International Workshop on Practical Implementation of Clinical Audit for Medical Exposure to Ionizing Radiation

Tampere Hall , Tampere, Finland
7-10 September 2008

PROGRAMME, GENERAL INFORMATION AND ABSTRACTS

International Workshop on Practical Implementation of Clinical Audit
for Medical Exposure to Ionizing Radiation

Tampere Hall, Tampere, Finland, 7-10 September 2008

PROGRAMME, GENERAL INFORMATION AND ABSTRACTS

Compiled and edited by H. Järvinen
2008-09-03

TABLE OF CONTENTS

WELCOME TO TAMPERE, FINLAND

Dear friends,

The EC directive 97/43/EURATOM (MED-directive) introduced the concept of **Clinical Audit** for the assessment of medical radiological practices. The radiological practices include diagnostic radiology, nuclear medicine and radiotherapy, and the main emphasis in the directive as well as in clinical auditing are the issues related to the safety of the patient.

All Member States are required to implement clinical audits in accordance with national procedures. So far there has been high variation between the Member States in the implementation of clinical audits and the need for further guidance has been evident since the conclusions from the first International Symposium on Clinical Audit in Tampere 2003.

The EC established in June 2007 a special project to review in detail the status of implementation of clinical audits in the Member States and to prepare European Guidance on clinical audits. The purpose of the project is to provide clear and comprehensive information on existing procedures and criteria for clinical audits in radiological practices and to provide guidance on clinical auditing for improved implementation of Article 6.4 of the MED-directive. The guidance will enable the Member States to adopt the model of clinical audit with respect to their national legislation and administrative provisions.

The purpose of the Workshop is to present the draft European Guidelines prepared by the EC project and to subject them to critical analysis and open discussion before publishing. Another purpose is to provide a forum for the presentation of both national experiences and national expectations on the implementation of clinical auditing. These objectives will inherently include a motivating element by providing the audience with a better understanding of the purpose and benefits of clinical audits as a tool for improving quality in medical radiation practices. Through a versatile programme, the Workshop will provide the audience with basic information or advice as well as exchange of experiences on clinical auditing, including the criteria for good practices. It will also provide the participants with a good opportunity to give impact on the final adjustment of the guidance to be published.

We are positive that the presentations and discussions at the Workshop will improve our understanding on clinical audit and the provisions for its practical implementation. In the same time, the Workshop will give valuable feedback and input the finalization of the draft European Guidelines. Last but nor least, the Workshop will provide a fascinating insight into the development in clinical audits in five years since the first international symposium in Tampere 2003. We want to welcome you heartily to Tampere!

Hannu Järvinen
Chair
EC project
Workshop Programme
Committee

Georgi Simeonov
European Commission

Seppo Soimakallio
Chair
Local Organizing
Committee

Jukka Laaksonen
Director General
Radiation and Nuclear
Safety Authority, STUK

ORGANIZERS

European Commission, Directorate-General for Energy and Transport, Directorate H - Nuclear Energy, Luxembourg

The EC Clinical Audit project consortium

Partners

Radiation and Nuclear Safety Authority (STUK), Helsinki, Finland (Lead contractor)
Pirkanmaa Hospital District, Tampere University Hospital (TAUH), Tampere, Finland
General Medical Council Westfalia-Lippe, Münster/Westfalen, Germany
British Nuclear Medicine Society (BNMS), London, United Kingdom
Radiation protection Centre (RPC), Vilnius, Lithuania
European Society for Therapeutic Radiology and Oncology (ESTRO)

Panel of Scientific Experts

Hannu Järvinen, Seppo Soimakallio, Eliseo Vano, Johannes Nischelsky, Adrian Dixon, András Vargha, Andrew Hilson, Lorenzo Maffioli, Julian Malicki, Hana Stankusova, Pierre Scalliet, Marta Bogusz-Osawa, Mary Coffey, Vincenza Viti, Päivi Wood, Gendrutis Morkünas, Joanna Izewska

EC project European guidance on Clinical Audit for medical exposure - CLINICA AUD is financed by the EC (Contract N TREN/07/NUCL/S07.71512)

Programme Committee

Hannu Järvinen (chair), Finland
Seppo Soimakallio, Finland
Johannes Nischelsky, Germany
Andrew Hilson, United Kingdom
Julian Malicki, Poland
Hana Stankusova, Czech Republic
Gendrutis Morkünas, Lithuania

Local Organizing Committee

Seppo Soimakallio (chair)
Hannu Järvinen
Simo Hyödynmaa
Mika Kähönen
Päivi Wood

International Workshop on Practical Implementation of Clinical Audit for Medical Exposure to Ionizing Radiation

Tampere Hall, *Small Auditorium (Pieni sali),*
Tampere, Finland, 7-10 September 2008

SCIENTIFIC PROGRAMME

Number of the presentation in square brackets [**No**]

Sunday, 7 September	17:00-19:00 18:00-19:00 19:15-21:00	*Registration at Tampere Hall* *Opening ceremony, Tampere Hall* *Tampere City Reception, Museum Centre Vapriikki*
Monday, 8 September	8:00-17:00	*Registration at Tampere Hall*
	9:00-10:30	INTRODUCTION TO CLINICAL AUDIT AND THE EC PROJECT *Chair: Hannu Järvinen, Mary Coffey* Clinical audit in terms of directive 97/43/EURATOM [**1**], *Georgi Simeonov, European Commission* Outcome of the International Symposium on Clinical audit in Tampere 2003 [**2**], *Seppo Soimakallio* Development of Clinical audits by the International Atomic Energy Agency (IAEA) [**3**], *Joanna Izewska* Objectives and structure of the EC Clinical audit project [**4**], *Hannu Järvinen*
	10:30	*Coffee*
	11:00-13:00	STATUS OF CLINICAL AUDIT IMPLEMENTATION IN EUROPE *Chair: Adrian Dixon, Marta Bogusz* Summary of the results of the European questionnaire with conclusions [**5**], *Hannu Järvinen* Panel discussion (legal framework, practical organization, checklists and criteria); focus on the problems but also highlighting benefits <u>Panel:</u> Radiotherapy: *Hana Stankusova, Julian Malicki, Mary Coffey* Diagnostic radiology: *Seppo Soimakallio, Johannes Nischelsky, Andras Vargha* Nuclear medicine: *Andrew Hilson, Lorenzo Maffioli*
	13:00	*Lunch*
	14:00-17:00	PRESENTATION OF THE DRAFT GUIDELINES *Chair: Seppo Soimakallio, Vincenza Viti* Purpose, scope and definitions [**6**], *Hannu Järvinen* Objectives and coverage of clinical audits [**7**], *Johannes Nischelsky* Interrelation of clinical audits with other audit and verification activities [**8**], *Marta Bogusz* Organization, financing and coordination [**9**], *Hana Stankusova* *Discussion*
	15:30	*Coffee*
	16:00	Practical procedures [**10**], *Pierre Scalliet* Standards for good practices [**11**], *Andrew Hilson* Summary and checklist for practical implementation [**12**], *Julian Malicki* *Discussion*
	19:00-	*Congress Dinner*

Tuesday, 9 September	8:30-17:00	*Registration at Tampere Hall*
	9:00-11:00	CRITICAL REVIEW OF THE DRAFT GUIDELINES *Chair: Johannes Nischelsky, Pierre Scalliet* *Critical review by invited representatives of* • ESR [**13**]: *Jane Adam, UK* • ESTRO [**14**]: *Michael Baumann, Germany* • EANM [**15**]: *Marica Bajc, Sweden* • EFOMP [**16**]: *Eduardo Guibelalde, Spain* • EFRS [**17**]: *Graciano Paulo, Portugal* • Authorities [**18**]: *Ciara Norton, Ireland* • Quality/competence assessment organizations [**19**]: *Tuija Sinervo, Finnish Accreditation Service (FINAS)* *Discussion*
	11:00	*Coffee*
	11:30-13:00	HEADLINE QUESTIONS (*Invited papers*) *Chair: Hana Stankusova, Andras Vargha* How to motivate for clinical audit [**20**], *Adrian Dixon* Training of auditors, including European co-operation [**21**], *Matti Liukko* Financing of audits [**22**], *Johannes Nischelsky* *Discussion*
	13:00	*Lunch*
	14:00-16:00	NATIONAL EXPERIENCES AND EXPECTATIONS Session 1 (*Proffered papers*) (see separate programme) *Chair: Julian Malicki, Lorenzo Maffioli* General papers and clinical audit for diagnostic radiology (X-ray diagnostics and nuclear medicine)
	17:00-	*Finnish evening in the countryside*
Wednesday, 10 September	8:30-12:00	*Registration at Tampere Hall*
	9:00-10:30	NATIONAL EXPERIENCES AND EXPECTATIONS Session 2 (*Proffered papers*) (see separate programme) *Chair: Päivi Wood, Joanna Izewska* Clinical audit for radiotherapy
	10:30	*Coffee*
	11:00-11:45	CONCLUSIONS *Chair: Andrew Hilson, Eliseo Vano* Status of implementation of clinical audit in Europe [**51**], *Mary Coffey* Major feedback on the draft EC Guidelines [**52**], *Hannu Järvinen* Checklist of practical implementation [**53**], *Vincenza Viti* *Panel Discussion: Project partners in the panel*
	11:45-12:00	CLOSING OF THE WORKSHOP • Closing remarks by *Georgi Simeonov* • Closing remarks by *Hannu Järvinen*
	12:00	*Lunch*

Scientific programme
Proffered paper sessions

Number of the presentation in square brackets [**No**]. Presenting author in **bold**.

Tuesday, 9 September		NATIONAL EXPERIENCES AND EXPECTATIONS Session 1 - General papers and clinical audit for diagnostic radiology (X-ray diagnostics and nuclear medicine) *Chair: Julian Malicki, Lorenzo Maffioli*
	14:00-14:15	Setting Standards for Clinical Audit: Making the best use of clinical radiological services [**23**] *D. Remedios, UK*
	14:15-14:30	Summary of clinical audits in Finland after the first complete audit round [**24**] *S. Soimakallio, H. Järvinen, A. Ahonen, K. Ceder, M. Hirvonen-Kari,* ***T. Lyyra-Laitinen****, T. Sinervo, T. Sipilä and T. Wigren, Finland*
	14:30-14:45	National Systems for Clinical Audit in the UK: The Role of the Clinical Radiology Audit Sub-Committee of the Royal College of Radiologists [**25**] ***S. Barter*** *and K. Drinkwater, UK*
	14:45-15:00	Treatment of data in national clinical audits undertaken by the Clinical Radiology Audit Sub-Committee of the Royal College of Radiologists [**26**] *K. Drinkwater, UK*
	15:00-15:15	AuditLive – A national radiology audit template library [**27**] ***C.J.Ryall****, S. Barter, K.A. Duncan****,*** *P. Lumb, UK*
	15:15-15:30	Experiences with clinical audit in Slovak mammography departments [**28**] ***D. Nikodemová****, M. Horváthová, M. Príkazská, Slovak Republic*
	15:30-15:45	Quality management in nuclear medicine [**29**] ***K. Solanki*** *and M. Dondi, IAEA*
	15:45-16:00	**Summary of posters** *H. Järvinen, Finland*
		Steering actions by a National Advisory Committee for Clinical Audits in Finland [**30**] *S. Soimakallio, H. Järvinen, A. Ahonen, K. Ceder, T. Lyyra-Laitinen, M. Paunio, T. Sinervo and T. Wigren, Finland*
		Clinical Audit programme for diagnostic radiology: Intent, design and early experiences [**31**] *B. Abdullah, P. Butler, K. Faulkner, H. Järvinen, D. McLean, M. Pentecost, M. Richard, IAEA*
		Clinical Audit In Diagnostic Radiology In Bulgaria – National Regulation And Practical Implementation [**32**] *J. Vassileva, V. Hadjidekovi, Bulgaria*
		Clinical audit introduction in Czech Republic (X-ray diagnostic and NM) [**33**] *J. Nozickova, Czech Republic*
		National Experiences and Expectations on Clinical Audit – the Irish perspective [**34**] *B. Moran, Ireland*
		Is Clinical Audit Useful in Continuous Improvement of Quality in Radiological Department? [**35**] *S. Soimakallio, P. Dastidar, R. Järvenpää, L. Mäkelä and T. Paakkala, Finland*
		Relation of clinical audit based radiology and reimbursement systems [**36**] *András Vargha and Csaba Dózsa, Hungary*

		A Standards-based Method for Collecting and Processing Radiology Dose Data [**37**] *K. O'Donnell, Toshiba Medical Systems, H. Blendinger & B. Hassold, Siemens Medical Solutions*
Wednesday, 10 September		NATIONAL EXPERIENCES AND EXPECTATIONS Session 2- Clinical audit for radiotherapy *Chair: Gendrutis Morkünas, Joanna Izewska*
	9:00-9:15	Experience with clinical audit in radiotherapy in the Czech Republic [**38**] *J.Petera, **H. Stankusova**, P. Slampa, P. Zavoda, Czech Republic*
	9:15-9:30	Status of Clinical Audit implementation in Poland in the field of radiotherapy [**39**] ***W. Bulski**, J. Rostkowska, M. Kania, B. Gwiazdowska, Poland*
	9:30-9:45	Audit in Greatpoland Cancer Center as an example of the national system for clinical audit [**40**] *M.Fundowicz, Poland*
	9:45-10:00	Clinical audit on quality indicators in radiotherapy selected for pathologies [**41**] *M. Amichett, C. Capirc., E. Emiliani, G. Gardani, P. Olmi, **A. Rosi**, G. Silvano, R. Valdagni, V. Viti, Italy*
	10:00-10:15	NORWEGIAN EXPERIENCE WITH WORKSHOP AS A CLINICAL AUDIT TOOL FOR RADIOTHERAPY OF SPECIFIC CANCER DIAGNOSES [**42**] ***B.L. Rekstad**, S. Levernes, I.E. Heikkilä, D.G. Johannessen, E. Sundqvist, H. Bjerke, T.P. Hellebust, H. Olerud, G. Frykholm, Norway*
	10:15-10:30	**Summary of posters** *M. Coffey, Ireland*
		Practical aspects of the implementation of QUATRO audits in Europe [**43**] *J. Izewska, E. Salminen, S. Steyskal, IAEA*
		The role of the Clinical Oncology Audit Sub-Committee (COASC) of the Royal College of Radiologists for clinical audits in radiotherapy in the UK [**44**] *D. Tait, UK*
		Clinical quality standards for radiotherapy - a useful tool for clinical audits [**45**] *P. Martenka, M. Bogusz-Czerniewicz and J. Malicki, Poland*
		Experiences Of A Clinical Audit In A Finnish Radiotherapy Clinic [**46**] *S. Hyödynmaa and T. Wigren, Finland*
		Approach for a National Quality Audit System for Radiotherapy in Latvia [**47**] *S. Plaude, S. Popov, Y. Dekhtyar, Latvia*
		Self-Evaluation Indicators for Head and Neck Tumors [**48**] *P. Olmi, Italy*
		The Norwegian Program On Quality Assurance In Radiotherapy (Kvist) – Organisation, Benefits And Experiences During Seven Years [**49**] *S. Levernes, T.P. Hellebust, I.E. Heikkilä, D.C. Johannessen, G. Frykholm, H. Bjerke, B.L.Rekstad, E. Sundqvist, H. Olerud, Norway*
		Seven years experience with external and internal clinical audits at a Radiation Oncology Department at an Oncology Hospital in Spain. [**50**] *S. Marín, M. Macià, M. Ventura, Marta Ballart, David Leon and F. Guedea, Spain.*

SOCIAL PROGRAMME

Sunday, 7 September 2008

18:00–21:00 hrs **Opening Ceremony at Tampere Hall and**
Reception of the City of Tampere at Museum Centre Vapriikki, street address: Alaverstaanraitti 5
Coach transportation from Tampere Hall to Museum Centre Vapriikki will be 19:00 (after close of the Opening Ceremony).

Monday, 8 September 2008

19:00-

Congress Dinner at Hatanpää Mansion
Street address: Hatanpään puistokuja 1
About 20-30 minutes walk from city centre.

Tuesday, 9 September 2008

17-24

Finnish evening in the countryside
Cruise on Lake Pyhäjärvi.
Dinner in a small village of Aitoo.
Cruise from Tampere to Nokia about 1,5 hours. Coffee/tee and snacks on board. After cruise a coach transportation to the village of Aitoo and a country style Dinner with programme and dancing at Honkala, the house of Aitoo voluntary fire brigade.
Return by mid-night by coach to Tampere.

TECHNICAL EXHIBITION

A small technical exhibition is arranged in the Lobby of the meeting room (Pieni sali), together with the poster exhibition. The exhibiting organizations or companies are as follows:

Labquality Oy
Agfa HealthCare Finland Oy Ab
Barco Oy
Lifemed Oy
Unfors Instruments Ab

INFORMATION TO SPEAKERS

All presentations will be in the Small auditoriium (Pieni sali) of Tampere Hall.

If you have not yet sent your PP-presentation to the organizers, or if you want to replace your earlier version by a new one, please give you pp-presentation on a memory stick or on a CD to the **Speaker Service Room (Palvelupiste 3)**, close to the registration desk, **between 4-6 p.m. on Sunday evening 7 September or 8-9 a.m. on Monday morning 8 September.** The service room is available for checking your PP-presentations all through the Workshop (daily), but if you want to submit your PP-presentation later than the above times, please inform/get advice from the Registration Desk.

INFORMATION FOR POSTER PRESENTATIONS

The poster exhibition will be in the Lobby of the meeting room (Pienen salin lämpiö). The poster stands have been numbered in accordance with the numbers of the presentation shown in Scientific Programme (the numbers in square brackets at the end of the title of the presentation). Please fix your poster according to this number. The posters should be put in **place between 7:00 –8:30 on Monday morning 8 September** and taken out by noon on Wednesday 10 September. If you need more advice, please contact the Registration desk.

LUNCH AND COFFEE BREAKS

The lunches and coffees/tees will be served in Restaurant Fuuga and in the Lobby of the meeting room, close to the meeting room (Pieni sali). Please keep your conference badge visible because it will be the netrance ticket to the services.

OTHER GENERAL INFORMATION

Badges

The congress badge, which will be handed at the registration desk, is the entrance ticket to all sessions. It is kindly requested to wear the badge also at social events, coffee breaks and lunches. Only badge holders are admitted to the sessions.

Banks

The opening hours are 10:00–16:30 hrs Monday – Friday.

Check-in/out

Hotel check-in time is 14:00–24:00 hrs. Check-out time is at 12:00 hrs.

Cheques

Personal or company cheques will not be accepted at the registration desks nor in shops in Tampere. Leading banks in Finland cash traveller's cheques.

Credit cards

The major credit cards are accepted in most hotels and shops. VISA, Eurocard and MasterCard are accepted at the registration desks.

Currency

The monetary unit in Finland is euro (EUR).
There are exchange bureaus in the centre of Tampere.

Dress

Informal summer dress is suitable for all occasions. See also "Weather".

Electricity

Electricity is 220 volts (50 HZ) and plugs are with the Northern European Standard two round pins. Most hotels provide 100 volt outlets for shavers.

Insurance

The registration fee does not include insurance.

Internet

Access to internet for the participants is available throughout the Workshop at the **Service Room 2 (Palvelupiste 2)** close to the Registration desk.

Time difference

The time in Finland is 2 hours ahead Greenwich Mean Time (GMT).

Tipping

All restaurant prices and taxi fares include service. Tips are not commonly used, but good service at a restaurant can be rewarded with a tip.

Weather

September is mostly sunny and quite warm. The afternoon temperature can vary from 10 °C to 20 °C. It is advisable to have clothes for cooler and rainy weather as well. Daily weather forecast can be checked from the website of the Finnish Meteorological Institute: www.fmi.fi/en/index.html

Workshop venue

Tampere Hall, inaugurated in 1990, is the largest congress and concert centre in Scandinavia. Tampere Hall is located on the edge of Sorsapuisto Park, within a short walking distance of the city centre, the railway station and all congress hotels.
The Workshop will take place in the Small auditorium (Pieni sali) of Tampere Hall.

Street address: Yliopistokatu 55, FIN-33101 Tampere, Finland
For futher information, see www.tampere.fi/TampereHall

FURTHER INFORMATION

*For any problems or questions please contact the **registration desk**. The registration desk is open every day during the Workshop.*

For any questions on the scientific programme please contact:

Hannu Järvinen
Principal Advisor
(for Radiation in Health Care)
Radiation Practices Regulation
Radiation and Nuclear Safety Authority (STUK)
P.O.Box 14, FI-00881 Helsinki, FINLAND
Phone: +358 9 75988447, Fax +358 9 75988248
e-mail: hannu.jarvinen@stuk.fi
portable phone : +358 400 408189

Seppo Soimakallio
M.D., Ph.D., Professor
Pirkanmaa Hospital District
Tampere University Hospital
Department of Radiology
P.O.Box 2000, FI-36321 Tampere, Finland
Phone: +358 3 311 65430
Telefax: +358 3 311 65585
e-mail:seppo.soimakallio@pshp.fi

DRAFT *TABLE OF CONTENTS:*
EUROPEAN COMMISSION GUIDELINE ON CLINICAL AUDIT
FOR MEDICAL RADIOLOGICAL PRACTICES
(DIAGNOSTIC RADIOLOGY, NUCLEAR MEDICINE, AND RADIOTHERAPY)

Draft of 28 June 2008

DRAFT *EXECUTIVE SUMMARY*: EUROPEAN COMMISSION GUIDELINE ON CLINICAL AUDIT FOR MEDICAL RADIOLOGICAL PRACTICES (DIAGNOSTIC RADIOLOGY, NUCLEAR MEDICINE, AND RADIOTHERAPY)

Draft of 28 June 2008

The purpose of this EC guideline is to provide guidance on clinical auditing in order to improve implementation of Article 6.4 of Council Directive 97/43/ EURATOM. The guideline will provide comprehensive information on existing procedures and criteria for Clinical audit in RADIOLOGICAL[1] practices: diagnostic radiology, nuclear medicine and radiotherapy.

The main recommendations of this guideline are summarized in this executive summary as follows:

Purpose, scope and general principles of clinical audit for radiological practices

- By definition, clinical audit is a systematic examination or review of medical RADIOLOGICAL procedures. It seeks to improve the quality and the outcome of patient care through structured review whereby RADIOLOGICAL practices, procedures, and results are examined against agreed standards for good medical RADIOLOGICAL procedures. Modifications of the practices are implemented where indicated and new standards applied if necessary.
- Clinical audit should
  - Be a multi-disciplinary, multi-professional activity.
  - Follow general accepted rules and standards which are based on international, national or local legal regulations, or on guidelines developed by international, national or local professional medical societies.
  - Be a systematic and continuing activity, whereby the recommendations given are implemented.
  - Combine both *internal* and *external* components in order to achieve optimal outcomes. For small units the internal audit could take a form of a self-assessment rather than actual audit. In external audits, the results of internal audits or self-assessments should also be reviewed.
  - NOT be research, quality system audits or regulatory activity.
  - Aim at evaluating the current status of the RADIOLOGICAL unit with respect to its RADIOLOGICAL services and to identify areas for future improvement.
- The general objectives of clinical audit should be
  - To improve the quality of patient care
  - To promote the effective use of resources
  - To enhance the provision and organization of clinical services
  - To further professional education and training
- The detailed objectives of clinical audit should be defined related to the standards of good practices
  - For *internal audits* the objectives of audits should be set by the management of the department
  - For *external audits*, the objectives should be set by the auditing organization and should be based on any regional or national surveys on the status of practices as well as on any recommendations by national coordinating organs or professional societies

[1] "RADIOLOGICAL", written in capital letters, is used throughout this document to denote all three fields of application: diagnostic radiology, nuclear medicine and radiotherapy. When only diagnostic radiology is concerned, the term is written in small letters ("radiological").

  - In defining the aims and objectives it is important to ensure that clinical audits supplement rather than duplicate other activities of quality assessment such as accreditations or regulatory inspections
- Clinical audits should
  - Address the practical clinical work by different professionals
  - Assess the local practice against the defined good practice, taking into consideration the local facilities and resources when the ultimate good practice cannot be reached by one step
  - Clinical audit should foster an environment which enhances professional relationships and the multidisciplinary approach required to optimise patient care
- All parties, those being audited and those carrying out the audit, should respect the confidentiality of patient data, the interviews and discussions with staff, the completed audit checklist and other performance data.

Priorities and coverage of RADIOLOGICAL practices

- Clinical audit should cover all (comprehensive audit) or part (partial audit) of the clinical pathway, outlining a course of care provided to a patient. To cover the whole clinical pathway in RADIOLOGICAL practices, clinical audit should address the three main elements: *structure, process,* and *outcome*. These should be covered both in internal and external audits.
  - It is accepted that the outcome can only partly be assessed through external audits. As a minimum approach for auditing the outcome, there should be a clear indication as to how outcomes are measured within the RADIOLOGICAL unit.
  - At a hospital level, a broad focus on the departmental level is required.
- Clinical audits should assess the parts of practices which are generic to all RADIOLOGICAL practices, and also go deeper into a selected individual RADIOLOGICAL examination, procedure or treatment.
  - Clinical audits should address both the critical issues of the radiation protection for the patient as well as key components of the overall quality system. The priorities should be set as specified in Table 1, Section 4.3.3 of this Guideline.
  - *Patient dose* from diagnostic radiology and nuclear medicine procedures and the *procedure of dose delivery to the patient* in radiotherapy should be the minimum physical parts of all clinical audits.

Standards of good practice

- Standards of good practice can be based on results of research, consensus statements, recommendations by learned societies, legal requirements or local agreement (if there is no other more universal reference). Evidence-based standards of good practice should be passed as fast as possible to the entire health care community. Clinical audit should promote the development and use of international standards of practice.
- Both generic and specific criteria should be applied for the standards of good practice, as highlighted in sections 8 and 9 of this Guideline. The recommendation in this document (Sections 8 and 9) should be considered as the minimum criteria, while more specific criteria should be developed for specific examinations and treatments, for the advanced level of clinical audits. The list of publication given in Appendix 6 of this document can serve as a source of information for developing and adopting the criteria of good practices.
- As a minimal approach, the criteria of good practice could be based on the professional knowledge and experience of the auditor. Professional judgement is truly the *minimal*

approach which can be applied for parts of the audits where there are no written criteria available. In the long term systematic implementation of clinical audits the aim should be to adopt or to develop suitable written criteria for good practices at least for the major parts of the audit.

- Quality indicators should be developed when possible as a practical measure of performance. These are useful in particular in internal audits.
- The standards of good practices should be reconsidered from time to time with the development of evidence based medicine.

Frequency of clinical audits

- The *internal* clinical audits should be a continuous activity with the aim of having significant parts of the overall audit programme covered *once a year*. The recommended frequency for *external* audits may depend on the local infrastructure and the intensity of other quality review activities, but a minimum frequency of *five years* seems to be a reasonable aim.

Relation of clinical audit with other quality assessment activities and regulatory inspections

- It is of high importance to understand that clinical audit is different from other quality assessment systems and from regulatory inspections. There are clear differences in the purpose and focus of the evaluation, scope, methods as well as in the consequences of the results of the observations, their impact and use. Clinical audits should be established and developed in a way which minimizes unnecessary overlap, or duplication of efforts, with the other systems.
- Regulatory bodies should neither carry out clinical audits nor directly and exclusively set up the criteria for the audits, except for giving advice, in particular in the early developing phase of clinical audits. Often the desired optimal role of the authorities can only gradually be achieved in the course of development of the necessary national infrastructure.

Role of professional societies

- The role of the professional societies can be of great value in developing the criteria of good practices for the evolution of clinical audits and in providing practical advice, stimulus and support for the establishment of appropriate clinical audit organizations or practical solutions on carrying out clinical audits.

Practical organizing of clinical audits

- Internal audits and special projects to undertake external clinical audit in a well defined purpose, as well as mutual audits, can be a good start of clinical auditing. However, the long term aim should be towards special organizations, in order to ensure the continuity and credibility of the audit system. Special organizations for clinical audits should preferably be non-profit organizations, when possible supported by the RADIOLOGICAL professional societies. International audit services may be exploited (if available) as long as no national systems exist.
- The basic competence of the auditors for clinical audits should be based on their professional competence and long-term clinical experience. Besides this basic competence, the

auditors should receive specific training on the general audit procedure and techniques, as well as the agreed audit programme and the criteria of good practices to be applied.

- Auditors should be as independent as possible of the responsibility for the process being audited. The requirements for the independence of the auditors from the audited unit should be defined.
- A team of auditors is usually needed, comprising different professionals (physicians, physicist, radiographers etc), the optimal composition depending on the scope of the audit and on type of application to be audited.
- The undertaking of internal audit, as well as the request for external clinical audit, should be endorsed by the top management of the unit. Thorough preparation by all partners of the audit process is important. Appropriate guidance for on-site procedures by the auditors need to be established in accordance with Section 7.2.4 of this Guideline.
- The costs of external audits need to be considered in the annual budgeting of the RADIOLOGICAL unit, unless the organization of clinical audits through a government body is funded direct. The general tendency in the health care structures seems to assume that the health care unit requesting the clinical audit and deriving the benefits of it should also cover the costs incurred.
- The unit to be audited has to append a lot of time to create motivation and open attitude about the audit in the unit before an audit, in particular for the first external clinical audit of the unit. This is important in order to avoid misunderstandings or prejudices or mixing clinical audits with other quality assessment activities. The top management of the unit should commit to the audit and give convincing support to the staff. Due attention should be paid to considering and fulfilling the recommendations given in the audit report, in order to achieve subsequent follow-up success and maintain high motivation of the staff.
- A special *national or regional advisory group,* or *steering committee,* of clinical experts, independent on the auditing organizations, may prove useful in the overall coordination and development of the clinical audit implementation, criteria and procedures. The group should preferably be established by the Health Ministry or other government organization, in order to ensure appropriate authority and financing.

DRAFT APPENDIX 1: SUMMARY OF REGULATORY FRAMEWORKS IN THE EU MEMBER STATES

Introduction

National regulatory frameworks in the EU Member States, i.e. the national provisions for the implementation of the requirements of Article 6.4 of Council Directive 97/43/Euratom on Clinical Audit, and the existing audit programmes, inspection and accreditation systems were surveyed through a special questionnaire. Relevant information about organizational, technical and administrative provisions for clinical auditing were surveyed, in particular relevant criteria, standards and procedures, documentation and reporting requirements, monitoring and control systems. The survey was addressed to the national societies (for diagnostic radiology, radiotherapy and nuclear medicine) and the competent or radiation protection authorities. For the questions of legislative requirements, the instructions of the questionnaire gave advice to the societies to consult appropriate ministries and/or radiation protection authorities.

The response to the questionnaire was about 80 %. Only a few countries did not supply any reply in spite of repeated enquiries to several recipients. In the following, a brief summary of both the legislative requirements and the practical implementation of the requirements will be reviewed.

Status of legislation

The results indicate that the basic requirements of the Council Directive 97/43/Euratom for clinical audit (Article 6.4) have generally been implemented in the national legislations.

The conditions (technical, infrastructural) in which RADIOLOGICAL practices should be performed have been regulated in most countries by law, decree or other regulation. The regulations are usually given by the Health Ministry or a special radiation protection authority. In many countries, there are also recommendations on these conditions, usually given by the radiation protection authority or the national scientific societies.

The practical implementation of clinical audits has been regulated in most countries. In most cases, this concerns both external audits and internal audits, or self-assessments. In several countries, also recommendations on the implementation have been given, and these are usually given by the radiation protection authority or the national scientific societies.

In about half of the countries, the legal requirements give some specification of the practices to be audited and on the part of practices to be covered. E.g., in Finland, conventional dental practices have been excluded from the requirement of external audits. In a few countries, there are also recommendations on the practices to be audited and the coverage of audits.

For Quality Systems, about half of the countries have regulations while some countries have also recommendations, or only recommendations. Certification of the quality system was reported as a requirement in three countries only, while in a few countries there are recommendations for it. Regulations or recommendations on accreditation were reported in about one fourth of the countries. In a few countries, there are regulations or recommendations also on other types of quality assessments. Relation of clinical audit with other quality assessment systems has been regulated or recommended only in a few countries, while the relation of clinical audit with regulatory inspection has been regulated or recommended in about one third of the countries.

The performer of clinical audits and requirements on auditor's competence and experience, auditor's training and independence have been regulated in about one third of the countries. Some countries have also, or only, recommendations which are usually given by authorities. The methods of audit have been regulated in about every fourth country, while recommendations are given in about every third country. The agreed standards of good practice have been regulated or recommended in about every third country; these are usually national or international standards, or recommendations by national professional societies or special committees.

The frequency of clinical audits has been regulated in about one third of the countries and seems to be 1-3 years when specified. The reports and follow-up of audits have been regulated also in about one third of the countries, and in a few countries there are also, or only, recommendation on them.

Practical implementation of clinical audits

In spite of the legislative requirements, the practical implementation of clinical audits in many countries is still not completed or in a very early development stage. The approaches in the practical implementation also vary considerably between the Member States.

The following conclusions can be drawn from the results:

- Clinical audits are mainly *occasional*. Clinical audits are carried out more regularly in Finland, France, Germany, Lithuania, Poland, Slovakia, Slovenia, UK and Switzerland. In some cases regular clinical audits are only internal (Spain, UK).
- Specific organizations for external clinical audits have been established in several countries, often by the Ministry of Health.
- Individual peer reviews are carried out besides the clinical audits by specific organizations.
- Financing of clinical audits is implemented either by charging the recipients (fees) or by government support; in some cases the financing is based on "mutual agreements".
- Professional experience and independence are generally required from the auditors, and they usually work as a team. Independence is usually interpreted so that the auditors have to be from different health care unit. Training of the auditors is not adequate and usually covers only audit techniques, not the applied criteria. There are various approaches with training institutes (ministries, universities, private institutes, accreditation authorities, auditing organizations etc)
- National *coordination* of clinical audits has been established in most cases, either by Ministry or an organization established by the Ministry; in one case this is by a scientific society. There is a high variation of tasks of these coordinating organizations. Local coordination has been established only in a few cases.
- A *checklist* for carrying out clinical audits usually exists. Criteria for good practices have been defined in most cases and are based on national or international standards or guidelines or recommendations by professional societies. In some cases the criteria have been prepared by the auditing organization.
- The practical methods in the existing systems of clinical audits tend to follow common principles of auditing (entrance and exit meetings, reviews and interviews, reporting, follow-up etc). The clinical audits include measurements (quality control, performance, radiation safety) in about half of the countries.
- The certifications of the quality systems or accreditations of the health care units for radiological practices are not very common, only from 0 to 20 % of the units.
- Regulatory inspections are carried out in most countries, with measurements mainly for occupational protection. The overlap of clinical audits with regulatory inspections was reported

only in a few cases (Finland, UK, Switzerland). Regular meetings of authorities and auditing organizations are not very common.

- The need for harmonization of clinical audits has been recognized by all countries replied. For the items to be harmonized, most of the replies quote audit program, standards of good practice, training of auditors and practical methods of auditing. However, all possible items have been quoted at least once when summing up all the replies. Also the borderline between clinical audit and certification, accreditation and regulatory inspections has been stated as an important point of consideration.
- The major *problems* identified in the replies were among other things: incomplete national legislation for clinical audit and the methods of financing, lack of formal framework of auditing, poor understanding of the purpose and contents of clinical audits, lack of criteria for the standards of good practices, difficulty to employ sufficient number of auditors, insufficient time available for auditors, lack of specific training of auditors, need of technological modernization of radiology equipment to meet quality standards (see more details in Appendix 2)
- The major *benefits* reported include: a tool for quality improvement, recognition for quality, prevention against litigation, improvement of practice, motivation of staff to increase quality, benefit to patients, improvement of local standards and adherence to national standards, recognition of malpractices, improvement of communication within the institution, increased communication and awareness of good practices, revealing weak points and promoting development of quality systems (see more details in Appendix 3).
- Some *specific proposals* presented in the replies include: organization of European team to perform "model" audit in a reference centre in the country, assessment outcome system which allows comparing the outcome of clinical audit European wide, more attention should be paid to the resources of the health care unit for audits, more unifying feedback from the results should be given to audited units, and ”Guidance is needed but should be simple and friendly”.

DRAFT APPENDIX 2: SUMMARY OF PROBLEMS IN THE IMPLEMENTATION OF CLINICAL AUDITS

Conclusions from the Symposium 2003 (Soimakallio et al., 2003)

- Lack of the fundamental understanding of the objectives, contents and the expected benefits of Clinical Audits for the medical RADIOLOGICAL procedures.
- Lack of qualified personnel resources (number of staff and dedicated work time) at the clinics for QA work (development of Quality Manual documentation needed for audits etc).
- Lack of trained and competent auditors.
- How to finance the necessary human resources.
- Lack of recommended or acceptable radiological procedures and criteria, validated at the EU level.
- The development culture and readiness for audits is varying from country to country. In some countries, a lot of work is needed to change the mentality of the radiation users towards recognizing the importance of audits.
- There is also a fear that Clinical Audits would be requested mainly by those who already have good practices and would not be in the highest need of audits. There is a need to look more at those who are not volunteering for Clinical Audits.

Extracts from the Questionnaire 2007

The recipients were asked to give three major problems encountered in the implementation of clinical audit in the Member State. The following is a list of problems mentioned, with the number of replies indicating how many of the replies specified the given problem.

Major problem	*No of replies*
Lack of well trained, independent auditors, who are well-known experts on their field of application (diagnostic radiology, nuclear medicine or radiotherapy) and in radiation protection, still actively working in a health care unit, but have time to travel and perform audits and report on it. - Small country, small units, only few specialists available - Lack of auditor training possibilities - Special difficulty in getting nuclear medicine experts as auditors - Lack of sufficient time for auditors to carry out effective audits	16
Problems of financing - No special financial support for performing clinical audits - Majority of units can not afford clinical audits	6
The purpose and scope of clinical audit is not clear to most stakeholders. - Not clearly stated procedures and outcomes / benefits. - Most consider it as an inspection with unknown consequences. - The involved authorities and medical environment are not ready to organize it.	6
Lack of appropriate standards of good practices	5

- Lack of European standards, requirements acceptable for all parties. - There is no agreement on quality criteria for diagnostic performance (specificity and sensitivity) or for the therapy outcome (cure, side effects)	
Lack of knowledge and guidance on audit methodology - Requirements for clinical audits - Checklist for clinical audit	5
Lack of motivation - Medical environment not feeling comfortable to be audited. - Auditing the Health System is not part of the training and education of the health professionals.	4
Bureaucratic and ineffective procedures and cooperation between ministries and organizations. - Clinical audit is a low priority – if any.	2
Incomplete national legislation with regard to clinical audit	2
Lack of a formal framework for clinical audits. - Establishment of competent auditing organization.	2
Problems appearing only in one reply	
- Difficulties to harmonise the different national approaches, regulations in order to establish the European auditing system. - Not enough radiation protection equipment and technical accessories for audits. - Audits should contain broader review and not just technical part. - No benefits or extra support from government after successful audit. - No coordinating organization. - Audits are not regularly performed. - Need of technological modernization of radiology equipment in order to meet quality standards. - Communication problems. - Assurance of use of data. - Lack of medical physicists	1

DRAFT APPENDIX 3: SUMMARY OF MAJOR BENEFITS IN THE IMPLEMENTATION OF CLINICAL AUDITS

Extracts from the Questionnaire 2007

The recipients were asked to give three major benefits expected in the implementation of clinical audit in the Member State. The following is a list of benefits mentioned, with the number of replies indicating how many of the replies specified the given benefit.

Major benefit	*No of replies*
Improvement of medical RADIOLOGICAL services, the quality of care and the radiation protection of patients (in a broad view). - Improved quality assurance - Achievement of required quality and acceptable tolerances in accordance with standards - Improved patient satisfaction - Benefit to patients - A tool for quality improvement - Improved capacity and efficacy	23
Improved standardization of procedures and practices. - More frequent application of evidence based guidelines and protocols - Development of internal and national standards - Adherence to national standards	8
Financial benefits. - Less expenditures on radiation related service - Special applications on a European basis	5
Decrease of dose - Lowering patient and staff exposure to ionising radiation - Optimization of the patient exposures	5
Revealing the weak points of the practices and malpractices - Recognition for quality - Demonstration of need for resources	5
Avoidance of incidents and accidents - Reduction of errors	3
Increased communication and awareness of good practices within the health care unit	2
New ideas, new thinking, new procedures - Reducing blinkers view - New and modern procedures for optimization of radiation protection of patients	2
Promoting the development of quality systems	2
Benefits appearing only in one reply	
- Confidence in the procedures, practices and services. - Improvement of the expertise of professionals. - Advancements of the technical level of the institution. - Team building effect. - Improvements are made in a positive approach from the owner of the process (no pressure from a legal authority). - Transparency of procedures. - High level of satisfaction for the residents. - Stimulation to professional continuing education, professional	1

growth of young specialists. - Possibility to control the use of the written procedures and regulations in the institution. - Good management tool for institution, gives better overview about the workers responsibilities and their self-regulation. - Motivation of the staff to increase quality. - Staff of health care institutions would become more familiar with factors upon which patients' care depend. - Prevention against litigation. - Benchmarking. - Confirming good practice.	

ABSTRACTS FOR INVITED PAPERS

Notes

1. All PP-presentations at the Workshop received by 1 September 2008 are given on the CD distributed with this document. The presentations are preliminary and can be modified/improved for the final presentation at the Workshop. The missing presentations will be available later on from the website www.clinicalaudit.net.
2. If you want to make use of the material in the PP-presentations, please ask the permission from the presenting author. The list of e-mail addresses is distributed in the conference bag.

Clinical Audit in Terms of Directive 97/43/EURATOM [1]

Georgi Simeonov, Radiation Protection Unit, DG TREN, European Commission

European legislation on radiation protection dates back to late 1950's when EURATOM Treaty was signed and the first EU Basic Safety Standards for radiation protection of the workers and the general public were established. Since then more than twenty EU legislative documents in the field of radiation protection have been adopted covering different aspects, e.g. protection of workers, medical exposure, radon, etc.

EU legislation on medical exposure was initially adopted in 1984 and later amended by the adoption of Directive 97/43/EURATOM (MED Directive) in 1997, which defines the current legislative framework in that area. MED Directive covers medical exposure (as defined in Article 2 of the Directive) and the protection of individuals helping in the support and comfort of patients undergoing medical exposure. The Directive defines specific requirements for justification and optimization of medical exposures and contains number of provisions applicable to different aspects of radiation protection in medicine and different medical exposure situations.

MED Directive defines the clinical audit as "systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary". It requires that clinical audits are carried out in accordance with national procedures.

MED directive contains number of provisions relevant to clinical audit the most closely related being the quality assurance requirements and the provisions on establishment and use of diagnostic reference levels (DRL). The Directive also defines requirements the implementation of which could be a topic for clinical audit; some examples are the requirements for justification of medical exposures, establishment and use of DRL in optimization of protection, distribution and delegation of responsibilities for radiation protection of patients, etc.

In order to facilitate the implementation of clinical audit requirements of MED Directive the European Commission started in 2007 a project for development of EU Guidelines on Clinical Audit for Medical Radiological Practices. The guidelines should provide an interpretation and explanations of the main elements of the clinical audit process and practical advice on its implementation to the different types of radiological procedures. This workshop is part of the mentioned project and will hopefully contribute to the development of the EU guidelines.

Outcome of the International Symposium on Clinical Audit in Tampere 2003 [2]
Seppo Soimakallio, Prof., Pirkanmaa Hospital District, Tampere University Hospiral

Directive 97/43/EURATOM given by European Commission has two main objectives:
1) To achieve optimum diagnostic efficacy at reasonable dose to the patient, and 2) To reduce the number of unnecessary radiation exposures. The Directive provides for a high level of health protection to ionizing radiation in medical exposure. The member states were required to implement Directive in their national law of radiation protection.

The International Symposium on Practical Implementation of Clinical Audit for medical Exposure was held in Tampere in May 2003. In Finland we started Clinical Audits according to our Law and Degree already in 2002. We wanted to tell our experiences outside Finland and also to learn the status of Clinical Audits in other Member States. The objectives for the 2003 symposium were: 1) to clarify the meaning of Clinical Audit, 2) to highlight the importance of Clinical Audit, 3) to promote the development on European guidelines in the field of Clinical Audit and 4) to help Member States to comply with the Directive requirements for implementing Clinical Audit.

There were active discussions and good presentations during the symposium and the symposium hosted almost 200 participants. As a conclusion CONSENSUS STATEMENTS were accepted. The most important and critical matters discussed were as follows:
1) The practical implementation of Clinical Audit varied much from country to country and a survey was proposed to obtain more information about the current status.
2) There was a need for harmonization of clinical audit criteria. Available relevant national and international recommendations should be used as the basis of selecting criteria.
3) Need for further guidance on procedures for the practical implementation of Clinical Audit was noted.
4) There was a need to clarify importance of other existing audit programmes and evaluation activities in respect to Clinical Audit (regulatory inspection, accreditation, certification etc.)

As a tentative proposal of the symposium the following was presented:
1) Clinical Audit should address the essential requirements introduced in the EC Med Directive.
2) Clinical Audit should comprise both external and internal audits with validated criteria of self-assessments.
3) Regulatory inspections should be balanced with the coverage and effectiveness on Clinical Audits.

With these official proposals there were many practical proposals from audience.

I can conclude that at that time very little was done in Europe with Clinical audit and different kind of information was necessary. Let us see what has been realized during the past five years in the Member States.

IAEA activities in comprehensive audit for radiation medicine [3]

J. Izewska, D. McLean, K. Solanki, M. Dondi, E. Salminen, E. Rosenblatt, P. Andreo
International Atomic Energy Agency, Vienna, Austria

The IAEA is involved in a spectrum of activities related to the prevention, diagnosis and treatment of health problems through the application of radiation techniques in diagnostic radiology, radiotherapy and nuclear medicine. The international basic safety standards require that radiation medicine centres establish a comprehensive quality assurance programme for medical exposures supported by internal and external audits.

In addition to the IAEA/WHO TLD postal dose audit programme in operation since 1969, for auditing radiotherapy services, the IAEA has introduced the concept of a Quality Assurance Team for Radiation Oncology (QUATRO). The objective of QUATRO audits is to review and evaluate the quality of all components of the radiotherapy process at a cancer centre to advise on practice improvement. A guidance document "Comprehensive audits of radiotherapy practices: a tool for quality improvement" has been published to define procedures for conducting the comprehensive audit and to guide the auditors. Several workshops were organized by the IAEA to train QUATRO auditors and over 25 missions were completed to date in Africa, Asia, Europe and Latin America. Individual radiotherapy centres received recommendations on quality improvement. Two 'lessons learned' meetings were convened in 2007 with both auditors and auditees to collect their feedback on the process of QUATRO, exchange experiences and outline future activities.

Similarly, an external clinical audit programme has recently been formulated in diagnostic radiology to examine the structure and processes at a clinical site and provide advice on improvement in the quality of patient care, promote the effective use of resources, enhance the provision and organization of clinical services and further professional education and training. The diagnostic radiology audit addresses quality management and infrastructure as well as patient-related and technical procedures.

In nuclear medicine, all-inclusive guidelines referred to as "QUANUM" are used for self appraisal and external audit. Regular quality management reviews which are systematic, patient oriented and outcome based play a vital role in improving nuclear medicine practices. The IAEA auditing methodology is being pilot-tested in Africa, Asia, Europe and Latin America, and in Europe the guidance document will be posted on the joint web-site of the European Union of Medical Specialists (UEMS) and the European Board of Nuclear Medicine (EBNM).

Acknowledgement
Numerous international experts who contributed to the development of the IAEA guidlines for comprehensive audits and conducted audit missions are acknowledged

Objectives and structure of the EC Clinical Audit project [4]
Hannu Järvinen, Finland

Contract N TREN/07/NUCL/S07.71512
European guidance on Clinical Audit for medical exposure - CLINICAL AUD

The EC directive 97/43/EURATOM (MED-directive) introduced the concept of **Clinical Audit** for the assessment of medical radiological practices. The Member States are required to implement clinical audits in accordance with national procedures. There has been high variation between the approaches of the Member States in the implementation of clinical audits and the need for further guidance has been evident since the conclusions from the first international symposium on clinical audit in Tampere 2003.

The *purpose* of the above European Commission project is to provide clear and comprehensive information on existing procedures and criteria for clinical audits in radiological practices (diagnostic radiology, nuclear medicine and radiotherapy) and to provide guidance on clinical auditing including best possible standardization for an improved implementation of Article 6.4 of the MED-directive. The guidance will enable the member States to adopt the model of clinical audit with respect to their national legislation and administrative provisions.

The project is conducted by *a consortium* with a lead contractor Radiation and Nuclear Safety Authority (STUK), Helsinki, Finland. Other partners are Pirkanmaa Hospital District, Tampere University Hospital (TAUH), European Society for Therapeutic Radiology and Oncology (ESTRO), General Medical Council, Westfalia-Lippe, Muenster, Germany, British Nuclear Medicine Society (BNMS), UK and Radiation Protection Centre (RPC), Vilnius, Lithuania. In addition, the consortium is supported by a Panel of Scientific Experts representing ten European countries and four European professional societies.

The first step of the project was to review the status of the implementation of clinical audits in the Member States through a *questionnaire.* The questionnaire reviewed both the existence and the essential contents of regulations and recommendations on various topics related to clinical audit, as well as the current practices for clinical audit implementation. Besides clinical audit, the questionnaire reviewed other systems of quality asssements (such as certification of quality systems and accreditations) and also regulatory inspections and their relationship with clinical audit.

The next step was to prepare *a draft European Guidance* on clinical audit, based on the results of the questionnaire and discussions among the project partners and the Panel of Scientific Experts. This was accomplished through two meetings of the consortium, together with the Panel of Scientific Experts, and extensive correspondence between the meetings.

The draft European Guidance was submitted to Critical reviews by the major European professional societies and by representatives of authorities and other quality assessment organizations. The summary of the questionnaire and the draft Guideline is introduced with the critical reviews for open discussion in an international Workshop 8-10 September 2008 at Tampere, Finland. Based on the feedback from the Workshop, the final Guidance will be completed and submitted to EC for approval and publication by the end of November 2008.

How to motivate for clinical audit [20]

Adrian K DIXON, MD; UK

In many ways it is easier to perform audit within a radiological department than in some other disciplines in medicine. This is partly because the radiological data is available for retrospective or secondary analysis and partly because a lot of radiological procedures culminate in a surgical procedure that provides histological proof. The UK National Breast Screening Programme (NBSP) is one of the few services within the NHS which was set up and funded in the days of compulsory audit. Work within this service is well audited: the sensitivity and specificity of each individual radiologist's results are known; biopsy results are also available. Such feedback provides information that is extremely valuable for continuing professional development. It might lead to a change in reporting style or biopsy technique, which could improve performance. This is an example of the 'audit loop' being completed.

Of course, audit can also be applied to the process of radiology rather than the actual radiological results.

Audit of the effect of radiological procedures on the clinician's leading diagnosis and clinical management may show that certain radiological procedures are more effective than others. For example, the effectiveness of plain radiography of the lumbar spine is highly questionable; audit showed that views over and above the lateral view are rarely helpful. Magnetic resonance imaging (MRI) is much more effective and a limited examination is not all that much more expensive. Intriguingly the effect of MRI varies for different clinical indications – referrals for some conditions have become so common that it has almost become a screening tool (eg looking for acoustic neurinomas) where a positive finding is rare. Even with careful audit it is a fine balance to determine which clinical conditions most deserve investigation using high technology. Audit can identify whether requests for radiology fall within approved guidelines/referral criteria.

Audit can also be used to improve the service delivery of radiology. Analysis of departmental activities might reveal a delay in certain procedures being reported. This might be due to the radiologist's reports not being typed until the next working day. This might lead to the employment of more secretaries in the afternoon/evenings. This could end up with reports getting back to clinicians in a more timely fashion. This is another example of the 'audit loop' being closed.

In any event, audit should be made to be enjoyable or else it will not be performed. Reviewing cases with colleagues is interesting, instructive and usually fun. Audit should not be perceived as a threat: an individual radiologist/department can take great pride when audit results are good; if the results are below average resources should be forthcoming to help with improvement. If time for audit is part of a radiologist's weekly job plan it is more likely to succeed. Likewise if the results of audit and associated processes are mandatory steps for annual appraisal and if the published outcomes eventually assist with promotion prospects, audit is more likely to succeed. The ultimate tool for persuasion is financial: it is interesting that many new contracts for outsourced services (eg MR reporting) will only be granted with assurance of 10% in house audit of results: many also perfume external audits for quality assurance. Many such audits have confirmed the effectiveness of double reporting which may become routine for many radiological examinations.

ABSTRACTS FOR PROFFERED PAPER SESSIONS

Notes

3. All PP-presentations at the Workshop received by 1 September 2008 are given on the CD distributed with this document. The presentations are preliminary and can be modified/improved for the final presentation at the Workshop. The missing presentations will be available later on from the website www.clinicalaudit.net.
4. If you want to make use of the material in the PP-presentations, please ask the permission from the presenting author. The list of e-mail addresses is distributed in the conference bag.

Setting Standards for Clinical Audit: Making the best use of clinical radiological services [23].

Denis Remedios (on behalf of the Royal College of Radiologists Guidelines Working Party), The Royal College of Radiologists, 38 Portland Place, London W1B 1JQ, UK.
denis.remedios@nwlh.nhs.uk

The design of an audit is wholly reliant on a satisfactory and acceptable standard which should be evidence-based whenever possible or agreed by consensus where the evidence is weak. The diagnostic impact and often economic impact of imaging for any common clinical problem relies on such evidence-based guidelines. In the UK this need has been heightened in 2006 by the correct inclusion of non-medically qualified health professionals as referrers. The Royal College of Radiologists has published clinical referral guidelines since 1989 and in September 2007 published the 6th edition of "Making the best use of clinical radiology services" both in paper and web versions.

The methodology for synthesis of these guidelines has evolved in recent years to provide more robust advice. Centralisation of literature searches has enabled a rigorous protocol with inclusion and exclusion filters and an electronic hand search of 7 high impact imaging journals. Expert panels drawn from the Special Interest Groups representing the main system based specialties, oncology and paediatrics ably assisted by modality based groups were invited to participate in a series of e-mail based questionnaires introducing the clinical problem, providing evidence from a centralised search and using a Delphi iterative process to agree recommendations and their grades. These groups included experts from several European states. Draft guidelines were then put out for consensus to over 100 colleges, institutions and learned bodies across the UK and Europe. The editorial process shaped the draft guidelines with further evidence gleaned through consultation. An electronic editorial group included members with graphics and web skills.

The resulting publication contains 315 guidelines incorporating 43 new guidelines. 67 recommendations are now Grade A, up from 52, with only 171/647 reliant on expert opinion or low evidence level studies. 280 Delphi members took part from 16 expert panels, representing almost a tenth of UK radiologists. Both the paper and web publications were designed to be user-friendly to encourage their everyday use and when required to provide the standard against which the modality and indication of referrals may be audited.

In conclusion, the value of evidence-based guidelines is to encourage good medical practice nationally and uniformly, ensuring the appropriate requesting of the best investigation which may not be the cheapest but the most helpful to clinician and patient.

Summary of clinical audits in Finland after the first complete audit round [24]

S. Soimakallio, H. Järvinen, A. Ahonen, K. Ceder, M. Hirvonen-Kari , T, Lyyra-Laitinen, T. Sinervo, T. Sipilä and T. Wigren, Finland.

The requirements for the implementation of clinical audit in Finland has been set by a Radiation Law (1142/1998) and in more detail by the Degree on the medical use of radiation (423/2000). According to the Degree, clinical audits shall be carried out by competent and experienced auditors, who are independent of the organisation to be audited. The Degree specifies ten points of interest which shall, among other things, be considered in clinical audits. The Degree further specifies as the goal that all radiological practices should be audited for all essential parts at the minimum every five years.

After the first five years period (2000-2006) since the above legislation came into force, the National Advisory Committee for clinical audits, set by the Ministry of Social Affairs and Health, conducted a survey of the results of the audits in order to review the implementation of audits and the type of recommendation given to various types of radiological health care units. The survey was carried out by a review of the audit reports from the files of the auditing organization (Qualisan Ltd), with the permission of the audited health care units. Altogether 346 reports were reviewed, comprising 312 diagnostic radiology units, 24 nuclear medicine units and 10 radiotherapy units.

Practically all radiological health care units in Finland had been audited for the first time within the first five years' period. All clinical audits had been carried out by the same organization, employing a total of 38 auditors from volunteered health care professionals (physicians, physicists, radiographers etc). The audits were typically carried out by a team consisting of a medical expert (physician) and a radiographer, in some cases (e.g. for radiotherapy) also a physicist. The audits were based on the guidance and check lists developed by the auditing organization. The criteria of good practices were derived mainly from the legislative requirements, while the audits to a great extent also relied on the professional judgement of the auditors.

The results indicate that the health care units comply fairly well with the applied criteria of good practices. However, a significant number of recommendations to improve the practices have been issued, on the average 4-7 recommendations per health care unit. The recommendations concern a number of topics, e.g., assessing examination and treatment outcome, supplementing of the quality system, providing of medical physics expertise, improving the referral practices, improving imaging practices in particular in paediatric radiology, improving planning and recording of radiation protection training and establishing self-assessment practices. While the results cannot be used to assess the accountability of clinical audits, it is concluded as a significant benefit of audits that the awareness of good practices has been widely increased.

The results also suggest a need for a few improvements of the audit practice. The criteria of good practices, now mainly based on legislative requirements, should be supplemented by more clinical criteria in order to avoid unnecessary overlap with regulatory inspections. It is also recommended that for the next audit round, the basic criteria of good practices be supplemented by more specific clinical criteria for "in depth" assessment of selected examinations or treatments. The consistency of audits should be improved by further development of the guidance and checklists and by increased training of the auditors. The composition of the audit group should always include an expert physician, also in the field of nuclear medicine. The coordinating and advisory role of the National Advisory committee will be of increasing importance in the future development of audits. The role of the radiation protection authorities will also be important in order to ensure the implementation of clinical audits with high quality and in compliance with the legal requirements.

National Systems for Clinical Audit in the UK: The Role of the Clinical Radiology Audit Sub-Committee of the Royal College of Radiologists [25]

S. Barter and K. Drinkwater on behalf of the Clinical Radiology Audit Sub-Committee of the Royal College of Radiologists, UK.

The Clinical Radiology Audit sub-Committee (CRASC) of the Royal College of Radiologists (RCR) was established to lead College focus to co-ordinate national radiology audit activity.

Among its functions is to promote and facilitate audit through nominated audit leads in each hospital Trust, who act as a liaison between the RCR and their department. They encourage members' and Fellows' participation in audit from within their own department taking into account national and local agendas, pilot audit projects and encourage colleagues' participation in relevant RCR national audits.

At least one national audit is carried out per year, on a topical issue with data collected via electronic submission and the anonymised results presented to the Audit leads at an annual Audit Forum. Individual departmental results are analysed using statistical process control (SPC) methodology to distinguish between common cause variation and special cause variation in performance data. This enables CRASC to tell departments if they are underperforming against the national mean and if so recommend corrective action, by redesigning the process being audited, or to identify and eliminate specific root causes locally.

Past National Audits include:

2003	Audit of detection of Colon Cancer by Double Contrast Barium Enema
2003	National Provision of MRI Services
2004	Compliance with NICE Head Injury Guidelines
2005	Audit of Diagnosis of Lung Cancer on Chest Radiography.
2006	Re-audit of National Provision of MRI Services
2006	Audit of outcomes of Nephrostomy
2007	Audit of Effective Communication

The Committee has recently developed a web-based tool for facilitating local audit, "AuditLive", a fully searchable collection of templates or "recipes" which RCR members can access, download, and adapt with the focus on dose reduction and best practice. Users are also able to submit their own templates for audit for consideration of publication hence sharing best practice nationally.

The RCR Standards Sub Committee produces a number of standards of best practice annually and CRASC works closely with them to provide a template for audit against each standard produced, so radiologists can monitor their performance against these standards.

We encourage radiologists in training to participate in audit by holding Audit Poster competitions at National Radiology Scientific Meetings. An audit newsletter is produced at least annually, and distributed to every member and Fellow of the RCR. We work closely with UK national bodies such as the National Institute of Clinical Excellence to enable audit of their priorities for healthcare in radiology.

Our experience leads us to believe that audit succeeds when relevant, locally owned and properly structured, and multi-professional, and our model encourages this.

Treatment of data in national clinical audits undertaken by the Clinical Radiology Audit Sub-Committee of the Royal College of Radiologists [26]

K. J. Drinkwater on behalf of the Clinical Radiology Audit Sub-Committee of the Royal College of Radiologists, UK

Clinical audit seeks to improve patient care and outcomes through a process of review against criteria, the implementation of change and confirmation of improved performance. At its most basic, local data analysis requires little more than calculating the percentage of events that complied with criteria before and after implementing change and determining whether improvements have taken place. The aim of national clinical audit is still to improve patient care, but it also seeks, as one of its objectives, to help local services compare their level of performance with that of their peers.

The league table approach, accessible to the patient as well as to the healthcare professional, is popular. However, it has been criticised on a number of fronts including: impact on public trust and professional moral, creative reporting and undue focus on performance measures. Furthermore, it is an assumption that quality of care equates to position in a league table, which may be decided by chance.

The Clinical Radiology Audit Sub-committee (CRASC) of the Royal College of Radiologists (RCR) has sought to use a different approach. Since 2004, it has applied statistical process control (SPC) methodology (e.g. see Mohammed *et al*., 2001), to distinguish between common cause variation and special cause variation in national audit data. As a result, CRASC is able to recommend, with a known degree of certainty, which of three actions to take following on from analysis (no corrective action, to redesign the process being audited, to identify and eliminate specific root causes locally) without rank ordering of services.

In conclusion, CRASC has been using SPC methodology for a considerable period of time in national clinical audit. Unlike the league table approach, SPC methodology does not involve rank ordering and avoids many of its criticisms. In addition, SPC methodology has two major advantages: there is reduced risk of identifying a performance difference between services when there is none (leading to reduced risk of tampering) and there is reduced risk of not identifying performance difference between services when there is (leading to reduced risk of unacceptable practice being overlooked).

AuditLive – A national radiology audit template library – the UK experience [27]

C.J. Ryall, S. Barter, K. A. Duncan, P. Lumb, UK

Background

The Royal College of Radiologists (RCR) has actively promoted Medical Audit for over 15 years. In 1996 a book "Clinical Audit in Radiology: 100+ Recipes" was distributed, free to all RCR members. A second publication "Clinical Governance and Revalidation" followed in 2000 focussing on the assessment of individual practice.

These books established a base set of audits suitable for clinical practice, and have since been widely used in Radiology departments throughout UK. RCR's Clinical Radiology Audit Subcommittee (CRASC) is updating its archive to address developments such as the advent of PACS, PET-CT and the modern Clinical Governance agenda.

Publication has been transferred into an online Internet format. This allows ready access to UK hospitals, regular periodic review of the "recipes", and easy incorporation of any new templates that might be developed within departments in the UK's Health Service.

Aim

The "AuditLive" website launched in February 2008 offering some 80 audit templates. Numbers are increasing with revision of heritage material, and incorporation of new recipes.

An RCR member wishing to audit a specific area of his practice may now search the general archive using an expandable keyword based index, or simply as free text.

Each template is structured into sections providing background, a standard, a method, suggested resources and some editorial advice or comment. Clickable links have been incorporated to download questionnaires, data forms and report pro formas

College members and Department Audit Leads may submit their own successful templates. These are added after consideration by the website editors and discussion in CRASC.

There has been much interest in RCR's new audit resource. It offers a mechanism to maintain freshness of content, an ability to respond to new or changing standards, and flexibility to meet the challenge of continuous technical innovation in our industry.

AuditLive helps avoid duplication of development effort within UK's Health Service, while facilitating audit against national and European guidelines, encouraging best clinical practice, and dissemination of valuable new ideas. It can provide methodology to address all aspects of clinical audit against governing British or European standards.

The authors hope it will remain a valued and well used resource for many years to come.

Archive URL: https://www.rcr.ac.uk/index.asp?PageID=1016 (RCR members only)

Experiences with clinical audit in Slovak mammography departments [28]

D. Nikodemová[1], M. Horváthová[2], M. Príkazská[1]
[1] Slovak Medical University, Limbova 12, 83303 Bratislava, Slovakia
[2] Trnava University, Faculty of Health and Social Care, Trnava, Slovakia

On the basis of EC Directive 97/43 the new Slovak legislation (Health Ministry 2006) improved the national system of acceptability of radiological examinations by implementation of Guidance Levels, system of education and necessity of introduction of Quality Assurance (QA), Quality Control (QC) programs and clinical audits in radiological departments.

Due to the increasing incidence of new breast cancers in Slovakia, systematic early detection, effective diagnostic pathways and quality assurance services were installed and the number of mammography units increased. In 2006 on 80 Slovak mammography units 271 755 mammography examinations were performed and from them 156 199 were noticed like preventive mammography examinations.

The Commission of Ministry of Health for QA in radiology developed in 2003 clearly defined and documented procedure for the realization of the QA/QC at mammography departments and developed the conditions for clinical audit.

In our contribution the experience of the national mammography audit at 58 mammography units are presented, running in the years 2003-2007. The program of mammography audit included three phases of work. The first phase dealt with the assessment of the existing status of radiological practice and equipment performance in the selected mammography units, as well as training and education of radiologists and radiographers. The second phase was devoted to the implementation of technical QC program and patient dose measurement. The third phase dealt with clinical image evaluation according to the criteria defined for CC and MLO projections by the European Guidelines. Unified criteria for realizing QA program in form of a manual were officially outlined and participating departments equipped by necessary measuring tools. The results of QC tests performed by radiographers of all mammography departments were sent every month for evaluation to our department. For evaluation of the quality of clinical images each mammography department sent 4 images of 10 patients (2 CC and 2 MLO). These images were evaluated by a group of independent experts nominated by the Slovak Health Ministry.

The results of the audit show improved quality of mammography examinations due to regular checkups of technical and clinical parameters and fulfillment of the required tolerances of measuring parameters. Detailed estimation of average glandular doses during mammography examinations was the basis for adoption of new national diagnostic reference level for mammography. The audit results are the groundwork for continuous quality assessment of mammography departments as a main prerequisite for conducting preventive examinations and for health insurance purposes.

Quality management in nuclear medicine [29]

K. Solanki and M. Dondi
International Atomic Energy Agency, Vienna, Austria

The development of all-inclusive IAEA guidelines on "Quality management in Nuclear Medicine" (also referred to as "QUANUM") will play a vital role for self appraisal and external audit. The foremost intention of this document is to introduce a culture of annual systematic review processes into the clinical arena. Each chapter is set out as a series of questions related to a specific component of nuclear medicine service. The quality of service takes into account the diversity of nuclear medicine practices and the multidisciplinary contributions. These elements are central to improving QA in nuclear medicine practice.

Each of the IAEA regions (Africa, Asia, Europe and Latin America) has technical cooperation projects under which the nuclear medicine audit programmes will be undertaken. A group of trained auditors for each region are being trained and will form the back-bone for standardized external audits in practices. Pilot audits are underway in each of the regions to assess practical implementation of the process in diverse geographic, economic and cultural settings. Regional workshops on the topic of quality management will introduce and train counterparts in the proper use of the "QUANUM" document and associated software files in Microsoft Excel. The latter is particularly useful for sustaining continous improvement through a self appraisal system and audit review. An external audit is recommended every 3 years.

Before external audit, a completed self appraisal and previous internal audit reports are submitted for review. The auditing team will therefore be fully aware of the nuclear medicine practices current status. A 3 day external audit starts with a briefing meeting and ends with debriefing on the finalization of the audit report. During the audit, a set protocol is followed which includes service orientation, introduction to key individuals and access to essential data. The audit team will follow sample clinical cases from clinical requests, clinical direction, patient preparation, radiopharmaceutical dispensing, individual scanning, data processing, report and follow-up of the report. In general standard of practice will be compared to national, regional or international guidelines (i.e. IAEA Nuclear medicine resources manual). In a few cases, discussions with individual referring physicians will be held to establish the impact of the service.

Any short-comings will be openly discussed with the counterpart. The required changes will be prioritised into three categories, critical, major and minor. An agreement on a work plan for changes should be reached before the end of the visit. A constructive final audit report is written in a standardised style to ensure accuracy, transparency and consistency.

In summary, the development of all-inclusive guidelines referred to as "QUANUM" is an important auditing and monitoring tool for strengthening and raising the standard of nuclear medicine practice particularily in developing countries.

Steering actions by a National Advisory Committee for Clinical Audits in Finland [30]

S. Soimakallio, H. Järvinen, A. Ahonen, K. Ceder, T. Lyyra-Laitinen, M. Paunio, T. Sinervo and T. Wigren, Finland.

In 2004, a national steering group, or an Advisory Committee for Clinical Audit, for the development and follow-up of the clinical audits in Finland was established by the Ministry of Social Affairs and Health. This was considered important for the quality and consistency of clinical auditing, because the legislation did not specify any particular organization to carry out clinical audits and more than one approach for the practical implementation was expected. The Advisory Committee is a multi-disciplinary group of clinical experts, independent of any auditing organizations. Its tasks include, among other things, evaluation of the suitability and coverage of the criteria used in clinical audits for different sub-areas (diagnostic radiology, nuclear medicine and radiotherapy), evaluation of the importance of other quality audits in medical practice (such as audits for accreditation), making proposals and promoting the use of special practice-specific criteria in clinical audits, and collecting summaries and review of the results, including analysis of the impact of audits on radiation protection of the patient. The Committee has been established in three years' terms.

One of the first actions of the Advisory Committee was to prepare guidelines on the detailed requirements of competence, experience and independence of the auditors (Recommendation 1, 2005). For example, the auditors are required to have practical clinical experience in the field to be audited, the lead auditors must have at least one week specific training on the audit techniques, and the composition of the audit team must generally include a physician (e.g., radiologist, oncologist, or nuclear medicine expert and a radiation technologist, and in certain cases (e.g. for radiotherapy), also a physicist.

By now, the Advisory Committee has issued three further recommendations:

- Development of clinical audits: Recommendations by the Advisory Committee for the second audit round (Recommendation 2, 2006)
- Taking into consideration of accreditations in the clinical audits of nuclear medicine (NM) units (Recommendation 3, 2006)
- Taking into consideration of the ten points of interest given in the Degree (423/2000) in clinical audits (Recommendation 4, 2008).

The second recommendation sets out the priorities for the next audit round, recommending specific topics of interest in the three fields (diagnostic radiology, nuclear medicine and radiotherapy) including more detailed "in depth" assessments of selected examinations and treatments. It also gives references to some recommended criteria of good practices. The third recommendation describes specific considerations to be taken into account in clinical audits of NM units which have been accredited, in order to avoid unnecessary overlap with the audits carried out for the accreditation. The fourth recommendation considers in detail the contents of the ten points of interest set out in the Degree (423/2000) and specifies the sub-items of each point where clinical audit should have the highest weight. The purpose of this recommendation is to unify auditor's interpretations of these ten points of interest and to avoid unnecessary overlap of clinical audits with regulatory inspections.
Beside the recommendations, the Advisory Committee has conducted a survey of the results of the complete first round of audits in Finland (2000-2006). The summary of this survey is given in another paper of this Workshop. In 2006, at the end of its first term of operation, the Advisory Committee organized a half-day seminar on clinical audits, where the recommendations of the Committee and the summaries and future development of the clinical audits, on point of view of auditing organizations and authorities, were presented and discussed. Information (so far in Finnish) on the Committee and its publications are available from the Committee website "www.clinicalaudit.net".

Clinical audit programme for diagnostic radiology: intent, design and early experiences [31]

B. Abdullah, University of Malaya, Malaysia
P. Butler, American College of Radiology, USA
K. Faulkner, Quality Assurance Reference Centre, UK
H. Järvinen, Finnish Center for Radiation and Nuclear Safety (STUK), Finland
I.D. McLean, International Atomic Energy Agency, Vienna, Austria
M. Pentecost, American College of Radiology, USA
M. Rickard, Sydney Breast Clinic, Australia

The International Atomic Energy Agency (IAEA) has a mandate to assist Member States in areas of human health and particularly in the use of radiation for diagnosis and treatment. Clinical audit is seen as an essential tool to assist in assuring the quality of radiation medicine, particularly in case of the multidisciplinary application of diagnostic radiology. Consequently an external clinical audit programme has recently been formulated to examine the structure and processes existent at a clinical site, with the basic objectives of (i) improvement in the quality of patient care, (ii) promotion of the effective use of resources, (iii) enhancement of the provision and organization of clinical services and (iv) to further professional education and training, for three general areas service delivery, namely in quality management and infrastructure, patient procedures and technical procedures. The audit process is initiated by a request from the centre seeking the audit. A three member team, comprising a radiologist, medical physicist and radiographer, subsequently undertakes a 5 day audit visit to the clinical site to make the audit and write the audit report. Preparation for the audit visit is crucial and involves the clinical centre reading the audit guidance document which includes the audit standards that are to be used. The centre also is required to provide the requested information on the clinical centre and other information required by the audit team.

While all main aspects of clinical structure and process are examined, particular attention is paid to radiation related activities as described in relevant documents such as the IAEA Basic Safety Standard, the Code of Practice for Dosimetry in Diagnostic Radiology and related equipment and quantity assurance documentation. It should be stressed however that the audit does not have any regulatory function, with its distinct purpose one of promoting quality improvement and learning.

The paper will include details of the preliminary results of the first audit mission to be held in August this year.

Clinical Audit In Diagnostic Radiology In Bulgaria – National Regulation And Practical Implementation [32]

Jenia Vassileva[1], Vassil Hadjidekov[2]
[1]National Centre of Radiobiology and Radiation Protection, Sofia, Bulgaria
[2]Department of Diagnostic Imaging, Medical University, Sofia, Bulgaria

In 2004 in Bulgaria was adopted the new Law on Health, which establishes the legislative basis for full transposition of the EC directives and recommendations. Ordinance 18/2005 of the Ministry of Health for accreditation of Health care establishments required all medical practices to be accredited by means of internal and external audit, based on the Medical standards. The requirements of the standard on Diagnostic Imaging, which was approved in 2004, became criteria for accreditation of Diagnostic imaging departments.

Medical Exposure Directive 97/43 EURATOM was implemented in Bulgaria in 2005 with the Ordinance No30/2005 of the Ministry of Health for conditions and order for providing protection of the individuals at Medical Exposure. This ordinance defined quality assurance, quality control and quality audit as important elements of the system of radiation protection at medical use of ionizing radiation. Medical Exposure Ordinance foresees external audit to be performed in 2 years basis by an auditing group including university professor in medical imaging and medical physics expert, which is proposed by the National consultants in medical imaging. This audit is outside the radiation protection inspections performed regularly by the Nuclear Regulatory Agency and Radiation protection inspectorates of the Ministry of Health.

During the last two years all diagnostic imaging departments passed through the auditing and accreditation procedure as an element of accreditation of the medical establishments. Most of the new quality criteria for diagnostic radiological equipment and especially on quality control were insufficiently understood and in fact not implemented. Patient exposure and image quality assessment were not taken into account during the accreditation. The auditing criteria have to be clarified; training of auditors needs improvement. Professional auditing team has to be established and trained in order to perform quality audit of the whole diagnostic process. In this regard European guidance and common criteria are welcomed. Organising of European team for performing “model” audit in a reference centre in the country could support the implementation of the guidance.

Clinical audit introduction in the Czech Republic (X-ray diagnostic and nuclear medicine) [33]

J. Nozickova, Czech Republic

Introduction

The demand for clinical audit (CA) is stated in the Czech Republic legislation in the Decree No. 307/2002 Coll. on radiation protection which is the implementing decree to the Act No.18/2002 Coll. (Atomic Act). The Atomic Act and its implementing regulations lie within the authority of SONS which is a regulatory body responsible for governmental administration and supervision in the fields of nuclear energy utilization and radiation protection. Medical legislation including specification of the clinical audit is currently being prepared; its enactment is supposed by the end of 2008. Ministry of Health in cooperation with professional societies carried out several "test clinical audits" in selected medical facilities in 2004-2006. The preparation, process and assessment of these "test clinical audits" (focused on radiotherapy) is the topic subject of the report "Experience in Clinical Audit in the Czech Republic" by Hana Stankusova.

National Radiological Standards

The written procedure (a standard) must be elaborated for all standard types of medical exposure in accordance with the above mentioned Decree No. 307/20025Coll.; the correspondence with the procedure at individual radiological workplaces will be verified by clinical audits.

The implementation of radiological standards and clinical audits in practice is a long and complicated process requiring the cooperation of number of stakeholders. From the viewpoint of a regulatory body it is rather difficult to join the strictly legislative requirements with all their consequences (inspections of requirements performance, methods of corrective actions enforcement, sanctions) and the comprehension of clinical audit as a means of establishing "a good practice". At present SONS in cooperation with the Ministry of Health is trying to implement the optimal policy of clinical audit into the recently created medical legislation. The draft law comprises the obligation to audit the health service facilities and the specifications for subjects responsible for CA performance including qualification requirements of the auditor´s team. The results of the clinical audit however will be used neither for inspection activities nor for sanctions, but only for following of the feed-back during the next internal clinical audit and the implementation of correctional actions. The feed-back will be checked by both - the SONS inspectors and by the Ministry of Health.

As a guidance for "Local Radiological Standards (LRS)" are "National Radiological Standards (NRS)" that were elaborated by Ministry of Health with participation of professional societies. NRS is a set of instructions and recommendations including demands on technical equipment and personnel resources of workplaces, staff qualifications, competences and responsibilities, indication and contra-indication of medical examination, data recording and documentation and their systematic archiving, procedures of correct performance of medical examination and its quality assessment including radiation protection, estimation and evaluation of patient doses. Currently, the standards are on the website of Ministry of Health for comments from stakeholders. CA should assess correspondence between the established clinical practice and LRS.

The NRS are divided into four groups:

1. **"NRS - Diagnostic Radiology and Interventional Radiology"**- containing diagnostic procedures of adult patients and the most frequent types of diagnostic procedures of children, especially newborns, sucklings and toddlers. Special attention is given to the justification of medical exposure and to selection of medical devices which are designed for medical exposure of children.

2. **"NRS - Nuclear Medicine"**- containing diagnostic procedures and requirements on medical application of radiopharmaceuticals including demands on palliative therapy and specialized methods, e.g. radiation navigated surgery.
3. **"NRS - Radiation Oncology and Radiotherapy"**- containing requirements on the basic types of radiotherapy and some specialized methods, e.g. IMRT, stereo tactical radiation.
4. **"NRS - Radiological Physics"**- containing methods of determination and evaluation of patient doses by means of the "local" diagnostic reference levels (LDRL) and method of effective dose estimation (for radiodiagnostic and nuclear medicine), for radiotherapy, assessment of treatment efficiency and risk-evaluation of deterministic effects on critical organs.

Conclusion

SONS unambiguously evaluates clinical audit as beneficial. CA can serve as a tool that

- contributes to improvement of technical equipment of workplaces,
- assures the application of quality standard working procedures for medical facilities,
- motivates staff, especially in the area of continuous education,
- avoids repetition of medical exposure and contributes to decrease of the radiation burden of patients.

National Experiences and Expectations on Clinical Audit – the Irish perspective [34]

B. Moran, Medical Exposures Radiation Unit, Environmental Health, Population Health Directorate, Health Service Executive, Ireland

In October 2002, Statutory Instrument SI 478 European Communities (medical Ionising radiation Protection) Regulations (2002), on the protection of patients exposed to ionising radiation, was passed in to law. This transposed 97/43/Euratom and earlier European Directives on the medical use of ionising radiation in to Irish law.

In the 97/43/Euratom, article 6 states "clinical audits shall be carried out in accordance with national procedures." SI 478 gave responsibility to the Irish Medical and Dental Councils to develop criteria for clinical audit with in two years' of the introduction of SI 478. The Health Service Executive, the body responsible for delivery of public health care in Ireland, was required to appoint a clinical auditor. All holders have responsibility to ensure that the clinical practice conducted in their installation is audited in accordance with agreed criteria once every 5 years. The first audit was to be undertaken by October 2007.

The competent authority for implementation is the Department of Health and Children. However, the legislative framework changed in 2005 with the establishment of Health Service Executive (HSE) subsuming 11 health boards into one and the establishment of Health Information & Quality Authority (HIQA) whose role is to set and monitor standards in health in Ireland.

In Ireland, a task force was established by the HSE in 2007 to make recommendations in relation to SI 478. The task force membership was drawn from the various statutory bodies and stakeholders with responsibilities under SI 478. The terms of reference for the task force were:

- To present proposals for the implementation of the SI 478.
- To make proposals for and commence a national clinical audit.

Recommendations:
The Task Force made specific recommendations with regard to clinical audit and the recommended approach. It is recommended that clinical audit will largely be self audit with an external input and independent monitoring overseen by the Health Information & Quality Authority (HIQA).
The Task Force has proposed that HIQA become the competent authority.

Progress to date:
1. The first baseline questionnaire has issued nationally, results are due in 2008. The Questionnaire aims to establish a "snapshot" of what level of clinical audit is currently being conducted and what structures are in place. The survey results will indicate what level of clinical audit is currently in place throughout the country.
2. The HSE, HIQA and the Medical and Dental Councils are working together to produce a set of agreed standards in radiation protection in Ireland. Standards already exist as adopted by the Irish Medical Council and Irish Dental Council and it is expected these will be incorporated. Clinical Audit will then be developed further based on these standards.
3. The National Radiation Safety Committee was established in 2007 to advise on radiation protection.

References
Statutory Instruments 478 (2002) and 303 (2007).
HSE Task Force Report on Recommendations for the Implementation of SI 478 (2002), April 2008.
97/43/Euratom, 1997.
Criteria for Clinical Audit, Irish Medical Council, 2005.

Is Clinical Audit Useful in Continuous Improvement of Quality in Radiological Department? [35]

Seppo Soimakallio, Prasun Dastidar, Ritva Järvenpää, Leena Mäkelä and Timo Paakkala
Dept of radiology, Tampere University hospital, Tampere, Finland

EC Directive 97/43/EURATOM introduced a new concept of Clinical Audit in 1997. Finland implemented this Directive in the national law of radiation in 1998 and a Degree was given on 1.1.2000. The first Clinical Audit according to the law was performed in Tampere university hospital 29.3. – 1.4.2004 and the second run on 5. – 7.5.2008. The aim of this presentation is to analyze if there are any advantages of Clinical Audits on the quality of daily practice.

Many problems arose during the preparation for the first audit: a) the time to finalize quality manual and resources for that, b) we had only PACS and RIS was coming, c) time for self-assessments and d) negative attitudes of personnel against audit. Clinical Audit was performed by a team (radiologist, physicist and radiographers) during 4 days in two hospitals consisting of 23 labs. Auditors were listed with 16 different recommendations in the audit report.

Between the first and second run of Clinical Audit we made many self-assessments to the most difficult part of procedure and corrections according to the recommendations. Also our daily practice changed much, because we changed our systems totally to electronic form (digital images, PACS, RIS, patient record, instructions, references, education record etc). We started to prepare ourselves for the second audit already a half year before updating our instructions, motivating personnel and reserving enough time for that procedure. We asked offers from two companies and after selecting the company we made time schedule and answered their questionnaire. The audit team was almost similar (4 persons) and it took 3 days to audit our two departments with only 5 recommendations.

Quality things are at the moment a normal part of our work. Attitudes have changed favourably and our personnel are motivated and positive for development and quality. Also negative feedback from clinicians and patients has diminished except that concerning our data system. Waiting time is under control and the level of common service has increased. Self-assessment is the best part of Clinical Audit procedure to promote quality in a daily practice of radiological department.

We can conclude that Clinical Audit has had favourable influence on continuous improvement of quality in our department.

Relation of clinical audit based radiology and reimbursement systems [36]

András Vargha and Csaba Dózsa, Hungary

There is heterogeneity in Europe in current reimbursement systems. Some states use the budget system, some - including Hungary - the „pay for result" system. More factors urge the implementation of clinical audit also in radiological practice. This would require clear patient routes, good interdisciplinary communication and common developing protocols. This would be optimal for patients and also from economic point of view. However in everyday practice we have to think of the financial balance of individual departments or institutes which can be controversial with the „best practice" and maybe also with a higher level (more global) economic point of view.

In the current DRGs and germain score-based performance oriented reimbursement scheme the service provider is continuously forced to produce more-and more services as a volume, without taking care the real quality and final outcome of the services. In Hungary we also face a considerable practice variation in the publicly reimbursed in- and outpatient secondary care. On the other hand, the pure yearly budget either wasn't a good solution, as the former reimbursement scheme in our country during the 80's.

There are disadvantages in both the pure performance and the pure budgetary systems which can cause malpractice, unjustified practice variation, financial loss and have bad influence in long terms, too. From all point of views the optimal would be to elaborate and run a combined reimbursement scheme where the patients get the most effective and quick diagnostic evidence proved protocols and the institutes are interested in achieving this. It requires the adjustment of purchaser-provider contracts with quality requirements and conditions (ex. application of clinical audit, calculation of quality indicators).

To face to a „pay for quality" reimbursement system a possible way would be to apply a quality based system and dynamically changing the reimbursement according to its results. Clinical audit could be a basic tool in this process.

A Standards-based Method for Collecting and Processing Radiology Dose Data [37]

Kevin O'Donnell, Toshiba Medical Systems, Heinz Blendinger & Bernhard Hassold, Siemens Medical Solutions

The IHE Radiation Exposure Monitoring (REM) Profile facilitates the collection and distribution of estimated patient radiation exposure information resulting from imaging procedures.
In the vast majority of medical procedures involving radiation, the potential diagnostic or interventional benefit to the patients' health far outweighs the potential risk, but the trade-off should not be overlooked, and technological mechanisms can automate and facilitate a deliberate evaluation of that trade-off.

Many regulations and guidelines (such as the European directive Euratom 97/43 and the American College of Radiology Dose Whitepaper) express the need for facilities to monitor radiation dose estimates for procedures they perform and keep procedure doses As Low As Reasonably Achievable (ALARA). Such efforts are easier, and more likely to occur regularly, when dose estimates are provided electronically

Integrating the Healthcare Enterprise www.ihe.net (IHE) is an initiative of professional societies to supervise and coordinate standards-based solutions to problems that span multiple vendors systems. The IHE REM Profile is an implementation guide for vendors documenting how to support dose reporting using existing standards (DICOM SR Dose Reports). By following this guide and participating in IHE Connectathons, vendors can release products that will interoperate to provide an exposure monitoring pipeline.

Imaging modalities are required to export radiation exposure details in a standard format. Radiation reporting systems can periodically query these "dose objects" from an archive, or receive them directly from modalities. The reporting system is expected to perform relevant dose QA analysis and produce related reports. Dose reports can also be submitted to centralized registries such as might be run by professional societies or national accreditation groups.

Dose details are recorded for each irradiation event, defined as one continuous irradiation applied to a patient. A CT scanogram and the associated helical scan are two separate events, as are two different presses of the fluoro pedal. Typically, one dose object is created at the end of each procedure step performed on the modality. That object collects all irradiation events from the procedure step and adds summary dose index values.

The Profile addresses CT, angiography, fluoroscopy, mammography, CR, DR, and plain X-ray. It does not yet address nuclear medicine (PET or SPECT), radiotherapy, or implanted seeds.
With automated methods, dose information can be collected and evaluated without imposing administrative burden on staff otherwise occupied with caring for patients.

Experience in Clinical Audit in the Czech Republic [38]

J.Petera, H. Stankusova, P. Slampa, P. Zavoda (on behalf of the Society of Radiation Oncology, Biology and Physics, Czech Republic)

Introduction:
Basic requirements for clinical audits are specified by Czech legislation in the Decree No 307/2002 Coll. on Radiation Protection that is regulated by the State Office for Nuclear Safety (SONS). The implementation of clinical audits into the health law is under preparation (Law on Specific Health Care Services) and hopefully will be adopted by the Parliament in 2008. In 2004-2006, Ministry of Health of the Czech Republic supported the "*Project of the Promotion of the Quality of Health Care*". The objective of the project was to develop the methodology of clinical audits and to perform clinical audits in selected radiology, radiotherapy and nuclear medicine departments in the hospitals managed by Ministry of Health. In 2004, the national standards in radiology, radiotherapy and nuclear medicine were developed by professional societies. National standards were a prerequisite for starting the clinical audits. In 2005-2006, clinical audits were executed in 11 radiology departments, 3 nuclear medicine departments and 8 radiotherapy departments. Our experience in clinical audit in radiotherapy is presented in more detail. The main purpose of the audits performed was to verify the methodology; therefore the selection of suitable radiotherapy departments was done by our professional association - the Society of Radiation Oncology, Biology and Physics (SROBF) and the Ministry of Health as the owner of the hospital.
Preparatory stage:
The group for development of clinical audit methodology and criteria was established. It consisted of radiation oncologists, radiological physicists, a representative of Ministry of Health and a representative of SONS.
National standards for radiotherapy procedures were developed in 2004 by the Society of Radiation Oncology, Biology and Physics. In 2005, the questionnaire for a comprehensive survey of radiotherapy infrastructure in the Czech Republic was prepared, data collected online and evaluated. The checklist of items to be audited was prepared. Experienced radiation oncologists, radiological physicists and RTT's were selected for audit teams, in which always a representative of Ministry of Health was present. All auditors passed l day training in auditing.
Clinical audit was always announced by Ministry of Health to the RT department three weeks before the planned date of the clinical audit. Information about the clinical audit programme and questionnaire (checklist) to be filled before the audit was sent to the department by the chief auditor.
Clinical audit:
Clinical audit always started with entrance meeting with the department staff and introduction of auditing team members and department personnel. It was followed by the department visit with detailed survey and evaluation of radiotherapy procedures and relevant documentation. Some staff members were interviewed.
Written local standards for all used procedures were demanded and checked for compliance with good clinical practice. At the conclusion of the audit, the auditors held the discussion with persons involved on the positive and negative findings, and made recommendations. Final audit report was elaborated during 2-3 weeks and sent to the head of radiotherapy department, to the director of the hospital and to Ministry of Health as audit organiser and hospital owner.
Conclusion:
Experience from clinical audits in radiotherapy departments was stimulating both for radiotherapy department staff and auditing team. Auditors gained experience in practical aspects of performing comprehensive clinical audit and in its organisation. For the audited radiotherapy department it was an impulse for improvement of local practice and local standards. The survey of radiotherapy practice in all RT departments provided us the knowledge of the proportion of irradiated cancer patients according to the diagnosis and detailed data about the infrastructure of radiotherapy equipment and staff in the Czech Republic.

Status of Clinical Audit implementation in Poland in the field of radiotherapy [39]

W. Bulski , J. Rostkowska,M. Kania, B. Gwiazdowsk
Department of Medical Physics, Maria Sklodowska-Curie Memorial Cancer Centre and Institute of Oncology, Roentgen str. 5, 02-781 Warsaw, Poland

An important part of a clinical audit in radiotherapy departments is a dosimetry audit. In this presentation stress shall be put on dosimetry audits.

In Poland, there are 23 oncological centres performing external beam radiotherapy and several more performing brachytherapy (25 in total). In total, there are 85 teletherapy machines (78 accelerators and 7 Co-60 units). These centres possess about 70 radiotherapy dosimeters. Each centre has to have at least one dosimeter with a valid calibration certificate. The calibration certificate may only be issued for a type of dosimeter recognized by the primary standard laboratory. The expiry period of the certificate is three years. The certificate may only be issued by a certified laboratory. In Poland, the Secondary Standard Dosimetry Laboratory (SSDL) of the Medical Physics Department of the Centre of Oncology in Warsaw is such a certified laboratory. This SSDL has become a member of the IAEA/WHO international network of such laboratories in 1988.

The SSDL has been also carrying-out the external postal TLD audits in teletherapy centres since 1991. Regular yearly audits runs have been carried out in reference conditions since 1999. Regular yearly audit runs have been extended to non-reference conditions since 2003.

The external postal quality audits of dosimetry proved to be very effective means of assuring the quality of dosimetry. The differences of ± 3.5% between the dose reported by the participant and the dose measured by the SSDL are considered as acceptance level (being also an intervention level). This value is consistent with the IAEA rules concerning audits of the SSDLs. The adoption of the intervention level, by the Polish SSDL, as low as ± 3.5% was possible due to relatively small number of radiotherapy centres and to easy contact with them.

Since 2006 the audits have been carried out in a variety of non-reference conditions: off-axis (symmetric and asymmetric fields) and for fields formed by MLC. The nation-wide runs of the off axis measurements for symmetric fields have been performed. The results of the audit in non-reference conditions for on axis measurements are in the majority of cases within the 3.5% tolerance limit which is usually used for reference conditions.

The results of the pilot studies for off-axis (symmetric and asymmetric fields) geometry and for irregular fields formed by MLC show that it is possible to keep the dose determination within tolerance limits by the implementation of correct methodology and carefully carried out measurements and calculations of doses. The nation-wide audit, off-axis for symmetric, asymmetric and irregular fields, show that measurements may be held within the ±5% limit.

At present, a system of external clinical audits based on IAEA QUATRO methodology is being prepared in the framework of IAEA national project POL/6/008. The clinical audits in Poland will become compulsory from the beginning of 2009.

Audit in Greatpoland Cancer Center as an example of the national system for clinical audit [40]

Fundowicz M, Greatpoland Cancer Center, Poznan, Poland

The order of the Minister of Health on "Ionizing radiation use safety" 25/08/2005 in article 44 specifies regulations for internal audit. The director of the hospital passes a written instruction to conduct the audit once a year. In Greatpoland Cancer Center (GCC) there has been appointed an interdisciplinary audit group, consisting of a radiation oncologist, a medical physics and a medical engineer. The group verifies the accordance of medical protocols, decision of appropriate to the treatment, process of the treatment plan and radiotherapy scheme, patient dosimetry in-vivo, portal verification and patient radiation protection. In accordance with the order in GCC there have been implemented treatment procedures which are adjusted to the hospital equipment. A decision to start radiotherapy in GCC is based on two documents: first - clinical procedures, second – therapeutic protocols describing all mandatory procedures performed to ensure safe and proper treatment of the patient. Quality systems have been implemented. GCC has ISO 9001:2000. In conformity with article 7.3 of Council Directive 97/43 Euratom all the employees of Radiotherapy and Radiology Departments have completed a course on patient radiation protection. Moreover, GCC has organized numerous courses on new technologies which are being introduced in the clinic. The results of the internal clinical audits in GCC have always been positive. However, there have been disclosed some minor imperfections in the protocols, which have been corrected. These resulted in the introduction of some changes in the treatment protocol. The document has also been supplemented with a patient immobilization form, which facilitates a proper patient arrangement on the treatment table. Article 45 the Minister of Health describes external audit. It consists of two parts: audit of procedures and dosimetry audit. External audit is organized and supervised by Oncological Radiotherapy Commission. After completing the audit, the Commission, the director of hospital, radiation oncology consultant and medical physics consultant are provided with the report. On GCC there has been such an audit conducted by IAEA in 2008, and GCC is currently expecting to be provided with its results. Polish law is adjusted to European regulations. Audits allow to supervise and unify the safety procedures in ionizing radiation in oncology units.

Clinical audit on quality indicators in radiotherapy selected for pathologies [41]

M.Amichetti[1], C.Capirci[2], E.Emiliani[3], G.Gardani[4], P.Olmi[5], A.Rosi[6], G.Silvano[7], R.Valdagni[8], V.Viti[6]
[1] ATreP, Agenzia provinciale per la Protonterapia, Trento, Italy
[2] UO di Radioterapia Oncologica, Ospedale S. Maria della Misericordia, Rovigo, Italy
[3] Servizio di Radioterapia, Ospedale Santa Maria delle Croci, Ravenna, Italy
[4] UO di Radioterapia Ospedale San Gerardo Monza ed Università la Bicocca, Milano, Italy
[5] Dipartimento di Radioterapia Istituto Nazionale per lo studio e la cura dei Tumori, Milano, Italy
[6] Dipartimento di Tecnologie e Salute, Istituto Superiore di Sanità, Roma, Italy
[7] Struttura Complessa di Radioterapia Oncologica, Presidio Ospedaliero SG Moscati, Taranto, Italy
[8] Direzione Scientifica, Istituto Nazionale per lo Studio e la Cura dei Tumori, Milano, Italy
on behalf of Working Group on quality indicators in radiotherapy selected for pathologies

The auto-evaluation indicators should be used in the framework of programs of continuous quality improvement to monitor services and characteristics of a Radiotherapy Centre during a program of accreditation or clinical audits.

Indicators are designed not only to identify structures of excellence, but mainly to assess operative conditions and draw up plans of action to provide a continuous quality improvement. A comprehensive indicator system should encompass structural, process and outcome dimensions, should produce information useful for decision making and should become both a sign and a source of motivation for quality commitment.

A research project " Quality indicators in radiotherapy selected for pathologies" have been funded by the Italian Ministry of Health for the development of the voluntary program of accreditation for radiotherapy based on the definition of several indicators for different pathologies: gynaecologic tumor, breast, lung, prostate, rectum, bone metastasis, and head and neck cancer have been selected.

A working Group for each pathology has been constituted involving, in a multidisciplinary approach, radiation oncologists, medical physicists and radiation technologists. Among the indicators to be defined, only one indicator of structure, at least one indicator of outcome and the remaining as indicators of process have been requested. Numerical values for the standards have been selected from the international literature, when present, and from Italian guidelines on radiotherapy or, empirically, on the basis of the experience of the Centres participating in the project. Sources, as well as limits, of applicability of the standards have been given for each indicator.

Therefore, the overall working program comprised three different steps:

1) identification and definition of the indicators;
2) data collection in the participating Centres of Radiotherapy and Medical Physics Departments;
3) analysis and evaluation of data.

30 Centres have been invited to participate in data collection; (18 Centres operating in Hospitals, 8 in Universities and 4 in IRCCS (*Institutes of Research and Therapy with Scientific Character*)). Each Centre has been asked to collect data for at least two pathologies. Final participation to clinical audit was:

Patology	Gynaecologic tumor	breast	bone metastasis	lung	prostate	rectum	head&neck
# of Centres	8	16	7	10	16	14	8

The capability of the proposed indicators as a tool to monitor the treatment quality has been widely demonstrated. In the present communication the final set of indicators will be presented along with comments on their applicability. Results of the clinical audit will be presented and discussed.

Norwegian Experience with Workshop as a Clinical Audit Tool for Radiotherapy of Specific Cancer Diagnoses [42]

Bernt L. Rekstad, Sverre Levernes, Ingrid E. Heikkilä, Dag Clement Johannessen, Eric Sundqvist, Hans Bjerke, Taran P. Hellebust, Hilde Olerud, Gunilla Frykholm, KVIST group, Norwegian Radiation Protection Authority (NRPA), Østerås, Oslo, Norway

The Norwegian Radiation Protection Authority (NRPA) has with the establishment of its radiotherapy quality assurance group (KVIST) in 2000, been a driving force in improving the quality of radiotherapy of cancer patients in Norway. This is achieved through a wide range of activities covering e.g. target volume definitions, statistical reports of activity, a national system for reporting treatment errors, dosimetry, radiotherapy guidelines and clinical audits.

A major annual event hosted by the KVIST group is the multidisciplinary "Norwegian radiotherapy meeting" gathering oncologists, physicists and radiotherapy technologists from all over the country. Invited lectures, presentations from different centres and discussions are part of the programme. The main issue is a workshop on radiotherapy of a specific diagnosis.

Planning the workshop includes choice of diagnosis and preparing cases for centre home work before the workshop. The clinical cases consist of two or three anonymous patient histories and CT-image sets for treatment planning. The first workshop in 2006 focused entirely on delineation of target volumes and organs at risk. Later meetings included treatment planning with field set-ups and dose distributions. Data from all centres have been compiled by the KVIST group. So far rectal, lung, prostate and breast cancer have been examined.

Two or three centres are asked to prepare a presentation of the cases on how they define treatment volumes, organs at risk, (presented by an oncologist) and their way of making a typical treatment plan (presented by a physicist or technologist). Members of the KVIST group present compiled data from all centres on selected CT-slices, both to demonstrate consensus and highlight differences. A multidisciplinary expert panel appointed by the KVIST group and national diagnosis working parties lead the sessions.

After the meeting, results are summarised in a report and presented by a national video conference making major points available to all radiotherapy centres. Guidelines may be changed as a result of inputs and discussions during and after the work shops.

The presentation will focus on this kind of meetings as a method of clinical auditing with this year's breast cancer workshop as a main example. The impact these meetings have on quality assurance of radiotherapy in Norway will also be discussed.

Practical aspects of the implementation of QUATRO audits in Europe [43]

J. Izewska, E. Salminen, S. Steyskal
International Atomic Energy Agency, Vienna, Austria

Since 2006 the IAEA has operated a series of projects in Africa, Asia, Europe and Latin America involving the Quality Assurance Team for Radiation Oncology (QUATRO). These projects focus on providing comprehensive audits to radiotherapy centres to improve their practices. The details of the QUATRO methodology are given in "Comprehensive audits of radiotherapy practices: a tool for quality improvement" published by the IAEA in 2007.

The operations of QUATRO are based on the use of three experts in the audit teams: a radiation oncologist, a medical physicist and a radiotherapy technologist. The aim of QUATRO is to review the entire radiotherapy chain, including patient-oriented and technical processes, as well as the organization and infrastructure. QUATRO also reviewes the professional competence, training programmes and research at the audited centre. The review is made bearing in mind the criteria of good radiotherapy practices, such as those described in the IAEA publication on design and implementation of radiotherapy programmes. The audit puts emphasis on radiotherapy structure and process rather than treatment outcome. The QUATRO methodology is applicable in a range of economic settings.

The success of an audit depends on thorough preparation of all parties involved, including the participating centre, the audit team and the IAEA. All QUATRO audits are conducted in a consistent manner. They are of five days duration. They start with the entrance briefing, followed by the tour of facility, staff interviews, documentation review, physical measurements and observation of working procedures. A series of checklists helps the auditors organize the audit programme and to ensure coverage of all relevant topics. The audit is concluded with the exit briefing where the preliminary recommendations are given to the audited centre. Follow-up missions may be recommended, as appropriate.The complete audit report is issued after the mission.

In Europe, based on voluntary requests, 18 missions have been completed to date including 50% in EU and 50% in non-EU countries. Gaps in technology, human resources and procedures have been identified so that the audited centres are able to document the areas for improvement for current services as well as they receive advice for further development. Some centres have been acknowledged for the operations at a high level of competence.

A 'lessons learned' meeting with both auditors and auditees of Europe region has concluded that QUATRO provides a very useful tool for improvement of radiotherapy practices.

Acknowledgement to QUATRO experts: I. Bruinvis, W. Bulski, M. Coffey, S. Davidson, Y. Davidson, G. Hartmann, I. Kunkler, Y. Lievens, B. Maciejewski, F. Milano, J. Novotny, H. Nystroem, A. Osztavics, B. Pastoors, P. Scalliet, P. Sipilae, M. Smoke, B. Smolinska, P. Strojan, G. Vandevelde.

The role of the Clinical Oncology Audit Sub-Committee (COASC) of the Royal College of Radiologists for clinical audits in radiotherapy in the UK [44]

Diana Tait and Karl Drinkwater on behalf of the Clinical Oncology Audit Sub-Committee of The Royal College of Radiologists, UK

The Clinical Oncology Audit Sub-Committee (COASC) of the Royal College of Radiologists (RCR) was established in the early 1990s to facilitate national audit activity. This national activity is coordinated by a designated audit lead in each of the 59 cancer centres (England / Wales). These Leads are responsible for departmental audit and liaise with the college, and other national bodies. A workshop is held annually to bring together Audit Leads and review completed, on-going and future audits.

The introduction of national targets for commencement of radiotherapy dates, and the college's own guidelines on this, has prompted Waiting Times audits in 1998, 2003, 2005 and 2007. These sequential audits were a means of establishing whether or not progress has been made and have provided useful information to inform planning. This, and other, audits are a basis for a dialogue between the college, the Cancer Action Team and the Department of Health.
Other Recent National Audits include:
2001 – National Audit of Radiotherapy in Head and Neck Cancer
2005 – Radiotherapy Dose-Fractionation, Access and Waiting Times
2006 – National Audit of Systemic Therapy Waiting Times
2007 – Single Fraction Radiotherapy for Bone Metastases
2008 – National Audit of Late Effects of Chemotherapy for Cervical Cancer

Use of radiotherapy resources have been addressed in audits of fractionation practice. The most recent one concerned palliative radiotherapy for bone pain and the proportion of patients treated with a single fraction. This has provided a benchmarking tool so that centres can compare their performance with other centres.

The RCR regularly produces guidance documents on various aspects of radiotherapy practice. A current example is a document on verification in radiotherapy exposures. It is now standard practice for these guidelines to include a section on the application of audit so that departments can rapidly establish an audit process and that this can subsequently be compared nationally.

COASC is increasing it's profile in audit training for specialist registrars. A representative from a trainee group sits on the committee and there are plans for COASC to be invoved in formal training. Audit templates, at various levels of development, will be published with their audit requirements. There is about to be an enormous shift in the way audit is carried out. National databases are now maturing and their linkage will allow radiotherapy treatment details to be analysed with other aspects of healthcare, including outcomes. Results will be more immediate with appreciation of trends in provision and outcomes, and the ability to establish regular monitoring. Deficiencies and problems in service output will be identifiable.

We believe that the college has an important role in national audit and that this will contribute to designing our future cancer services.

Clinical quality standards for radiotherapy – a useful tool for clinical audits [45]

Piotr Martenka, Marta Bogusz-Czerniewicz, Julian Malicki, Poland

Clinical audit is not a new concept as it has long been applied in the assessment of the quality of medical practices other than radiological. In these contexts the objectives of clinical audit have generally been specified as follows: (i) improve quality of patient care (ii) educate and train clinicians, (iii) make best use of resources, (iv) improve service delivery. The EC Medical Exposure Directive (MED, 97/43/EURATOM) has introduced this concept also to the medical radiological practices.

The aim of this work was to develop clinical quality standards for radiotherapy for the purpose of clinical audit.

Materials and methods:
Clinical quality standards proposed by authors have been developed based on the review of a) European recommendations passed between 1980 and 2006; articles on quality assurance and quality control standards for radiotherapy published between 1984 and 2008 and current recommendations and guidelines of American, International, European and National bodies (associations, societies, agencies such as AAPM, ESTRO, IAEA, OECI) for QA in radiotherapy.

Results:
In this study standards regarding clinical issues such as completeness of medical records, toxicity monitoring system, imaging modalities used in treatment planning, presence of site specific institutional treatment protocols, maximum quantity of workload per staff and other has been defined. As a result over 120 clinical standards for radiotherapy were developed and divided into the following categories:

1. Patient's referral/ treatment prescription
2. Therapeutic protocol
3. Interdisciplinary approach
4. Communication
5. Treatment planning
6. Verification of treatment planning
7. Conduction of treatment
8. Verification of treatment
9. Treatment termination/cancellation
10. Radiological incidents and accidents
11. Quality control of treatment
12. Reference levels of radiation doses
13. Documentation and records
14. Follow-up
15. Clinical audits

Conclusions:
Development of institutional clinical standards is a key to the successful clinical audit. Proposed clinical quality standards for radiotherapy, can be used by any institution using ionizing radiation for medical procedures. Nevertheless standards are only of value if they are implemented, reviewed, audited and improved and if there is a clear mechanism in place to monitor and address failure to meet agreed standards.

Experiences of Clinical Audit in a Finnish Radiotherapy Department [46]

S. Hyödynmaa and T. Wigren
Department of Radiation Therapy, Tampere University Hospital, Tampere, FINLAND

The Audit

The clinical audit of the radiation therapy department of Tampere University Hospital in Finland (with four linear accelerators, one brachytherapy afterloading unit and a simulator) was carried out in June 2005 by a group of three experts (one oncologist, one physicist and one RT technician). The audit comprised the evaluation of pre-sent document information (quality manual, radiation user's organization etc.) and a subsequent three-day site visit by the group. During the visit selected oncologists and radiation workers were interviewed, samples of medical records were analysed, and instructions and documentation were reviewed. The accuracy of dosimetry was not included in the audit, since it is covered by the audits of the national Radiation and Nuclear Safety Authority.

Audit results

The written report of the audit comprised the findings, observed deficiencies and suggested points of improvement. Also a summary feedback meeting was arranged at the end of the audit. Out of 51 audited topics only two produced a deficiency. In addition to these, ten remarks for improvement were recorded. Two topics produced especially positive comments: the internal auditing was found to be thorough and of good quality, and the documentation of the indications in the medical records for justification of the therapy, and the documentation of the dose delivery to the patient were excellent (in two samples of ten breast cancer patients each, with 24 evaluated items, the proportion of documentation that was judged to be complete was 97.9%).
The following points of development were identified:
1) setting up a system for the follow-up of the radiation therapy outcome and complications
2) improving the written instructions, especially for activities at the radiation treatment units
3) instructions for the utilization of observed errors and incidents in improving the radiation therapy process.

Conclusions

We conclude that the findings were useful for us in two ways. On one hand we received confirmation that generally our procedures in radiation therapy proved to be of good quality. On the other hand we obtained support for the most urgent development areas and could use the report as an outside statement, when seeking resources for the development. In some areas the audit criteria were derived from diagnostic radiology, and more specific criteria for radiation therapy need to be developed for the next round of the clinical audit.

Approach the National Quality Audit System for Radiotherapy in Latvia [47]

Sandija Plaude[1], Sergey Popov[1], and Yuri Dekhtyar[2]
[1] Latvian Oncology Centre of Riga Eastern Clinical University Hospital, Riga, Latvia
[2] Riga Technical University, Riga, Latvia

Increasingly complicated Conformal Radiotherapy (RT) technique is used in the clinics worldwide for patient treatment. Intensity Modulated Radiotherapy (IMRT) is one of such the techniques, that is gaining increasingly widespread use.

IMRT is used in Latvian Oncology Centre of the Riga Eastern Clinical University Hospital. Currently since 2003 Majority the IMRT patients are with head and neck tumors and only some patients with breast tumors. There are also ambitions to employ IMRT for patients with other localizations.

Before IMRT patient receives treatment, there is a need in accurate Quality Control of dose delivery and dose calculation systems, patient related dosimetry and treatment plan verification. All the checks and measurements are made according to International guidelines.

Presently the Latvian Oncology Centre is only clinic in Latvia with Conformal RT and IMRT capacity. Conformal RT will be available at the other three clinics in Latvia in next year. Therefore, Quality Audit for conformal RT including IMRT becomes a very important issue at the National level.

It is very important to create National Quality Audit system in RT to ensure accurate conformal RT delivery. It is necessary to develop an Audit system to inspect all Conformal RT and IMRT delivery net of all hospitals that will exploit the Quality checks of linear accelerator, Multileaf Collimator (MLC) system, RT simulator and/or Computer Tomography (CT) scanner used for virtual simulation, target and tissue delineation process, plan evaluation, and delivery. Errors at any step of the IMRT or Conformal RT can lead to catastrophic mistakes in dose delivery. All the checks and measurements must be well defined, documented and put into practice to ensure more precise, accurate and qualitative patient treatment. In addition, to the requirements for linear accelerator, IMRT demands accurate positioning of the MLC leaves. There are a series of tests that should be performed on an MLC to validate its use in both static cases (conformal RT) and dynamic delivery. At the same time the patient related Quality control is an important part of Quality Assurance program. The core problem is the comparison between calculated and measured dose distribution as well as patient positioning.

Within the framework of National Quality Audit for Conformal RT and IMRT it would be possible to control local Quality Control of each above mentioned treatment delivery chain and to provide intercommunication and exchange of experience. To reach this a complete documentation and appropriate execution that encompass all technical and dosimetry data is necessary to develop.

Self-Evaluation Indicators for Head and Neck Tumors [48]

*P.Olmi**
**Chief of Radiotherapy Dept. of National Institute of Health*
and AIRO°,AIFM§, ISS^ Study Group
(G.Balasso°, F.Grillo Ruggieri°, S.Maggi§, G.Pavanato°, C.Soatti°, P.Zorat°, M.Luzi^, P.Morosini^, P.Roazzi,^ A.Rosi^, V.Viti^)

Aims

The self-evaluation indicators represent useful tools to monitor the services, the performances and other peculiar features of a health structure in the frame of a programme of continuous quality improvement, for projects of certification or clinical audits.

In 2002 a booklet was published by the Istituto Superiore di Sanità (ISS), Rapporto Istisan 02/2, on general evaluation indicators to be used as measurement tools in radiotherapy centers. Those indicators were elaborated by a Working Group (including radiation oncologists, radiotherapists, physicists) altogether with physicists and biologists of the Technology and Health Department of the ISS.

After that, a project of ISS, supported by a grant of the National Health Service Ministry, was approved in 2002 and finished in 2005: it was devoted to the development and application of evaluation indicators for different pathologies, among which the head and neck (H&N) tumors.

The Working Group of H&N indicators decided to choose common indicators for the different subsites of this anatomy district, selecting features fitting to the quality of radiotherapy treatment. After the elaboration, the indicators have been validated by 8 radiotherapy centers to verify their applicability.

Material and Methods

The proposed indicators for H&N tumors are 7, concerning the following matters:

H&N 01- waiting time for post-operative radiation therapy

From the literature data it is well known that an interval longer than 45 days can compromise the benefit achievable with post-op RT planned for patients at high-risk of relapse. According to recent criteria, a period of 100 days from the operation day and the end of RT may be considered the ideal interval time.

H&N 02 – waiting time for exclusive RT with curative intent

A waiting time no longer than 30 days is the time, in which the disease and symptoms tend to be stable.

H&N 03 –CT simulation

The CT images are used to define the treatment volumes according to a standard nomenclature (GTV, CTV, PTV and OAR) with slice spacing of 3 to5 mm. The CT-based treatment planning is mandatory for modern techniques as 3D-CRT (3-Dimensional Conformal Radiation Therapy and IMRT (Intensity Modulated Radiation Therapy), and is useful also for 2-D techniques.

H&N 04, 05 – multimodality approaches and written guidelines

The multidisciplinary approach with collegial decision-making, written and shared guidelines can assure the best treatment for the patient.

H&N 06 – Staging MR/CT

The clinical assessment of the stage uses information from physical examination, imaging, endoscopy and biopsy. A modern diagnostic imaging is essential for treatment planning also in cases previously operated on, who undergo to RT for high-risk factors of relapse, in order to outline the CTV.

H&N 07 – interruptions caused by acute toxicities

In the H&N radiotherapy treatment the interruptions are generally caused by intense mucositis; prolonged interruptions can compromise the outcome measured as loco-regional control. No interruptions even in presence of grade 3 and 4 mucositis, is a synonym of adequate supportive therapy and can assure the best results.

Conclusions

The outcome of the audit has been judged positively, the records resulted appropriate and understandable: furthermore, they resulted very suitable for the aims.

The Norwegian Program on Quality Assurance in Radiotherapy (KVIST) – Organisation, Benefits and Experiences During Seven Years [49]

Sverre Levernes, Taran P. Hellebust, Ingrid E. Heikkilä, Dag Clement Johannessen, Gunilla Frykholm, Hans Bjerke, Bernt L. Rekstad, Eric Sundqvist, Hilde M. Olerud. The Norwegian Radiation Protection Authority (NRPA), Østerås, Oslo, Norway

As a part of the national cancer strategy, the Norwegian Radiation Protection Authority (NRPA) was engaged from the Ministry of Health to develop a national quality assurance programme in radiotherapy in the late nineties. A multidisciplinary group (oncologists, medical physicists, RT technologist) has been allocated to the task since 2000; all experienced professionals in shared positions between a RT department in a hospital and the NRPA. This group, named the "KVIST group", coordinates a national reference group which again proposes task groups with a range of mandates, all with consideration to multicenter representation and in close collaboration with the medical societies. The aim is to stimulate collaboration by focusing on clinical, technical and administrative problems that can be solved through a national plan. An important objective is to establish a positive attitude towards quality assurance and better communication between centres and the various professions involved in radiotherapy.

The KVIST initiative has been a driving force in improving the quality of radiation treatment of cancer patients on a national basis, and has caused a range of harmonised national recommendations. This is achieved through a wide range of activities covering e.g.

- A system of annual reporting and documentation of radiotherapy activities in Norway provides useful statistics both for the hospitals in evolving their own quality systems, and for information to the health authorities.
- An extranet solution serving the KVIST reference group, the working groups, the RT departments, the medical society and the health authorities, is under construction.
- A national system for reporting treatment errors is implemented as a part of the hospital quality systems, and condensed statistics sent annually to KVIST.
- The IAEA dosimetric protocol (TRS 398) has been implemented in the hospitals. In close collaboration with NRPA's secondary standard dosimetry laboratory (SSDL), dosimetry revisions were performed in 2004 and will be provided again in 2008.
- KVIST provides two phantoms for quality control of the non-dosimetric information exchange between different data systems in the radiotherapy chain.
- A post-qualifying educational system for medical physicists with calculus exercises is provided. This is particularly useful in Norway since we do not have formal system for authorization of medical physicists.
- A mutual understanding of the target volume definitions (the new ICRU report on this topic is anticipated).
- A common radiotherapy prescription form is in course preparation with necessary parameters for radiotherapy, also to be used as a tool to register intended treatment.
- A system for clinical audits have been developed and tested on the treatment of bone metastases in 2002–2004. In 2008 we will further develop this method for treatment of breast cancer.
- As a national reference standard for clinical audits, radiotherapy guidelines are needed. Per 2008 draft guidelines are provided for gastro intestinal cancer and lung cancer, furthermore, work have been initiated to provide guidelines for prostate cancer and lymphomas.
- KVIST has established the Norwegian Radiotherapy Meeting, an annual meeting where oncologists, RT technologists and physicists meet to discuss radiotherapy related issues. Workshops dedicated specific cancer diagnoses are also arranged as part of these meetings.

Information about the KVIST initiative and ongoing work is found on www.nrpa.no (search KVIST). An updated information booklet on English will be published for the conference.

Seven years experience with external and internal clinical audits at a Radiation Oncology Department at an Oncology Hospital in Spain [50]

S. Marín, M. Macià, M. Ventura, Marta Ballart, David Leon and F. Guedea.
Department of Radiation Oncology
Institut Català d'Oncologia. Catalonia.

In 1988, to comply with the EURATOM directive, the Spanish Government approved a Royal Decree on quality assurance in radiation oncology. This new law obligated all Radiation Therapy Departments in Spain to establish a quality control system.

In 2001, our department chose to implement the ISO 9001 norm for quality assurance. After putting our processes, procedures, and circuits into writing, we informed staff member of the ISO methodology and started to measure our performance. A list of indicators was constructed and most staff members participated in all the aspects of the quality management system while some served as internal auditors.

After 2001, several internal and external audits have been carried out and recommendations were made for improving our performance. The results of these audits and the measures implemented to improve and correct deviations of the norm are presented in this presentation. Future directions of the quality assurance system will also be presented.