2007, research evidenced variable and often lacking, or minimal, practice of clinical audit in Member States [2]. In 2009, the European Commission published a guideline on clinical audit for medical radiological practices [4]. Nevertheless, in 2017, the European Commission evidenced continuing difficulties in clinical audit implementation within the Member States [5].

In this context, it is important to consider the key safety issues involving patientand staff as well as the potential ongoing heterogeneity and challenges in European clinical audit uptake andimplementation. Thus, the European Commission presented the tender for the QuADRANT project in 2019 [2], entitled "Constant improvement in quality and safety of radiology, radiotherapy and nuclear medicine through clinical audit", being summarised with the acronym QuADRANT (Quality Improvement Through Clinical Audit in Diagnostic Radiology, Radiotherapy and Nuclear Medicine (Including Therapies)). The aims of this project were as follows: (a) review the status of implementation of clinical audits in the Member States of the European Union (EU); (b) identify good practices in Member States and available guidance and resources for clinical audits at national, European and international levels; (c) provide further guidance and recommendations on improving the implementation and integration of clinical audits into national healthcare systems; (d) identify potential for further co-ordinated EU action on quality and safety of radiology, radiotherapy, and nuclear medicine. A consortium led the project, including the European Society of Radiology (ESR), the European Society of Radiotherapy and Oncology (ESTRO), and the European Association of Nuclear Medicine (EANM). The project included two workshops, a pan-European survey,

expert interviews, and a literature review, with a final report [2].

Core principles of clinical audits

In the position paper from the Committee for Accreditation of Nuclear Medicine Departments, UEMS/EBNM, on the general guiding principles of clinical audit, clinical audit was defined as a means of improving the quality, experience, and outcomes of patient care through the systematic evaluation of systems, applicable care trajectories, and results comparing results with defined norms and implementation of results-based changes [6]. More recently, the Esperanto guidelines indicated that a clinical audit should be Achievable, Local, Practical, Inexpensive, Non-threatening, and Easy (ALPINE) [7].

The general objectives of a clinical audit should be focused in improving the quality of patient care, promoting the effective utilization of resources, enhancing the provision and organisation of clinical services, and furthering professional education and training [8, 9].

Multi-disciplinarity; combination of internal and external assessments, focused on practical clinical work of different specialists; professional initiation; and promotion of an environment that facilitates professional relationships and multi-disciplinary approach needed to optimise patient care are other important characteristics of a clinical audit [2].

Clinical audits in nuclear medicine before the QuADRANT project

Focusing on the field of nuclear medicine, a multi-centre evaluation of accuracy and reproducibility of planar and SPECT image quantification evidenced the need for training and standardised protocols to achieve appropriate levels of harmonization [10]. This study demonstrated that international multi-centre trials for image quantification in nuclear medicine therapy are possible and could be the first step towards improved traceability of dosimetry studies in patients. Following this study, a series of publications, promoted by the International Atomic Energy Agency (IAEA), analysed in detail this peer-review process on Quality Management Audits in Nuclear Medicine Practice (QUANUM). A key aspect for globally implementing audits are standardised guidelines and guidance. The first edition of the QUANUM manual, published in 2009 [11], was favourably implemented globally. In 2012, the IAEA updated the QUANUM manual with its second edition [12]. Later, Seminars in Nuclear Medicine published another four articles summarising the whole IAEA process in this direction: the QUANUM peer-review process Program and Methodology [13, 14], the Analysis of Results [15], and the Implementation of Quality Systems in Nuclear Medicine [16]. Distinctly, the analysis of the requirements of daily routine practices in audited centres evidenced a significant improvement in all checklists.

Another requisite for harmonising procedures in medical imaging is reaching consistent results between different readers, as it affects the comparability of results between different institutions and also among studies performed at different time points, even in the same institution [17]. Another IAEA study analysed the outcome of IAEA training activities in nuclear cardiology in an international clinical audit on myocardial perfusion imaging [18]. Participants had to report studies distributed from a core lab. The results evidenced that the quality of reporting is influenced by the global adherence to process quality, confirming the key role of IAEA training in in low- and middle-income countries.

With regard to molecular radiotheraphy, the EANM published a guideline to evaluate uncertainties in molecular radiotherapy, in an essentially theoretical analysis. The fact is that this could also apply to selective internal radiotherapy [19].

Overall findings of the QuADRANT project

The aim of QuADRANT was to evaluate the status of implementation of clinical audit in the EU27 + 4 and to assess good practice and available guidance and resources for clinical audit at national, European, and international level. The response rate was good, taking into account the survey was done during the COVID-19 pandemic. There were 83 respondents, including at least one survey response from each of the EU27 + 4 countries. Emphasis was put on a national perspective, rather than on the different scientific specialty societies. The main findings of the QuADRANT project and its final recommendations were grouped into the eight sections summarised below [2].

(i) Clinical audit co-ordination and prioritisation at national level: (a) A national clinical audit programme must be implemented. This program, which can collaborate with healthcare stakeholders, must develop national guidance, good practices, and a culture of clinical audit using a "top down, bottom up" methodology. (b) The main obstacles are scarce resources and low national prioritisation of clinical audit.

(ii) Regulatory control — clinical audit and the BSSD: A pan-European drive is required to raise awareness on the BSSD and the needs for supporting clinical audit. All departments or clinics using ionising radiation

should undergo clinical audit as mandated within the BSSD.

(iii) Development of infrastructure — the role of the national professional societies: The national professional societies have a potentially pivotal role in the development of a national clinical audit infrastructure, providing guidance, networking opportunities, expertise, and clinical leadership.

(iv) Barriers and enablers: (a) Barriers to clinical audit activity include not only insufficient funding/resourcing and low national/hospital priority, but also a lack of time and expertise. (b) Enablers can be used as appropriate to facilitate clinical audit activity, and these may include remuneration of healthcare professionals and hospitals, exemption from clinical work, enhanced hospital accreditation, academic promotion and recognition, or improved access to staff and equipment.

(v) Accreditation and certification: (a) Accreditation systems for hospitals can provide a marker of quality for use by healthcare commissioners, staff, and patients. However, hospital accreditation schemes are often voluntary and may not involve assessment of clinical audit activity. (b) Likewise, certification of healthcare professionals (licence to practice), where in use, usually does not involve demonstration of clinical audit activity. (c) Where used and resourced appropriately, these schemes can provide a mechanism for ensuring quality of services. Hospital accreditation and healthcare professional certification schemes should involve an assessment of clinical audit activity.

(vi) Education of healthcare professionals: Development of a holistic, "no-blame" culture of clinical audit is a key desired outcome. As part of this process, embedding structured education around clinical audit practice and process is needed in undergraduate and postgraduate education for healthcare professionals. Sharing educational resources and best practices must be encouraged.

(vii) Patient involvement: Active involvement of patients is also strongly recommended at all levels of the healthcare system with input into clinical audit policy and projects. A harmonised European approach around patient consent for healthcare records access for clinical audit purposes would be beneficial.

(viii) Good practice, available guidance and resources in clinical audit: The QuADRANT project has proven to be a rich source for good practice and guidance in clinical audit. These can be shared and/or adapted by countries across Europe, according to national priorities and available resources, to allow development of clinical audit infrastructure and to improve safety, experiences, and outcomes for patients [2].

Analysis of the findings of the QuADRANT project focused on nuclear medicine

The objective of QuADRANT was to evaluate the status of implementation of clinical audit in the EU27 + 4 and to assess good practice and available guidance and resources for clinical audit at national, European, and international level. The response rate was good, taking into account that the survey was done during the COVID-19 pandemic. There were 83 respondents, including at least one survey response from each of the EU27 + 4 countries. Emphasis was put on a national perspective, rather than on the different scientific specialty societies [2].

With regard to nuclear medicine, it is worth commenting on the following results of the survey, presented organised into the 8 thematic components of the survey [2].

(i) Clinical audit co-ordination and prioritisation at national level: Most countries indicate there is a clinical audit governance and policy at a national level (in 22 countries), having an already functioning centralised responsible organisation in 21 of them. A national clinical audit guide or manual is in place for nuclear medicine in 13 countries (in development in 2).

(ii) Regulatory control — clinical audit and the BSSD: The awareness of the obligation to perform clinical audit of medical radiological practice as mandated by the BSSD is still variable, even after all the work done by the European Commission and the professional associations, among others. There was more awareness towards this obligation in national professional associations (in 17 countries) and higher governmental levels (in 16 countries). For the EU27 + 4, it is mandatory to undergo clinical audits for departments using ionising radiation procedures outside radiology, radiotherapy, and nuclear medicine. Regarding private radiology, radiotherapy, and nuclear medicine services, in 5 countries, it is mandatory, whereas in 5, it is voluntary and, in another 5, it is not required [2].

(iii) Development of infrastructure — the role of the national professional societies: National professional associations are involved in the process of producing good practice guidance or standards in relation to clinical audit in 22 countries. Multi-disciplinary co-operation happens in 20 countries and international (i.e. IAEA and WHO) involvement happening in 13 countries. These numbers allow certain optimism, as only 8 countries have no national guidance in place [2].

(iv) Barriers and enablers: Regarding enablers, respondents from 18 countries indicated that, given the fact

that clinical audits were mandatory by law, it was not necessary to implement enablers. However, five of them reported the application of selected enablers.

(v) Accreditation and certification: Although hospital accreditation systems are in place across most countries of the EU27 + 4 (only four countries without it), participation is often voluntary (in 13), being a requirement for accreditation only in 11 countries. Regarding the accreditation of healthcare professions, most countries (in 17) do not have requirements for registration to practice. In 9 countries, evidence of participation in clinical audit is required for registration to practice for some (in 4) or all (in 5) professions [2].

(vi) Education of healthcare professionals: Education and training programmes include clinical audit teaching in only 3 countries, with limited incorporation in 4, being absent nor planned in 17, and in process of instauration in 4 countries.

(vii) Patient involvement: In most countries (in 21), there are no opportunities for patient involvement. With regard to formal patient consent for records access for clinical audits, it is not a requirement in 20 countries, being mandatory in 7.

(viii) Good practice, available guidance, and resources in clinical audit: Additional details provided by respondents included relevant clinical audit guidance and directives or publications from national professional associations, national auditing organisations, or governmental agencies or other professional bodies [2]. The main documents related to nuclear medicine are summarised below:

a. National: Focusing on the available resources in English, the 2021 publication from National Institute for Clinical Excellence (NICE) [20] on audit and service improvement in the United Kingdom (UK) is well known internationally. The Royal College of Radiologists (UK) has AuditLive, an open-access collection of audit templates providing a framework identifying best practice in key stages in the audit cycle [21]. Other resources in English published since 2019 come from the UK [22] and Ireland [23, 24], among others. Regarding the resources available in languages different from English, it is worth naming those published in: (a) Spanish [25]; (b) French [26]; (c) Dutch from Netherlands [27, 28], Belgium [29] and Luxemboug [30]; (d) Czech [31]; (e) Slovak [32, 33]; and (f) Latvian [34]. Examples of good practice in clinical audit at the national level come from:

   i. Ireland: The National Office of Clinical Audit facilitates national clinical audit and quality improvement processes, clinically directed with multi-professional involvement, although they are not BSSD specific. It allows continuous monitoring of outcomes, feedback, identification of outliers and practice improvements as needed which are timely and actively responsive [35].

   ii. UK: The Healthcare Quality Improvement Partnership (HQIP) works mainly in England and Wales [9]. It controls a programme of over 30 national clinical audits (not BSSD specific) on behalf of NHS England, collecting and analysing information supplied by local clinicians to provide a national picture of care standards. In some instances, "real time" collection of data allows quick and flexible responses to changes in practice or outliers in performance. Benchmarking is done, sending reports of compliance and performance to local hospitals. Moreover, the Royal College of Radiologists (RCR), among other professional societies, provide external audit direction. The RCR has developed an effective network of communication and feedback network with over 200 audit leads in all UK radiology departments [36].

   iii. Finland: It has a well-developed and very successful programme of external clinical audit with a National Advisory Committee co-ordinating and overseeing it, with the support of national professional societies and the National Radiation and Nuclear Safety Authority (STUK) [37].

   iv. Belgium: BELMIP [38], a multi-disciplinary and multi-professional collaboration aiming to the promotion of appropriate and qualitative use of medical imaging, provides a platform to perform clinical audit. BELMIP based its clinical audit manual on the method published by IAEA in its B-QUANUM handbook for Nuclear Medicine [39], based on IAEA handbooks [2].

   v. Germany: Each Federal State has the authority for radiation protection. There are frameworks for auditing organisations in the key specialty areas (radiology, radiotherapy, and nuclear medicine) [2].

   vi. Luxembourg: The Ministry of Health begun a national action plan auditing imag-

ing requests, awareness about radiation protection, among other issues [2].

vii. Switzerland: The Federal Office of Public Health established a steering committee with multi-professional representation to define a national strategy and implementation programme for clinical audits.

viii. France: In July 2021, a voluntary standard NF S90-300, "A Comprehensive Approach Towards Quality in Medical Imaging" [26] was published. In it, the entire patient pathway in medical imaging is analysed as a whole. It includes patient care and safety before, during, and after the examination and, also, clinical audit and radiation protection.

b. International: The IAEA proposed a clinical audit method for nuclear medicine in its QUANUM handbook [39]. The World Health Organisation (WHO) published in 2010 its recommendations on clinical audit "Using Audit and Feedback to Health Professionals to Improve the Quality and Safety of Healthcare" [40].

Conclusions

The objective of the QuADRANT project, which is providing an overarching view of clinical audit practice in Europe, with all its related aspects, showed that the awareness of the BSSD requirements for clinical audit is variable. Therefore, there is need to dedicate efforts towards ensuring regulatory inspections that include an assessment of clinical audit, affecting all clinical work and specialties involved in patient exposure to ionising radiation. Another relevant aspect is that clinical audit processes, as indicated in the BSSD, should be integrated in the clinical audit, both in structures from both governance and resource-allocation perspectives.

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Declarations

Conflict of interest The authors declared no competing interests.

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