

APPENDIX 1 Survey Questionnaire and FAQ



March 27-April 27, 2012

PDF file for information only
Please fill in survey online at
https://www.surveymonkey.com/s/EC_lmagingReferralGL_Survey

In case of questions, please contact
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Monika Hierath (monika.hierath@myesr.org)

Availability of Guidelines

IMPORTANT INFORMATION TO SAVE YOU TIME. PLEASE READ FOLLOWING BEFORE STARTING SURVEY.

Imaging referral guidelines are useful in the justification and selection of appropriate radiological and nuclear medicine procedures, help with radiation safety of patients and may enhance cost-effectiveness in health organisations. The European Society of Radiology is leading a project (together with the RCR, SFR, CIRSE and ESPR) sponsored by the European Commission which will guide initiatives to improve the availability of imaging referral guidelines in Europe.

The Council Directive 97/43/Euratom stipulates that member states shall ensure that recommendations concerning referral criteria for medical exposure, including radiation doses, are available to the prescribers of medical exposure.

[Euratom ref. http://ec.europa.eu/energy/nuclear/radioprotection/doc/legislation/9743_en.pdf]

This survey is to assess the current situation in EU member states. Please fill in the survey on behalf of your Organisation. Responses will be treated confidentially.

Representatives of competent authorities (regulatory bodies) are requested to answer only starred questions and need not answer questions regarding guideline methodology.

Technical instructions:

- The survey does not have to be completed in one sitting; it can be saved and re-accessed via the link provided in the invitation email at any point of time until the closing date. Please complete the survey at the SAME WORKPLACE (same IP address) and within the SAME BROWSER in which it was started. This is necessary to identify you correctly as the same participant.
- Every given answer is saved immediately, therefore no replies will be lost if the survey is not completed in one sitting
- Answers can be amended until the closing date of the survey; please just re-enter the survey and select the new answer for the concerned question(s).
- Square check boxes stand for questions that allow multiple answers to be selected; round radio buttons only enable the selection of 1 answer per question.
- Starred questions (*) are mandatory.
- For navigation, please use the two buttons (PREV or SAVE AND NEXT) at the bottom of the page, NOT the arrows on the browser".

Please fill in all full-text answers in English.

Availability of Guidelines

*2	2. Please indicate if you are responding on behalf of a
0	National radiology society
0	National nuclear medicine society
0	Competent authority (regulatory/advisory body)
*2	3. Please give the name in English of the organisation on whose behalf you are
	npleting the questionnaire:
*4	l. Please indicate your Member State / Country:
	i. Does your Member State have a legal requirement for imaging referral guidelines luding radiation doses ("Guidelines")?
0	Yes
0	No
0	Don't know
*6	5. Does your Member State transfer responsibility for making Guidelines available?
0	Yes
0	No
0	Don't know

Availability of Guidelines

*7. To wh	om is responsibility transferred?
☐ Departmen	ats/ministries of health (competent authorities)
☐ Health orga	anisations
☐ Hospital/en	nployers
Professiona	al organisation
Referring n	nedical practitioners
Other (plea	ise specify)

Availability of Guidelines

*8. Does your Member State recommend (please tick all that apply):
☐ Non-European Guidelines
☐ European Guidelines
☐ National Guidelines
☐ Local Guidelines
None of the above
Other (please specify)

EC Survey on Imaging Referral Guidelines					
Availability of Guidelines					
9. Please specify which Non-European Guidelines your Member State recommends:					

Availability	of Guidelines
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C Yes (please spec	ify below)							
O No								
C Don't know								
If yes, please specify r	equirements (partic	ularly regarding	pre-authorisa	ation of proced	lures by insu	ers).		
, , , , , , , , , , , , , , , , , , , ,	The state of the s		~		,	,		
*11. In your N professionals	make reque	sts: Radiographic				lowing grou		ealthcare
	radiography	contrast procedure	US	СТ	MRI	radiology	PET-CT	medicine
General practitioner								
Emergency dept. clini	cian \square							
Specialist / hospital do	octor							
Chiropractor								
Nurse								
Physiotherapist								
Other [please specify pelow]								
Other								
*12. In your Neferral from a		•		lities can	a patie	nt self-pres Interventional radiology	ent (wit	hout Nuclear medicine
Patient								
*13. In your Nappropriatence O Yes No								idelines

National Guidelines

14. The following section relates to the development of Guidelines which may not be relevant to representatives of competent authorities (regulatory bodies) who need not answer this section.
Representatives of competent authorities who do not wish to answer the section on Guideline development, please tick the box to go on to the next section.

Please state source:

Respondents from competent authorities need not answer questions on this page. 15. Are these Guidelines: Imaging Guidelines including radiation doses issued by a single source Imaging Guidelines including radiation doses from multiple sources Clinical Guidelines with imaging guidance including radiation doses None of the above (please specify nature of Guidelines): 16. Please give the name of your Guidelines in English: Main Guidelines (to which further questions refer) Additional Guidelines (if applicable) 17. What is the source of the National Guidelines? (please select best option) Nationally developed Modified from another recognised source (please state source below) Adopted without modification from another recognised source (please state source below)

EC Survey on Imaging Referral Guidelines **National Guidelines** Respondents from competent authorities need not answer questions on this page. 18. Please give the web address of your Guidelines (if available): 19. Which organisation(s) were involved in the development of your Guidelines? Please give the name(s) in English. 20. Which specialty groups took part? Please give the name(s) in English. 21. Please give the year of the first edition of your Guidelines: 22. Please indicate the approximate duration of the review cycle in years (period between editions). ▼ |

National Guidelines: Financing

Res	spondents from competent authorities need not answer questions on this page.
23.	What is the model (source) of funding (financing)? (Please indicate all that apply)
	Licensed distribution / sales
	Development grant
	Funded by Ministry/Department of Health
	Funded by other governmental department (please specify below)
	Commercial support
	Philanthropic donation
	Issuing organisation funded
	Other (please specify below)
Plea	se specify:

National Guidelines: Scope

Res	spondents from competent authorities need not answer questions on this page.
24.	Which imaging modalities are included in your Guidelines? (Please indicate all that
app	oly)
	Plain radiography
	Radiographic contrast procedure
	Ultrasound
	СТ
	MRI
	Interventional radiology
	Nuclear medicine
	PET-CT
	Other (please specify)
25.	Is there separate guidance for children?
	Yes
0	No
0	Don't know
26.	Is there guidance for the pregnant woman and the unborn child?
0	Yes
0	No
0	Don't know

EC Survey on Imaging Referral Guidelines 27. Which groups of diseases / medical conditions are covered for adults? (Please indicate all that apply) ☐ Breast Cancer Cardiovascular Chest ENT/Head and Neck Endocrine Gastrointestinal Gynaecology Musculoskeletal Neurological Obstetrics Trauma Urogenital 28. Which groups of diseases / medical conditions are covered for children? (Please indicate all that apply) ☐ Breast Cancer Cardiovascular Chest ■ ENT/Head and Neck Endocrine Gastrointestinal Gynaecology Musculoskeletal Neurological Trauma ☐ Urogenital

Gynaecology Musculoskeletal Neurological Trauma Urogenital 29. What do your Guidelines focus on? (Please indicate all that apply) Clinical presentations and their imaging investigations Imaging procedures and their indications

Routinely Occasionally Never Strength of evidence C C C C C C C C C C C C C C C C C C C	C Survey on Imaging Referral Gational Guidelines: Development	duidelliles		
Strength of evidence Grading of recommendation Cockeffectiveness Cost-effectiveness Cost-effectiveness Cost-effectiveness Cost-effectiveness Cost-effectiveness Cost-effectiveness Cost-effectiveness Cockedited and the second	Respondents from competent authorities need not a	answer questions on this	page.	
Strength of evidence Grading of recommendation Cockeffectiveness Cost-effectiveness Cost-effectiveness Cost-effectiveness Cost-effectiveness Cost-effectiveness Cost-effectiveness Cost-effectiveness Cockedited and the second	30. In developing an individual Guidelin	e, which of the follo	wing were cons	idered?
Grading of recommendation Grading of recommendation using a recognised system? Grading ref. http://www.gradeworkinggroup.org/publications/index.htm http://www.bmj.com/content/328/7454/1490.full.j) Grading ref. http://www.gradeworkinggroup.org/publications/index.htm http://www.bmj.com/content/328/7454/1490.full.j) Grading ref. http://www.gradeworkinggroup.org/publications/index.htm		Routinely	Occasionally	Never
Radiation doses Cost-effectiveness Cost-effe	Strength of evidence	O	0	O
Cost-effectiveness C	Grading of recommendation	O	O	0
Availability of equipment/expertise C C C C S1. Do you use recognised evidence levels (hierarchy of evidence) in your process Yes No Don't know If yes please specify (eg Centre for Evidence-based Medicine [ref http://www.cebm.net/index.aspx?o=1025]; Fryback and Thornbury [ref. http://www.ajronline.org/content/176/4/873.full.pdf+html]): 32. Do you apply a grading of recommendation using a recognised system? Yes No Don't know If yes please specify (eg GRADE; AHRQ [Grading ref. http://www.gradeworkinggroup.org/publications/index.htm http://www.bmj.com/content/328/7454/1490.full]) 33. Was a recognised process of consensus used? (please indicate all that apply) (Consensus ref. http://www.bmj.com/content/311/7001/376?sso=]	Radiation doses	O	0	0
31. Do you use recognised evidence levels (hierarchy of evidence) in your process Yes No Don't know If yes please specify (eg Centre for Evidence-based Medicine [ref http://www.cebm.net/index.aspx?o=1025]; Fryback and Thornbury [rhttp://www.ajronline.org/content/176/4/873.full.pdf+html]): 32. Do you apply a grading of recommendation using a recognised system? Yes No Don't know If yes please specify (eg GRADE; AHRQ [Grading ref. http://www.gradeworkinggroup.org/publications/index.htm http://www.bmj.com/content/328/7454/1490.full]) 33. Was a recognised process of consensus used? (please indicate all that apply) Consensus ref. http://www.bmj.com/content/311/7001/376?sso=]	Cost-effectiveness	0	0	0
 Yes No Don't know If yes please specify (eg Centre for Evidence-based Medicine [ref http://www.cebm.net/index.aspx?o=1025]; Fryback and Thornbury [rhttp://www.ajronline.org/content/176/4/873.full.pdf+html]): 32. Do you apply a grading of recommendation using a recognised system? Yes No Don't know If yes please specify (eg GRADE; AHRQ [Grading ref. http://www.gradeworkinggroup.org/publications/index.htm http://www.bmj.com/content/328/7454/1490.full]) 33. Was a recognised process of consensus used? (please indicate all that apply) Consensus ref. http://www.bmj.com/content/311/7001/376?sso=] 	Availability of equipment/expertise	0	O	\circ
C Yes C No C Don't know If yes please specify (eg GRADE; AHRQ [Grading ref. http://www.gradeworkinggroup.org/publications/index.htm http://www.bmj.com/content/328/7454/1490.full]) 33. Was a recognised process of consensus used? (please indicate all that apply) [Consensus ref. http://www.bmj.com/content/311/7001/376?sso=]	If yes please specify (eg Centre for Evidence-based Medicine [re	ef http://www.cebm.net/index.as	px?o=1025]; Fryback and	d Thornbury [ref
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Consensus ref. http://www.bmj.com/content/311/7001/376?sso=]	If yes please specify (eg Centre for Evidence-based Medicine [rehttp://www.ajronline.org/content/176/4/873.full.pdf+html]): 32. Do you apply a grading of recommendation of the commendation of the commendat	ndation using a rec	ognised system	
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☐ Delphi process	If yes please specify (eg Centre for Evidence-based Medicine [rehttp://www.ajronline.org/content/176/4/873.full.pdf+html]): 32. Do you apply a grading of recommendation of the commendation of the commenda	ndation using a rec w.gradeworkinggroup.org/public nsus used? (please	ognised system ations/index.htm	ı?
	If yes please specify (eg Centre for Evidence-based Medicine [rehttp://www.ajronline.org/content/176/4/873.full.pdf+html]): 32. Do you apply a grading of recommendation of the commendation of the commenda	ndation using a rec w.gradeworkinggroup.org/public nsus used? (please	ognised system ations/index.htm	1?

Radiation dose	
Cost-effectiveness	
If yes to one or both, please specify:	
25 Total number of clinical cond	itions/diagnostic problem
35. Total number of clinical cond	itions/diagnostic problen
36. If recommendations are grade	ed, please indicate the n
Grade A recommendations	
Grade B recommendations	
Grade C recommendations	
Grade D recommendations (if any)	

Respondents from competent authorities need not answ	er questions on	this page.						
37. In which format(s) are your Guidelines available?								
	Free to all	Free to society members	For purchase	Not available				
Print (paper copy)								
Downloadable digital version								
Web version (password protected)								
Web version (not password protected)								
PDA/tablet (app)								
Smartphone (app)								
Providers of the service (eg, radiologists, radiographers)								
Referrers (general practitioners)								
Referrers (emergency dept. clinicians)								
Referrers (specialists / hospital doctors)								
Referrers (non-medical healthcare professionals)								
☐ Medical students								
Funders (eg, healthcare commissioners, medical insurers)								
☐ The public								

National Guidelines: Dissemination Respondents from competent authorities need not answer questions on this page. 39. Do you advocate or recommend reinforcement of Guidelines by (please indicate all that apply): Periodic reminders Educational messages Other If yes to "other" please specify: 40. Have your Guidelines been incorporated into clinical decision support systems (CDSS)? [CDSS ref. http://www.ncbi.nlm.nih.gov/pubmed/17412171 http://www.jacr.org/article/S1546-1440(10)00389-3/abstract] Yes (please specify below) O No O Don't know If yes, please specify: 41. For what other purposes have your Guidelines been used? (please indicate all that apply) ☐ For education By healthcare providers for planning local services □ By health insurers ☐ By departments of health for planning national services For academic/research purposes

Future Developments In addition to the above questions member states are invited to explore how, in the future, they may wish to meet the requirements of MED 97/43 (Article 6.2: Member states shall ensure that recommendations concerning referral criteria for medical exposures, including radiation doses, are available to the prescriber of medical exposures).

EC Survey on Imaging Referral Guidelines

Type of Guidelines

*42. Please rate the level of support of your Organisation for the following models for imaging referral guidelines.

	1 (oppose)	2	3	4 (neutral)	5	6	7 (support)	N/A
a. Pan-European referral Guidelines developed centrally	0	0	0	\odot	\odot	0	0	0
b. European Guidelines developed by combination of multiple national Guidelines agreed by consensus	0	0	0	0	0	0	0	0
c. Adopting, modifying and translating national Guidelines from other member states	0	0	0	0	0	0	0	0
d. Independently produced national Guidelines	0	0	0	0	0	0	0	0
e. Adopting, modifying, and translating non-European Guidelines	0	0	0	0	0	0	0	0
f. Global Guidelines	\circ	0	0	\circ	0	0	0	0

Guideline format

*43. Please rate the level of support of your Organisation for the various Guideline formats listed below.

	1 (oppose)	2	3	4 (neutral)	5	6	7 (support)	N/A
a. Narrative (plain text)	0	0	0	0	\odot	0	0	0
b. Tabular (tables showing initial investigations with alternatives)	0	0	0	\circ	0	0	0	0
c. Flowchart (box and arrow diagrams showing initial and subsequent investigations)	0	0	0	0	0	0	0	0

Media/mode for distribution

*44. Please rate the level of support of your Organisation for the media / modes for distribution listed below.

	1 (oppose)	2	3	4 (neutral)	5	6	7 (support)	N/A
a. Print (paper copy)	0	0	0	0	0	0	0	\odot
b. Web version (password protected)	0	0	0	0	0	0	0	0
c. Web version (not password protected)	0	0	0	0	0	0	0	0
d. Smartphone/tablet (app)	0	0	0	0	0	0	0	0
e. Clinical decision support system (at the point of request incorporating automated, non-mandatory change of modality according to rules based on Guidelines)	O	0	О	0	0	0	0	0
f. Provision of Guidelines through electronic requesting systems (computerised order entry) as a future development	0	0	0	0	0	0	0	0

Potential barriers/challenges to the effective distribution of Guidelines

*45. Does your Organisation see the following as potential barriers/challenges to Guideline availability or use in your Member State? Please rate the level of agreement / disagreement.

Rate the level of agreement on a scale of 1-7 where 1= strongly disagree, 4= neither agree nor disagree, and 7= strongly agree.

	1 (disagree)	2	3	4 (neutral)	5	6	7 (agree)	N/A
a. Limitation of resource (human)	0	0	0	0	0	0	0	\odot
b. Limitation of resource (financial)	\circ	0	0	0	0	0	\odot	0
c. Translation/language barriers	0	0	0	0	0	\odot	0	0
d. Dissemination / distribution barriers	\circ	0	\circ	0	0	0	0	0
e. Awareness, access and acceptability	0	0	0	0	0	0	0	0
f. Limited involvement of referring clinicians in the development process	0	0	0	0	0	0	0	0
g. Conflicting Guidelines from multiple sources	0	0	0	0	0	\odot	0	0
h. Lack of support or endorsement by ministries of health	\odot	0	0	\circ	0	0	\odot	0

Suggestions of solutions to barriers limiting the availability of Guideline...

46. Would your Organisation support the following solutions to barriers limiting the availability of Guidelines?

Rate your level of support on a scale of 1–7, where 1 is strongly oppose, 4 is neither oppose nor support and 7 is strongly support.

	1 (oppose)	2	3	4 (neutral)	5	6	7 (support)	N/A
 a. Clinical decision support systems (for automated, non-mandatory change of clinican-requested modality according to rules based on Guidelines) 	0	O	0	О	0	0	0	0
b. Provision of Guidelines through electronic requesting systems (computerised order entry) as a future development	0	0	0	0	0	0	0	0
c. Education (undergraduate, specialist and continuing professional education)	0	0	0	0	0	0	0	0
d. Involvement of referring clinicians	0	0	0	0	0	0	0	0
e. Other (please specify below)	0	0	0	0	0	0	0	0

Oti	
	Α.
	7

Other

Preferred methods for monitoring Guideline use

47. Does your Organisation support the following methods for monitoring Guideline use?

	1 (oppose)	2	3	4 (neutral)	5	6	7 (support)	N/A
a. Local internal clinical audit	0	0	0	0	0	0	0	0
b. External clinical audit	0	0	0	0	0	0	0	0
c. Voluntary reporting	0	0	0	0	0	0	0	0
d. Inspection by regulatory body	0	0	0	0	0	0	\circ	0

C Survey on Imaging Referral Guidelines	
48. Please feel free to include further comments, inform We are particularly interested to hear of good practices	
	A



EC SURVEY ON IMAGING REFERRAL GUIDELINES IN EUROPE

Frequently Asked Questions

1. What is Euratom 97/43?

The Council Directive, Euratom 97/43 was issued in 1997 to direct Member States of the European Union in radiation protection matters. One important element of this directive is the requirement that member states shall ensure that recommendations concerning referral criteria for medical exposure, including radiation doses, are available to the prescribers of medical exposure.

[Euratom ref. http://ec.europa.eu/energy/nuclear/radioprotection/doc/legislation/9743 en.pdf]

2. Who are the ESR/RCR/SFR/CIRSE/ESPR?

The following organisations are the partners of a consortium led by the European Society of Radiology for this European Commission (EC) project to assess availability of guidelines in Europe and to recommend future directions:

European Society of Radiology (ESR) – http://www.myesr.org/cms/website.php?id=/en/eu_affairs/newfilename.htm

Royal College of Radiologists (RCR) – http://www.rcr.ac.uk/

La Société Française de Radiologie (SFR) - http://www.sfrnet.org/

Cardiovascular & Interventional Radiology Society of Europe (CIRSE) - http://www.cirse.org/

European Society of Paediatric Radiology (ESPR) - http://www.espr.org/

3. Where can I see examples of imaging referral guidelines?

Online and print copies of imaging referral guidelines can be obtained at the following web addresses

RCR - iRefer Making the best use of clinical radiology 7e http://www.rcr.ac.uk/content.aspx?PageID=995

SFR – Le Guide du bon usage des examens d'imagerie médicale http://www.sfrnet.org/sfr/professionnels/5-referentiels-bonnes-pratiques/guide-bon-usage-examens-imagerie-medicale/guide-en-ligne/index.phtml

EC – Radiation Protection 118 http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/118_en.pdf

4. Who should complete the questionnaire?

The questionnaire should be completed on behalf of the organisation and should reflect the organisation's opinions, not the individual's.

The survey does not have to be completed in one sitting; it can be saved and re-accessed via the link provided in the invitation email at any point of time until the closing date.

EC Tender ENER / 11 /NUCL/S12.6O691 5 – Implementation of Council Directive 97/43/Euratom requirements concerning referral criteria for medical imaging in the European Union



Please complete the survey at the SAME WORKPLACE (same IP address) and within the SAME BROWSER on which it was started to ensure correct identity.

5. What is the PDF version of the survey for?

The PDF version of the survey is not for completion but is available to share with other members of your organisation for the purposes of correct completion of the web questionnaire. If you have a query or require clarification, it is useful to use the numbering of the questions in the PDF version for reference.

6. What are competent authorities?

Competent authorities are the official organisations (usually governmental advisory or regulatory bodies) empowered to execute functions or advise on radiation protection issues.

7. Do representations of the competent authorities need to answer all questions?

The results of the survey are highly dependent on a representative response from all European Member States (and also those countries adopting European legislation). It is essential to complete sections on guideline availability and on future developments but competent authority representatives need not answer questions on national guideline methodology and distribution.

8. What is self-presentation?

Self-presentation is the presentation of an individual for an imaging procedure without a medical referral. This is often done in the context of an individual health assessment or 'whole body health screening'.

9. What is clinical decision support?

Clinical decision support systems use interactive software for healthcare professionals to make choices for improved patient care. These systems usually utilise evidence-based guidance e.g. imaging referral guidelines to help referrers request appropriate imaging procedures usually through a pathway involving input of presenting clinical features in a system with limited fields.

[CDSS ref. http://www.ncbi.nlm.nih.gov/pubmed/17412171
http://www.jacr.org/article/S15461440(10)003893/abstract]

10. What is meant by grade of recommendation?

The grade of recommendation is a measure of either the importance of the recommendation or the strength of evidence informing the recommendation. There are several different systems to grade recommendation.

Eg. GRADE; AHRQ [http://www.gradeworkinggroup.org/publications/index.htm http://www.bmj.com/content/328/7454/1490.full]

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APPENDIX 2 National Guidelines

Imaging referral guidelines in Europe in 2012

Country	Organisation responding	Name of your Guidelines in English	Source of the National Guidelines?	Web address of your Guidelines	Organisations involved in Guidelines development?
Austria	Austrian Society of Nuclear Medicine and Molecular Imaging	Support for Orientation in Radiology	Nationally developed	http://orientierungshilfe.vbd o.at/ (accessed 14.2.13)	
	Austrian Roentgen Society	Guidelines Radiology	Nationally developed	http://orientierungshilfe.vbd o.at/ (accessed 14.2.13)	Austrian Roentgen Society, Austrian Medical Association, Austrian Radiation protection Association, Austrian Association of Medical Imaging
Belgium	Belgian Society for Nuclear Medicine	Recommendations for Medical Imaging	Modified from another recognised source: French guidelines for medical imaging	www.health.belgium.be/richt lijnen-medische- beeldvorming (accessed 14.2.13)	College of Medical Imaging Royal Belgian Society for Radiology Colelgium Radiologicum
	Royal Belgian Radiological Society (RBRS)	The Royal College of Radiologists guidelines (United Kingdom)	Modified from another recognised source: The Royal College of Radiologists guidelines	www.health.belgium.be/richt lijnen-medische- beeldvorming (accessed 14.2.13)	Royal Belgian Radiological Society
Bulgaria	No guidelines identified initially				
Croatia ‡	No guidelines identified initially				
Cyprus	No guidelines identified initially				

Czech Republic ‡	Czech society of nuclear medicine	National radiological standards	Nationally developed	http://www.csnm.cz/society/national-radiologic-standarts (accessed 14.2.13)	Czech society of nuclear medicine Czech society of radiology Czech society of radiation oncology Czech society of interventional radiology state office for nuclear safety Czech association of medical physicists
Denmark	The Danish Society of Radiology	Guidelines from the national institute for radiation protection	Nationally developed	www.drs.dk (accessed 14.2.13) (However these guidelines are not up-to-date since the society has decided to wait for European guidelines. Until these are available we refer to local guidelines at the hospitals and eventually iRefer which has been sent out to all our members)	The Danish Society of Radiology
Estonia ‡	No guidelines identified initially				
Finland	Radiological society of Finland	Radiation safety law	Adopted without modification from another recognised source: Euratom	http://www.stuk.fi/julkaisut maaraykset/viranomaisohjee t/en_GB/stohjeet/ (accessed 14.2.13)	STUK - Radiation and Nuclear Safety Authority

France	French Society of Radiology	Guidelines for appropriate use of medical imaging	Nationally developed	www.sfrnet.org (accessed 14.2.13)	French Society of Radiology French Society of Nuclear Medicine and Molecular Imaging High Health Authority Nuclear Safety Agency
Germany	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety	Guidance Document for Medical Imaging Applications	Adopted without modification from another recognised source: EC RP 118 Ref. Guidelines f. Imaging	www.ssk.de (accessed 14.2.13) (see left side on homepage - German: Orientierungshilfe) Heft 51: Orientierungshilfe für bildgebende Untersuchungen Empfehlung der Strahlenschutzkommission. http://www.ssk.de/SharedDocs/Publikationen/Berichteder SSK/Heft 51.html (accessed 11.03.2013)	German Commission on Radiological Protection (SSK)
Greece	No guidelines identified initially				
Hungary	George Hevesy Hungarian Society of Nuclear Medicine		Modified from another recognised source: EANM	www.nmc.dote.hu/mont (accessed 14.2.13), http://www.szote.u- szeged.hu/nuclear/ (accessed 14.2.13)	Hungarian National Advisory Board of Nuclear Medicine
Ireland ‡	No guidelines identified initially				

Italy	Italian Association of Nuclear Medicine (AIMN)	GUIDELINES AIMN Recommendations on Nuclear Medicine Procedures	Nationally developed	http://www.aimn.it/pubblica zioni/LG/LG.php (accessed 14.2.13)	Italian Association of Nuclear Medicine (AIMN)
	Italian Society of Medical Radiology	Diagnostic Imaging Guideline of National reference	Nationally developed	http://www.sirm.org/index.p hp/component/docman/cat view/78-documenti-di- riferimento?Itemid=135 (accessed 14.5.13)*	State and Regional conference
Latvia	Slovak Society of nuclear medicine and radiation hygiene		Modified from another recognised source: EU recommendations	http://www.ssnm.sk/ (accessed 14.5.13)*	some are part of national legislative
Lithuania	No guidelines identified initially				
Luxembourg	Ministry of Health, Radiation protection Department	Guide of good usage of medical imaging examinations	Adopted without modification from another recognised source: French Society of radiology, French society of Biophysics and Nuclear medicine	www.sfrnet.org (accessed 14.2.13)	French Society of Radiology French Society of Biophysics and Nuclear Medicine
	Luxembourg Society of Radiology	European Commission (doc.118)	Adopted without modification from another recognised source	www.conseil-scientifique.lu (accessed 14.2.13)	national scientific council for Health affairs Luxembourg society of Radiology
Malta	No guidelines identified initially				
Netherlands	Nederlandse Vereniging voor Nucleaire Geneeskinde (NVNG)	Recommendations	Adopted without modification from another recognised source	www.nvng.nl (accessed 14.5.13)*	Nederlandse Vereniging voor Nucleaire Geneeskinde (NVNG)

	Dutch Radiological Society	Dutch Diagnostic Reference Levels phase 1 and phase 2	Nationally developed	en <u>www.referentieniveau.nl</u> (accessed 14.2.13), <u>www.stralingsdosimetrie.nl</u> (accessed 14.2.13)	Royal Institute for Health and Environment (RIVM)
Norway ‡	No guidelines identified initially				
Poland	No guidelines identified initially				
Portugal	No guidelines identified initially				
Romania	Romanian Society of Nuclear Medicine	Guideline of medical practice for Radiology and Nuclear Medicine - Guideline for using Radiology and Medical Imaging procedures	Adopted without modification from another recognised source: French Society of Radiology; French Society of Biophysics and Nuclear Medicine	www.ms.ro (accessed 14.2.13)	Romanian version of the mentioned French Guideline was elaborated by experts of: Romanian Society of Radiology Romanian Society of Nuclear Medicine National Commission for Nuclear Activities Control
	SRIM: Romanian Society of Radiology and Medical Imaging	Good practice in radiology and imaging	Modified from another recognised source	http://www.srim.ro/legislatie/legislatie/(accessed 14.5.13)*	SRIM
Slovakia	Public Health Authority of the Slovak Republic	Referral Guidelines for Imaging	Modified from another recognised source: EC Radiation Protection 118	http://www.slovakradiology.s k/article?element=61&parent ld=214&type=45 (accessed 14.2.13)	Slovak Radiology Society
Slovenia ‡	No guidelines identified initially				

Appendix 2: National Guidelines

Spain	Nuclear Medicine and Molecular Imaging Spanish Society (SEMNIM)	18F-FDG CT-PET guideline, Bone SPECT-CT, Sentinel Node detection in breast cancer	Nationally developed	http://www.semnim.es/index .php?option=com_content&v iew=article&id=154:procedim ientos- mn&catid=53:procedimientos -de-medicina- nuclear&Itemid=29 (accessed 14.2.13)	Spanish Society of Nuclear Medicine and Molecular Imaging (SEMNIM)
	Spanish society radiology	Guidelines of college of radiologists	Modified from another recognised source	http://seram.es/modules.php ?name=webstructure⟨=E S&idwebstructure=100 (accessed 14.5.13)*	
Sweden ‡	No guidelines identified initially				
Switzerland	Swiss Society of Nuclear Medicine	PET guidelines of the Swiss Society of Nuclear Medicine	Modified from another recognised source: mainly German and American guidelines	http://www.nuklearmedizin.c h/index.php/fachpersonen_kl v-richtlinien_menu- item/fachpersonen_klv- richtlinien_fdg-pet-ct_article (accessed 14.2.13)	Federal Office of Health, Swiss Society of Nuclear Medicine
United Kingdom	Department of Health	iRefer	Nationally developed	www.irefer.org.uk (accessed 14.2.13)	Royal College of Radiologists
	The Royal College of Radiologists	iRefer: Making the best use of clinical radiology	Nationally developed	www.irefer.org.uk (accessed 14.2.13)	The Royal College of Radiologists

^{*} These website links were added by the authors of the Referral Guidelines Final Report, and were not provided by the respondents in the survey. They identify the National Society websites, point to their online Guidelines, or in the case of Luxembourg, it points to the online French guidelines which the respondent identified as the ones which they use, unmodified.

Appendix 2: National Guidelines

For completeness, all 30 countries surveyed in the questionnaire have been included in this table. Where a particular country did not respond to this question, this has been marked in the table as "No guidelines identified initially".

‡ Since the survey was carried out a further 7 countries have identified Guidelines or have begun adoption / adaptation of Guidelines.

APPENDIX 3 Workshop Programme



Imaging Referral Guidelines in Europe: Now and the Future EC Referral Guidelines Workshop

September 20-21, 2012, Vienna, AUSTRIA

Final Programme

Partner organisations:

European Society of Radiology (ESR)
Royal College of Radiologists (RCR)
French Society of Radiology (SFR)
European Society of Paediatric Radiology (ESPR)
Cardiovascular and Interventional Radiology Society of Europe (CIRSE)
European Commission, DG Energy

Venue: Billrothhaus

Frankgasse 8, A-1090 Vienna http://www.billrothhaus.at/index.php

The Workshop is part of the EC Tender Project "Referral Guidelines Study" and will provide background, feedback survey results and explore possibilities for future European community initiatives. This anticipated outcome will be a consensus as to the measures needed for taking forward the development and distribution of imaging referral guidelines in Europe.

The project is funded by the European Commission and coordinated by the European Society of Radiology.















Imaging Referral Guidelines in Europe: Now and the Future EC Referral Guidelines Workshop

September 20–21, 2012, Vienna, AUSTRIA

Thursday	September 20
Session 1	: Scene setting

19:00

Dinner

Chair: Myriam Hunink, ESR Rapporteur: Pete Cavanagh, RCR

Rapporteur: Pete Cavanagh, RCR			
13:30-13:45	Registration and coffee		
13:50-13:55	Opening and Welcome Georgi Simeonov, EC		
13:55-14:05	Scene setting Denis Remedios, ESR Project Lead		
14:05-14:15	Euratom 97/43 and implementation Georgi Simeonov, EC		
14:15-14:25	Referral Guidelines: the WHO perspective Maria Perez, WHO		
14:25-14:35	Referral Guidelines: The IAEA expert's perspective Madan Rehani, IAEA expert		
14:35-14:45	Imaging guidance in Europe: the ESR vision <i>Guy Frija, ESR</i>		
14:45-15:15	Tea break		
15:15-15:30	Referral Guidelines in the UK Pete Cavanagh, RCR		
15:30-15:45	Referral guidelines in France <i>Philippe Grenier, SFR</i>		
15:45-16:00	Referral Guidelines in Western Australia Richard Mendelson, Western Australia		
16:00-16:15	Referral Guidelines in Canada <i>Martin Reed, CAR</i>		
16:15-16:30	Referral Guidelines in the USA Michael Bettmann, ACR		
16:30-17:00	Discussion and questions All speakers		

Friday, September 21 Session 2: Specific issues

Chair: Mario Bezzi, CIRSE Rapporteur: Nick Ashford, RCR

09:00-09:10	Particular paediatric points Jean-François Chateil, ESPR
09:10-09:20	Referral guidelines and Interventional Radiology Mario Bezzi, CIRSE
09:20-09:30	Referral guidelines and Nuclear Medicine Fred Verzijlbergen, EANM
09:30-09:40	Radiation dose issues and risk Reinhard Loose, German Commission on Radiological Protection (SSK)
09:40-09:50	Imaging referral guidelines and implementation issues Steve Ebdon-Jackson, Radiation Protection Division, UK HPA
09:50-10:00	Imaging referral guidelines and radiography Graciano Paulo, European Federation of Radiographer Societies (EFRS)
10:00-10:10	Imaging referral guidelines for general practitioners Wolfgang Spiegel, Austrian Society of General Practice and Family Medicine
10:10-10:20	The patient's perspective Alison Meyric-Hughes, Patient Liaison Group, RCR
10:20-10:50	Discussion and questions All speakers
10:50-11:10	Coffee break



Imaging Referral Guidelines in Europe: Now and the Future EC Referral Guidelines Workshop

September 20-21, 2012, Vienna, AUSTRIA

Fri	day,	Sej	ptem	ber	21	
-		-	-			

Session 3: Survey feedback

Chair: Jean-François Chateil, ESPR Rapporteur: Steve Ebdon-Jackson, UK HPA

11:10-11:20 Guidelines survey development

Nick Ashford, RCR

11:20-11:40 Guidelines survey and analysis of questionnaire

Valérie Vilgrain, SFR

11:40-12:00 Good practices in Europe

National radiology societies, Competent authority

representatives (5min each)

12:00-12:30 Discussion and questions

All speakers

12:30-13:30 Lunch

Session 4: Innovations

Chair: Guy Frija, ESR

Rapporteur: Fred Verzijlbergen, EANM

13:30-14:30 Innovations for improving Guideline use

Myriam Hunink, ESR Francesco Sardanelli, ESR Pete Cavanagh, RCR Richard Mendelson, WA Martin Reed, CAR Michael Bettmann, ACR

Any or all of the following:

- Clinical decision support systems
- Radiology benefit management
- Quality and outcomes framework / Payment for performance
- $\bullet \ Other \ innovations$
- Up to 10mins for each presentation

14:30-15:00 Discussion and questions

All speakers

15:00-15:30 Tea break

Session 5: Conclusions

Chair: Denis Remedios, ESR Project Lead

15:30-15:40	Summary of scene setting session Pete Cavanagh, RCR Rapporteur session 1
15:40-15:50	Summary of specific issues and good practices session Nick Ashford, RCR Rapporteur session 2
15:50-16:00	Summary of survey feedback session Steve Ebdon-Jackson, UK HPA Rapporteur session 3
16:10-16:20	Summary of innovations session Fred Verzijlbergen, EANM Rapporteur session 4
16:20-16:40	Discussion and questions All speakers
16:40-16:50	Summing up and Conclusions of the workshop and project Denis Remedios, ESR Project Lead

16:50-17:00 Closing remarks Georgi Simeonov, EC Guy Frija, ESR

The workshop is kindly supported by



APPENDIX 4 Workshop Registrants

Workshop Registrants

Country	First Name	Last Name	Organisation	E-mail
Australia	Richard	Mendelson	University of Western Australia	Richard.Mendelson@health.wa.gov. au
Austria	Peter	Baierl	European Society of Radiology (ESR)	peter.baierl@myesr.org
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			Environmental Board	
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Appendix 4: Workshop Registrants

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USA	Michael	Bettmann	American College of Radiology	mabettmann@gmail.com

APPENDIX 5 Workshop Proceedings

Project ENER/D4/315-2011 Implementation of Council Directive 97/43/Euratom requirements concerning referral criteria for medical imaging in the European Union

IMAGING REFERRAL GUIDELINES IN EUROPE: NOW AND THE FUTURE. EC REFERRAL GUIDELINES WORKSHOP Billrothhaus, Vienna. September 20-21 2012

Workshop Proceedings

Start date of project: December 2011 Duration: 15 months

Coordinator European Society of Radiology, ESR

Project Lead Denis Remedios, ESR Project Manager Monika Hierath, ESR

Authors Workshop speakers contributed with presentation-summaries, which were included in the following proceedings, supported by Monika Hierath (ESR), Angelika

Benkovszky (ESR), and Catherine Lloyd (ESR)

Attention of European Commission, Directorate General, Mr. Georgi Simeonov

1. Introduction

As an integral part of the EC Imaging Referral Guidelines Project a 1.5-day workshop was held in Vienna on 20-21 September, 2012. At this workshop, models and good practices regarding appropriateness and use of referral guideline in Europe and worldwide were presented, together with the results of a survey of guidelines in Europe. The latter included ideas, innovations and wishes for future Community action.

Over 60 participants attended the workshop in Vienna, with registration of representatives from national radiology societies and representatives from the regulatory bodies of 30 European countries. Speakers from Europe, USA, Canada and Australia included expert advisors from the WHO, IAEA, EANM as well as key stakeholders such as representatives from patient groups, radiographer societies and general practitioners.

The programme included over 30 talks divided into five sessions. Each session allowed ample time for discussions with enthusiastic participation from the floor.

2. Programme

The workshop programme was divided into five sessions, each dealing with a specific subject within the area of Imaging Referral Guidelines in Europe.

Session 1, *Scene Setting,* served as an introduction to the topic and gave an overview on the current status of Referral Guidelines in Europe. Experts from International Organisations such as the WHO and IAEA presented their perspective and invited speakers from Europe, USA, Canada and Australia shared their views on Referral Guidelines from a national perspective.

Session 2, *Specific Issues*, addressed the perspectives of stakeholders from paediatrics, interventional radiology and nuclear medicine, as well as representatives from radiographer societies and patient groups.

Session 3, **Survey Feedback**, dealt with the formulation and findings from the survey of imaging referral guidelines in Europe, conducted as an earlier part of the EC Referral Guidelines Project. Within this session workshop participants were given an opportunity to present good practices from their own countries.

Session 4 dealt with *Innovations* for improvement in Guideline use. Examples of innovations in use worldwide and potential solutions drawn from other areas of medicine were discussed.

Session 5, *Conclusions*, summarised the presentations and discussions from the earlier sessions of the workshop with the support of sessional rapporteurs. Conclusions were reached, based on participants' presentations and discussions.

3. EC Referral Guidelines Workshop

Session 1: Scene Setting

Chair: Myriam Hunink, European Society of Radiology (ESR) Rapporteur: Pete Cavanagh, Royal College of Radiologists (RCR)

Talk 1: Scene Setting

Denis Remedios, European Society of Radiology (ESR) Project Lead

Dr. Denis Remedios Northwick Park Hospital, Harrow, UK denis.remedios@imperial.ac.uk

Introduction

The Project ENER/D4/315-2011, Implementation of Council Directive 97/43/Euratom requirements concerning referral criteria for medical imaging in the European Union fulfils the obligation of Member States "to ensure that recommendations concerning referral criteria for medical exposures, including radiation doses, are available to the prescriber of medical exposures". (Article 6.2 of Council Directive 97/43/EURATOM (Medical Exposures Directive, MED) [1]

Based on this requirement, a number of Member States have developed national referral guidelines for clinical imaging as guidance for the referring physicians to justify radiological imaging procedures and to ensure the highest possible safety of patients when submitted to radiation exposure. Imaging referral guidelines (Guidelines) have been available in Europe since 1989 when the Royal College of Radiologists (RCR) first published "Making the best use of a department of clinical radiology" [2]. The Radiation Protection 118 Referral Guidelines for Imaging (RP 118) [3] were published in 2000 by the European Commission, (based on the Royal College of Radiologists 1998 publication "Making the best use of a department of clinical radiology: guidelines for doctors"). The French Society of Radiology (SFR) published imaging referral guidance in 2005 and updated in 2013, "Guide du bon usage des examens d'imagerie médicale" [4]. Rapid developments in imaging technology and new advances in medical imaging required an update of the guidelines by the European Commission in 2003.

The value of evidence-based Guidelines for justification at International Commission on Radiological Protection (ICRP) level 2 [5] and reduction of unhelpful medical exposures was shown in early studies [6, 7]. Such guidance is also helpful to promote good medical practice and may improve cost effectiveness by encouraging the best test first.

The proposal for the project "Implementation of Council Directive 97/43/Euratom [6] requirements concerning referral criteria for medical imaging in the European Union" was submitted as a consortium of several partners in June, 2011. Partner organisations are:

- European Society of Radiology (ESR) http://www.myesr.org/
- Royal College of Radiologists (RCR) www.rcr.ac.uk/
- French Society of Radiology (SFR) www.sfrnet.org
- Cardiovascular and Interventional Radiology Society of Europe (CIRSE) http://www.cirse.org/
- European Society of Paediatric Radiology (ESPR) http://www.espr.org/

Members of the steering committee are:

- Denis Remedios, ESR, chair
- Monika Hierath, ESR project manager
- Peter Cavanagh, RCR (and Nick Ashford)
- Philippe Grenier, SFR (and Valerie Vilgrain)
- Mario Bezzi, CIRSE
- Jean-François Chateil, ESPR (and Karen Rosendahl)
- Georgi Simeonov, EC representative

The overall aim of this project is to review the situation in European Union (EU) Member States regarding the fulfilment of their obligations under MED Article 6.2.

The full project comprises 3 main tasks:

- the conduct of an EU-wide study on the availability, development and implementation of referral guidelines for radiological imaging in the EU Member States,
- 2. the organisation of a European Workshop with relevant representatives from the EU Member States, and
- 3. the development of conclusions of the workshop regarding the need for national and/or Community action.

Related international projects

World Health Organization (WHO)

- Global Initiative on radiation safety in health care settings launched in 2008 [8]. Sixty-seven participants, including experts from 25 countries and representatives from 15 international organisations, professional associations and scientific societies, have agreed to collaborate in this initiative. Based on the collected feedback the global strategy was developed; main activities were identified under three areas of work: risk assessment, risk management and risk communication; ways for enhancing collaboration and engaging key stakeholders were proposed; and a roadmap was outlined.
- Guidelines consultancy 2010 [9]. Key representatives of the world's leading medical imaging societies have recommended that a common set of global referral guidelines for appropriate use of medical imaging be produced, in the first such global meeting of experts convened under WHO auspices in nearly two decades.

International Atomic Energy Agency (IAEA)

- International Workshop on Justification of Medical Exposure, Brussels 2009 [10]. This Workshop organised by the IAEA with the EC, addressed: referral guidelines; communication and risk; audit & justification; and special problems.
- Triple A, "Awareness, appropriateness and audit", 2010 [11]. Clinical audit was regarded as a key tool in ensuring that justification becomes an effective, transparent and accountable part of normal radiological practice. Justification would be facilitated by the "3 As": awareness, appropriateness and audit.

Awareness: The need for guidelines

There is wide recognition that imaging referral guidelines are needed to support decisions for imaging investigations globally. This is driven by the following key points:

- Diagnostic radiology in USA now accounts for almost as much radiation as natural causes (15% in 1980 to 48% in 2006) [12] (Fig. 1).
- CT exams have increased at 10% pa in USA from 3-80 million since 1980.
- Up to 44% of CT exams not justified in USA [13].
- The low level of knowledge of dose; only 1:3 doctors received formal training in radiation protection [14].
- The per capit annual effective collective dose from medical imaging varies considerably between countries (Fig.2).

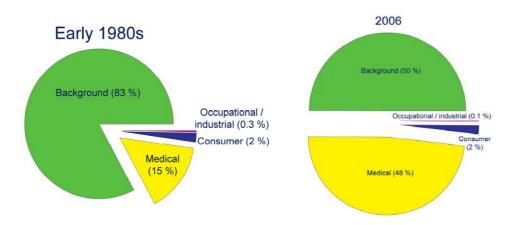


Fig. 1. Components of background radiation in USA in 1980 and 2006. From NCRP 160 [12].

Per caput annual collective dose /mSv Hart et al. 2010 [15]

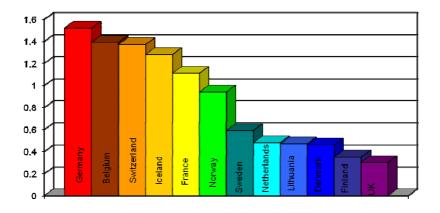


Fig 2. The variation in per capit collective radiation dose in Europe. From Hart et al, 2010 [15].

- Reasons for wasteful diagnostic radiology [2]:
 - 1. Unnecessary, unhelpful repeated procedures
 - 2. Investigations whose results are unlikely to affect patient management
 - 3. Investigating too early in the course of self-limiting conditions
 - 4. Inappropriate procedure performed which may not fully answer the clinical question, when an alternative investigation may have been best, and
 - 5. Inadequate clinical information on which to select the best procedure.

Appropriateness: Examples of Referral Guidelines in Europe

Imaging Referral Guidelines have been developed, adopted and adapted by several European Member States and by the European Commission (Figs. 4-7). An integral part of such guidance has been radiation dose information for imaging procedures which is essential to guide the referring physician and patient and to inform advice on radiation risk (Figs. 8-9). Some Guidelines have separate sections dealing with imaging of children.



Fig. 4. RCR, iRefer: Making the best use of clinical radiology [2]



Fig. 5. SFR, Guide du bon usage des examens d'imagerie médicale [4].



Fig 6. Radiology Guidelines from the Austrian Society of Radiology [16].

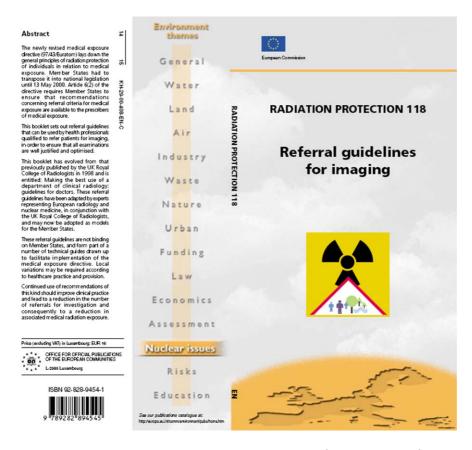


Fig. 7. The European Commission Radiation Protection Referral Guidelines for imaging [3].

Diagnostic procedure	Typical effective dose (mSv)	Equivalent number of chest X-rays	Approx equivalent period of natural background radiation*			
Radiographic examinat	Radiographic examinations					
Limbs and joints (except hip)	<0.01	<1	<2 days			
Chest (single PA)	0.015	1	2.5 days			
Skull	0.07	5	12 days			
Thoracic spine	0.4	30	2 months			
Lumbar spine	0.6	40	3 months			
Mammography (2 view)	0.5	35	3 months			
Pelvis	0.3	20	1.5 months			
Abdomen	0.4	30	2 months			
IVU	2.1	140	11.5 months			
Barium swallow	1.5	100	8 months			
Barium meal	2	130	11 months			

Fig. 8. Dose information from the RCR guidelines, iRefer: Making the best use of clinical radiology [2].

Table 3. Band classification of the typical doses of ionising radiation from common imaging procedures ^{23,26}				
Symbol	Typical effective dose (mSv)*	Examples	Lifetime additional risk of fatal cancer/exam	
None	0	US; MRI	0	
☆	<1	CXR; XR limb, pelvis, lumbar spine; mammography	<1:20,000	
♦	1–5	IVU; NM (eg, bone); CT head and neck	1: 20,000–1:4,000	
♦	5.1–10	CT chest or abdomen; NM (eg, cardiac)	1: 4,000–1: 2,000	
♦♦♦	>10	Extensive CT studies, some NM studies (eg, some PET-CT)	> 1: 2,000	

Fig. 9. Risk information from the RCR guidelines, iRefer: Making the best use of clinical radiology [2].

Audit: Monitoring and quality improvement of safe radiological practice

Even where available, imaging referral guidelines have not been used as widely as anticipated. Encouragement for use will require greater awareness and education. The need to monitor and reinforce referral guideline use is essential to promote good practice. Initiatives to monitor and promote safe radiological practice include clinical audit, both external [17] (Fig. 10) and local internal audit [18]; voluntary reporting and inspection.

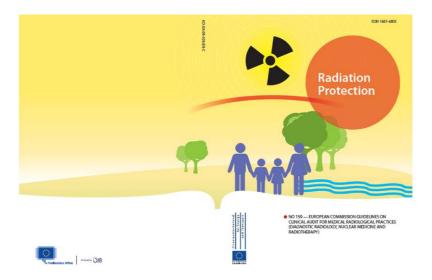


Fig. 10. The European Commission Guidelines on Clinical Audit for Medical Radiological Practices (diagnostic radiology, nuclear medicine and radiotherapy) [17].

Summary

With imaging referral guidelines, the needs, methods for development and value have been established. Good practices are found in Europe (and abroad) but uniform availability, uptake and implementation may not yet be established.

The objectives of the EC Guidelines Project will help address some of these issues. They include:

- A survey of availability of referral guidelines in EU member states and countries taking EC legislation;
- The workshop where the survey findings are disseminated, ideas for European initiatives discussed and the way forward debated;
- Recommendations for future Community action; and
- The final report to the EC within 15 months from project kick-off, a tight time scale but essential for guiding urgent action.

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Talk 2: Referral Guidelines for Imaging in Euratom: Legal Framework and Implementation Efforts

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Legal Basis

The obligation of the EU Member States "to ensure that recommendations concerning referral criteria for medical exposures, including radiation doses, are available to the prescriber of medical exposures" is established by Article 6.2 of Council Directive 97/43/EURATOM (Medical Exposures Directive, MED) [1].

European Referral Guidelines for Imaging

European referral guidelines for imaging were first published by the European Commission, as "Radiation Protection 118" (RP118), in 2000 and further updated in 2003. They were based on the current editions of the Royal College of Radiologists guidelines and adapted by experts representing European radiology and nuclear medicine. RP118 was freely available online and served as a basis for national guidelines published in several European countries.

In 2009 the EC published a tender to update Radiation Protection 118, which failed mostly due to the escalating costs for this work. Later, in September 2010, RP118 was officially withdrawn from publication as "outdated" [2].

Referral Guidelines Project, 2011-2012

In 2011 the European Commission published a new call for tenders [3] with the overall objective to review the situation in EU Member States regarding the fulfilment of their obligations under MED Article 6.2. The specific tasks defined in the tender include:

- The conduction of an EU-wide study on the availability, development and implementation of referral guidelines for radiological imaging in the EU Member States.
- The organisation of a European Workshop with relevant representatives from the EU Member States.
- The development of conclusions of the workshop regarding the need for national and/or Community action.

The contract for this tender was signed at the end of 2011 with a Consortium consisting of:

- ESR European Society of Radiology Project Coordinator
- RCR Royal College of Radiologists
- SFR Société Française de Radiologie
- CIRSE Cardiovascular and Interventional Radiology Society of Europe
- ESPR European Society of Paediatric Radiology

Observers included the World Health Organizations (WHO), and the International Atomic Energy Agency (IAEA).

As part of the project, a questionnaire was distributed at the end of March 2012 to three contact points in 30 different countries, throughout the EU and also Switzerland, Croatia and Norway. The questionnaire asked the participants not only about the actual status of imaging referral guidelines in the respective country but also for their views on several issues, including on the need of European solutions.

The Directorate General (DG) Energy Perspective

According to the Referral guidelines 118: "Continued use ... can lead to a reduction in the number of referrals and also to a reduction in medical radiation exposure. However, the primary objective of the guidelines is to improve clinical practice." In response to this, the DG Energy believes that the development process involves mostly search and grading of clinical evidence, while contribution of radiation protection, e.g. dose per examination [4], is quite limited.

Other potential ways to improve justification include:

- The empowerment of radiologists to refuse / modify examination requests, e.g. through the EC proposal for substituting 'prescriber' with 'referrer' in the revised Euratom BSS [5]
- Provision of education and training to referrers and radiological practitioners, e.g. through European educational initiatives [6]
- Provision of information to patients, also emphasized in the revised Euratom BSS
- Clinical audit [7]

Further European needs could include the continued development of referral guidelines, although national and international work in this area is already occurring. More importantly,

the implementation of existing referral guidelines has to be decisively improved, but exactly how has yet to be confirmed, including through work within the current project. The advancement in this area would bring multiple benefits going beyond the narrow area of radiation protection. In order to achieve this contributions would be required from different disciplines. The work should be undertaken within the most appropriate European policy area(s), including health research, electronic healthcare (eHealth) and public health.

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Talk 3. Referral Guidelines: the WHO perspective

Maria Perez, The World Health Organization (WHO)

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Appropriateness is more than a radiation protection issue

The increasing use of radiation in medical imaging and the need to control radiation exposure and minimize health risks, while maximizing the associated health benefits, represent a major challenge. However the appropriateness of usage is not only an issue for radiation in health care. The World Health Organization (WHO) estimated in 2010 that more than half of all medicines are inappropriately prescribed, dispensed or sold. This incorrect use may take the form of overuse, underuse and misuse of prescription or non-prescription medicines.

Good medical practice encompasses radiation safety

For an individual patient, the risk-benefit balance favours the benefit when the procedure is appropriately prescribed and properly performed. The balance is no longer in the patient's favour if the procedure is prescribed without a clear clinical indication or when patients receive a higher dose than is necessary (for example if adult settings are used for children).

The new International Basic Safety Standards (BSS) adopted by the WHO in May 2012 particularly address justification and explicitly mention referral guidelines. There are three levels of justification outlined:

- 1. General/overarching justification of the use of ionizing radiation in medicine;
- 2. Justification of a radiological medical procedure for a given clinical condition; and
- 3. Justification of a radiological medical procedure for an individual patient.

These justification levels are then further developed in chapter 3 of the BSS, addressing questions such as "what" and "who"?

Need for clinical guidelines

Evidence-based medicine means integrating (i) the best available external clinical evidence from systematic research with (ii) the individual clinical expertise, to consider what may be applicable to or appropriate for an individual patient. It is unrealistic to expect clinicians to keep abreast of all the medical advances reported in primary journals. Instead referral guidelines represent decision-support tools systematically developed to assist practitioners on decision about appropriate healthcare for specific circumstances.

However there can be barriers to guideline implementation. There are many gaps between best available evidence and current clinical practice (evidence-practice gaps). There is a need to identify the barriers to guidelines implementation, to change the practice and close the gaps. In 1996, Pathman et al. developed a four-step model to look at the utilisation of clinical guidelines: awareness, agreement, adoption, adherence. Patterns of "leakage" indicated that it was progressive through the 4 steps.

Potential solutions to these barriers include end-user involvement, local adaptation (format, media), Computerised Physician Ordered Entry (CPOE) systems, to integrate referral guidelines into the daily workflow, education and training.

One of the greatest challenges is to build a global platform to share evidence and resources for guidelines development and update. In collaboration with professional societies and relevant international organizations including the European Commission (EC), the WHO is conducting a Global Initiative on Radiation Safety in Health Care Settings (GI) to mobilise the health sector towards safer use of radiation in medicine. This GI provides multiple opportunities for cooperation with European countries on topics related to radiation safety in medical exposures, with the ultimate goal of promoting appropriate use of radiation in healthcare.

From a public health perspective, the impact of EU developments on radiation protection in healthcare goes beyond the region. The WHO welcomes this EC study on Imaging Referral Guidelines that provides a new opportunity to expand the horizons of EU achievements to a global dimension: jointly building a global platform to share evidence and resources for guidelines development and implementation.

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Talk 4: Referral Guidelines: The IAEA expert's perspective

Madan Rehani, International Atomic Energy Agency (IAEA)

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International Atomic Energy Agency (IAEA) has not only been active in optimization action in patient protection but also in appropriateness of imaging to reduce unnecessary exposures of patients. The RPOP website of the IAEA (http://rpop.iaea.org) provides information directed at referring physicians about appropriateness and there is training material for different professionals [1]. In particular there is information on: what is justification and what is the framework; is the referring medical practitioner responsible for justification of radiological procedures?; how should justification be practiced and what knowledge is required for proper justification of a radiological procedure?; is the acquisition of patients' consent important?; when is an investigation useful and what are the reasons that cause unnecessary use of radiation?; what are the reasons for over-investigating; is there any guidance available and the response provides listing of appropriateness criteria and referral guidelines from different sources. The IAEA also recommended triple A (AAA) approach implying appropriateness, awareness and audit [2, 3]. A number of other actions and project results are available as described below.

Requirements in Standards

There are requirements in Basic Safety Standards (BSS) on referral criteria. The international BSS published by the International Atomic Energy Agency (IAEA) in cooperation with a number of organizations states [4] "The specific objectives of the exposure, the clinical circumstances and the characteristics of the individual involved have to be taken into account through referral criteria developed by professional bodies and the health authority". It further states that the "relevant national or international guidelines shall be taken into account for justification of the medical exposure of an individual patient in radiological procedure". The European BSS, which is at advanced stage of approval [5] states that "Member states shall ensure that referral guidelines for medical imaging, taking into account the radiation doses, are available to the referrers".

Further, the international BSS states under requirement 36, "Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks.

In a way, while European BSS emphasizes on availability, the IAEA BSS goes a step in requiring use and appropriate referral. Thus there is emphasis on process and ensuring appropriateness.

IAEA Studies in 40 countries

The IAEA conducted a survey of practice of appropriateness in pediatric CT in 40 less resourced countries and the results have been published [6]. The countries were: Algeria, Armenia, Belarus, Bosnia and Herzegovina, Brazil, Bulgaria, China, Costa Rica, Croatia, Czech

Republic, Estonia, Indonesia, Iran, Israel, Kuwait, Lebanon, Lithuania, Malaysia, Malta, Mexico, Montenegro, Moldova, Myanmar, Oman, Pakistan, Paraguay, Peru, Poland, Qatar, Serbia, Singapore, Slovakia, Slovenia, Sri Lanka, Sudan, Syria, Tanzania, Thailand, the Former Yugoslav Republic (FYR) of Macedonia, and United Arab Emirates (UAE).

Also a survey was conducted by the IAEA among 728 referring physicians from 28 countries, which indicated preference for mandatory provisions for justification of a CT examination [7].

In an IAEA study, it was shown that although regulations in many countries assign radiologists with the main responsibility of deciding whether a radiological examination should be performed, in fact radiologists alone were responsible for only 6.3% of situations. Written referral guidelines for imaging were not available in almost half of the CT facilities. Appropriateness criteria for CT examinations in children did not always follow guidelines set by agencies, in particular for patients with accidental head trauma, infants with congenital torticollis, children with possible ventriculo-peritoneal shunt malfunction and young children (<5 years old) with acute sinusitis.

The question, "Who decides whether a CT examination of a pediatric patient is to be performed?" was answered by 127 radiologists. Of these, 72 (56.7%) stated that the decision is usually shared by the radiologist and referring clinician, 47 (37%) said that it is made by the referring clinician, and only eight (6.4%) declared that the decision is made by the radiologist. From a total of 132 answers to another question, "Are written referral guidelines for imaging available in your hospital?" 66 (50%) said "Yes," 59 (44.7%) said "No," and seven (5.3%) answered, "Don't know."

On the question "Is head CT mandatory for a pediatric patient with an accidental head trauma?" the answers are reflective of current practice in the different institutions worldwide. The implementation of clinical practice guidelines to refer pediatric patients with minor head trauma for CT may focus resources on those most likely to benefit from a CT, or may even reduce its usage in pediatric patients [8, 9].

The European Commission's Referral guidelines for imaging [10] do not recommend CT in patients with a low risk of intracranial injury. CT is recommended in patients with medium to high risk for intracranial injury. According to the NICE clinical guideline 56 [11], CT is recommended in children presenting with loss of consciousness, amnesia, drowsiness, three or more episodes of vomiting, clinical suspicion of non-accidental injury, post-traumatic seizures, Glasgow Coma Scale (GCS) less than 15 for a baby under 1 year old, suspicion of open or depressed skull injury or tense fontanelle, any sign of basal skull fracture, focal neurological deficit, bruise or swelling more than 5cm for a baby under 1 year old and dangerous mechanism of injury.

In response to the first choice examination for an "infant with congenital torticollis", the large variation in responses amongst the participants was observed to reflect institutional preference in narrowing the differential diagnosis. The European Commission's Referral guidelines for imaging [10] do not recommend X-ray because the deformity is usually due to spasm with no significant bone changes. If persistent, further imaging (e.g. CT) may be indicated following consultation.

For a "child with clinically suspected appendicitis", 90% chose US as the first choice examination. This is in line with the ACR appropriateness criteria recommending US as the first investigation. CT may be performed following a negative or equivocal US [12].

For a "child with pleural effusion", plain X-ray was the initial investigation in 53% and US in 41% of cases. The European Commission's Referral guidelines for imaging recommend chest X-ray [10]. US may be performed to prove fluid consistency and to guide aspiration.

The first choice examination for a "child with persistent headache" was MRI 48% and CT 45%. The European Commission's Referral guidelines for imaging [10] recommend MRI in preference to CT because of the absence of ionizing radiation. The ACR appropriateness criteria [12] indicate that MRI and CT are usually not appropriate in children with headache unaccompanied by neurological signs and symptoms.

For a "child with possible ventriculo-peritoneal shunt malformation", 63% of radiologists chose CT as the first choice investigation. The current recommendation in the European Commission's Referral guidelines for imaging [10] is US if practical or MRI in older children. CT may be performed if MRI is unavailable. If CT is used, the CT technique may be modified to reduce the radiation dose because ventricular size is the main object of the CT and noisier images can be tolerated.

For a "small child (< 5years old) with sinusitis", X-ray was chosen in 72% and CT in 18% of cases. The European Commission's Referral guidelines for imaging [10] do not recommend imaging for children less than 5 years of age because the sinuses are poorly developed at this age.

Appropriateness criteria for referral for CT examinations in children varied between different countries and did not always follow guidelines set by agencies. Knowledge and use of these guidelines would improve clinical practice and lead to a reduction in the number of unnecessary CT examinations in children.

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Talk 5: Imaging guidance in Europe: the ESR vision

Guy Frija, European Society of Radiology (ESR)

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Actions of the European Society of Radiology (ESR) in the field of patient radioprotection include:

- an active participation in EC tenders (EMAN and MEDRAPET);
- an ongoing approach on how to develop Clinical Decision Support Systems in Europe with several Directorate Generals (Energy, Sanco, Connect and Research);
- the methodological development of Clinical Audit in Radiology;
- an international involvement by participating to several meetings organised by IAEA and WHO;

- a contribution to a worldwide approach in Quality and Safety (including Patient Radioprotection aspects) by organising a global summit with the American College of Radiology and the International Society of radiology; and
- the issuing of several papers dealing with patients radioprotection.

In addition the ESR training charter includes a section on radiation protection, and training for undergraduate education, which is in preparation.

The ESR recently welcomed the availability of two recently updated referral guidelines in Europe (France and UK), which in our opinion, might be used as such by the member states, without any need of a supplementary work; however there are pending copyrights issues which have to be solved. Nevertheless, the actual use of Referral Guidelines was strongly questioned in a separate survey made by the ESR towards the national Societies of the MS, Belgium, France, Hungary, Italy, Germany, The Netherlands, Spain, and Ireland. Responses to this survey stated that whilst referral guidelines were available, they were not used in practice. We strongly believe that a comprehensive survey conducted by the consortium on this specific point has to be undertaken.

The different methods used in the field of medicine which have the goal of improving clinical practice by increasing the use of evidence based data, were quickly reviewed, including consensus conferences, meetings, educational sessions, and incentives based policies (P4P). This review showed that the different methods had very limited efficacy (except for P4P approaches which need to be evaluated in the field of imaging). In this context, the first experiences conducted in the US with Clinical Decision Support are looking very promising, and it is our strong belief that this kind of approach must be developed in the EU, with an appropriate level of funding support from the EC.

Talk 6: Referral Guidelines in the UK

Pete Cavanagh, The Royal College of Radiologists (RCR)

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The Royal College of Radiologists (RCR) has produced the referral guidelines, *iRefer: Making the best use of clinical radiology*,¹ (formerly known as *Making the best use of clinical radiology services*) to help clinicians, radiologists, radiographers and other healthcare professionals to determine the most appropriate imaging investigation(s) for a wide range of clinical problems. Despite the new name, this is the seventh edition of the radiology referral guidelines, demonstrating through more than 20 years' support, the RCR's commitment to the importance of guidelines in the delivery of radiology services for patients. Evidence from the increasing use of diagnostic radiation and publications on the percentage of unnecessary test requests indicates that such a resource is essential.

First published in 1989 on a four-yearly cycle, the RCR published the seventh edition at the end of 2011. Each edition is lead by a Guideline Development Lead, with the first being Professor Adrian Dixon and the current lead being Dr Denis Remedios.

The process and methodology for content review and updates has evolved and developed with each edition. The fourth edition of the guidelines underwent an appraisal by the Health Care Evaluation Unit at St George's Hospital Medical School, while the fifth edition of the guidelines was jointly funded by the RCR and the European Commission.

Each version of the guidelines has grown considerably in size, ranging from just 73 guidelines in the first edition to 307 in the seventh.

Content development

The iRefer process recognises that preparation of evidence-based guidelines is a demanding task, and one that requires a rigorous approach to routine practices and the assimilation of new evidence. The design is aimed to minimise geographical and personal bias through a Delphi consensus process and to consult widely to gather appropriate foreign language and grey literature to further strengthen the evidence base. The process has evolved and improved from edition to edition and now involves hundreds of experts (RCR members and Fellows representing 10% of the Clinical Radiology Faculty) covering all modalities and procedures review and update the guidelines, with a nominated Expert Lead for each section. Extensive literature searches are carried out by the Delphi Search Co-ordinator, involving thousands of papers – 100,000 references in raw search, 30,000 references considered, 3,000 used.

Each edition of the guidelines has been subject to external peer review. Wide consultation of the seventh edition of the guidelines was undertaken among more than 100 organisations, including Royal medical Colleges, learned bodies, specialist societies, professional associations and other professional groups in the UK and Europe. To ensure that the patient remains at the centre of this work, our Patients' Liaison Group was involved at every stage of the process.

This seventh edition of imaging referral guidelines marks a significant leap forward in guideline development. The enhanced guidelines methodology has been accredited by NHS Evidence, managed by the National Institute for Health and Clinical Excellence (NICE) in the UK. In this edition of the guidelines, the Delphi process was used for **every** guideline further strengthening the evidence base. There has also been consideration of relevant clinical guidelines to inform the process and inclusion of important clinical (red flag) features where relevant. The seventh edition features an updated Table 2. Typical effective doses from diagnostic medical exposure based on the latest Health Protection Agency (HPA) survey from 2008². The seventh edition also features the following brand new guidelines:

Cancer

CA23 – Colon cancer: diagnosis
CA24 – Colon cancer: staging
CA25 – Colon cancer: follow–up
CA26 – Rectal cancer: diagnosis
CA27 – Rectal cancer: staging
CA28 – Rectal cancer: follow–up
CA29 – Anal cancer: diagnosis
CA30 – Anal cancer: staging
CA31 – Anal cancer: follow–up

CA56 – Melanoma: diagnosis CA57 – Melanoma: staging CA58 – Melanoma: follow–up

Gastrointestinal system

G33 – Asymptomatic patients 50–75 years old with a positive faecal occult blood test on screening for bowel cancer

Urogenital & adrenal

U22 - Asymptomatic men with elevated PSA

The Delphi process

The Delphi consensus is used to agree recommendations, comments and grading of evidence for each guideline. These Delphi groups comprise approximately ten experts and a mix of specialty and modality base. Consensus is reached with 75% participation and 75% agreement at 5, 6 or 7 on a 7-point Likert scale. Expert bias is avoided by anonymising data and geographical bias avoided by use of Delphi experts from different centres.

Evidence for each guideline identified through the literature search supplemented by the Delphi group or through consultation is graded by Delphi members and Lead. Evidence levels for diagnostic, therapeutic, prognostic and economic studies were based on the levels of evidence for primary research adapted from *The Journal of Bone and Joint Surgery*.³

Who are they for?

Aimed at GPs, referring clinicians, radiologists, radiographers, and other healthcare professionals and healthcare organisations, these guidelines steer referrers clearly through disease and system-based imaging, help with justification, avoid the chief causes of unnecessary patient irradiation and the wasteful use of radiology, and ensure the best use of imaging for the benefit of patients. Designed to be used in both primary and secondary care, they are particularly helpful for the non-specialist referrer.

The guidelines have international application in the global imaging world, with adoption in Ireland, India, Hungary, Japan, Russia, Portugal, Norway, Netherlands, Canada, Croatia and Saudi Arabia.

Challenges

With so many benefits, the case for guidelines is obvious but despite this the RCR, like others, struggles to get healthcare professionals to embrace their use. It is difficult to get referring clinicians to use them without some form of encouragement, effective feedback or sanctioning. The reasons for this are many, including issues around time pressures, inaccessibility of guidelines, information overload, mixed messages from different guidelines, and patient expectations.

The future

Added to the challenges of implementation is the ongoing production of up-to-date evidence-based guidelines. The RCR has relied heavily on the enthusiasm and dedication of a significant number of its members giving up their time to support this work. Even so, there is a considerable cost required to resource the process and the production of the final versions,

particularly as the process becomes, rightly, more robust and the delivery more complex. In the past, this process has been supported by funding nationally outside the College, but recurrent support in its entirety has proved difficult and so the challenge is to look at other models of ensuring effective use of the guidelines.

The RCR is committed to the continued publication of the guidelines and to an everimproving process of update to ensure that the UK imaging population continues to be the best informed in the world. The RCR is particularly keen to develop decision support software based on its guidelines, so that *iRefer* can be used exactly when needed – when the decision to refer is made.

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- **3.** The Journal of Bone and Joint Surgery instructions to authors. http://www2.ejbjs.org/misc/instrux.shtml

Talk 7: Referral guidelines in France

Philippe Grenier, the Société Française de Radiologie (SFR)

Prof. Philippe Grenier, Former General Secretary of the Société Française de Radiologie and Coordinator of the French Referral Guidelines

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In 2003, the European Directive EURATOM 97/43 was transposed in the French law. Despite the European Society of Radiology (ESR) recognized the referral guidelines from the Royal College of Radiology (RCR) and proposed to the national societies to use these guidelines after translation in their national language, the French Society of Radiology [Société Française de Radiologie (SFR)] and the French Society of Nuclear Medicine [Société Française de Médecine Nucléaire (SFMN)] decided to develop French referral guidelines for the clinical use of medical imaging (Guide du Bon Usage des Examens d'Imagerie Médicale).

Two reasons explained this decision. The first was a translation of the European Guidelines in French which was of insufficient quality, and the second was the willingness to initiate appropriation of the guidelines by French professionals.

The main objectives of these referral guidelines were not only to avoid the non-clinically indicated examinations, and to improve the clinical practices by rationale of imaging examination indications, but also to serve as a standard of reference for clinical audits. This initiative was supported by the French national authorities [Haute Autorité de Santé (HAS) and Autorité de Sûreté Nucléaire (ASN)]. It was decided to use the methodology of Delphi consensus for harmonization with international guidelines, following in this way the footprints of the RCR.

A <u>steering committee</u>, including representatives of both societies (SFR and SFMN), national authorities [HAS, ASN and Institut de Radioprotection et de Sûreté Nucléaire (IRSN)], and professional organizations (union of private radiologists, union of public hospital radiologists, academic colleges of radiologists and nuclear medicine physicians) was established.

<u>Fourteen subcommittees</u> were created representing the different subsections of medical imaging (neurology, head and neck, musculoskeletal, vascular disease, chest diseases, gastrointestinal, gynecology/obstetrics, breast, paediatrics, endocrinology, lymphoma, cardiology, urogenital, polytrauma). Every subcommittee included three main components: a writing group made of 2 to 9 expert radiologists and nuclear medicine physicians, a multidisciplinary evaluation group made of 12 to 20 experts (50% radiologists and nuclear medicine physicians, and 50% clinicians), and a multidisciplinary reading group made of 30 to 60 experts (50% radiologists and nuclear medicine physicians and 50% clinicians). The expert radiologists were selected from the different subspecialty societies of medical imaging. The expert clinicians were nominated by the scientific societies of clinicians in all specialties in medicine and surgery. Twenty-five of these scientific societies accepted to participate in the process and designated experts.

The writing group of every subcommittee was in charge to establish the first proposals for recommendations. The experts selected items representing various clinical situations (symptoms or suspected disease), analysed the bibliography from the five previous years after interrogation of international data bases, summarized their analysis and wrote a list of arguments to support their recommendations. Then they proposed recommendations presented in five columns: entry word (clinical symptom or suspected disease), imaging modalities, recommendations of indications, grade of recommendation, comments, and level of radiation effective dose. All imaging modalities and techniques were taken into consideration, not only those delivering ionizing radiation such as radiography, CT, nuclear medicine, angiography but also ultrasound and magnetic resonance imaging. For every clinical situation and for every imaging modality, the level of recommendations included: indicated, indicated only in particular situations (described in the comments column), specialized examination (complex or expensive examination ordered only by experimented physicians in the field of the disease, whose indication needs a multidisciplinary consultation or a consultation with a radiologist subspecialized in the field), not indicated initially (but may be considered according to the patient outcome or specific patient-related conditions), contra-indicated.

The grading of recommendations permitting to express evidence-based diagnostic impact included three levels: Grade A: high level of scientific proof (randomized controlled trials, meta-analysis); Grade B: intermediate level of scientific proof (comparative non randomized studies, cohort studies, randomized comparative studies of mild power); Grade C: low level of scientific proof (www.has-sante.fr). For every modality, the intensity of effective dose was evaluated on the basis of national reference doses provided by the national organization of radioprotection (IRSN). The scores ranged from grade 0 (0 mSv), grade I (< 1mSv), grade II (1-5 mSv), grade III 5-10 mSv, and grade IV (> 10 mSv).

In every subcommittee, the <u>multidisciplinary evaluation group</u> was in charge to analyse the recommendations proposed by the writing group. The guidelines, bibliography analyses, and

lists of arguments were sent to the members who were asked to reply to a questionnaire using a scoring scale (1-9) on every component of each item (1: inappropriate, 9: fully appropriate). Medians of scores were calculated. Then, the members met together with the leaders of the writing group at the SFR office. All items having a median score lower than 7 were discussed in order to get to a formalized consensus between experts. The following step consisted to a second evaluation using the same scale and questionnaire, requested either on site at the end of the meeting or in the 48 hours following the meeting. This was considered as the formalized consensus between experts.

The <u>multidisciplinary reading group</u> was in charge to analyse the recommendations proposed by the formalized consensus. The recommendations were sent to the members of this group for reading and comments, and the finalization of the recommendations (taking into account the replies) were made by the subcommittee leaders and the members of the steering committee.

The <u>first edition</u> of the French referral guidelines came out in <u>2005</u>. It was available on line and published on booklets. The guidelines included 381 clinical situations, and 889 imaging modality recommendations of grade A (n = 62), grade B (n = 618) or grade C (n = 209). Five-hundred and seventy-five physicians were involved in the process including 315 radiologists and nuclear medicine physicians and 260 clinicians. The booklets were sent to all members of the both imaging societies (SFR and SFMN) and all experts having participated to the procedure. Booklets were also sent to the associated scientific societies and national health authorities. The rest of the booklets were sold on demand by the SFR. An electronic version of the document was put on different websites (SFR, SFMN, HAS and ASN). Thirty per cent of cost payment was supplied by the ASN. The rest was taken in charge by the SFR. Unfortunately there was not a general distribution of the document to the general practitioners and specialists in the country. There was no national publicity for the document provided by national authorities. The electronic version of the guidelines was static (PDF) without software permitting rapid consultation. No assessment of the guidelines impact was performed.

In <u>2009</u>, it was decided to prepare a <u>new version of the referral guidelines</u>. A new steering committee and new subcommittees were established. The analysis of the bibliography was asked for the previous 10 years. The list of clinical entry words was submitted to a panel of general practitioners and 20% of items were changed compared to the first edition. The same Delphi process (Consensus formalisé entre experts, version longue) as that used in the first edition was applied. This new version is only electronic, run on specific software. It is available on line and can also be uploaded on computers and tablets. An application for smartphones is in course of preparation. The official presentation of this new edition will be done at the "Journées Françaises de Radiologie" in Paris on October 2012. The French authorities of health have promised a large publicity for the guidelines.

The college of academic radiologists [Collège des Enseignants en Radiologie de France (CERF)] has decided to incorporate the referral guidelines in the training programmes of students at medical faculties. A new committee will be in charge to ensure continuous update of the guidelines. These guidelines might be used as a frame of reference in continuous professional development programmes [Développement Professionnel Continu (DPC)] which is the new format for continuous medical education (CME) in France. The SFR

has raised the project to integrate the referral guidelines in clinical decisions system support for MR requests.

In summary, this experience of developing referral guidelines at a national level has made it clear that to set up referral guidelines is a long and costly process, involving a high number of physicians. A Delphi process, performed at a national level, certainly helps appropriation of referral guidelines by radiologists and clinicians in the country. Advertisement, distribution, reminders, and education are necessary to ensure the use of guidelines by physicians, and, a web version of guidelines should be recommended to facilitate practical use, availability, distribution, and continuous update.

Société Française de Radiologie (SFR) Société Française de Médecine Nucléaire (SFMN) Autorité de sûreté nucléaire (ASN) Institut de Radioprotection et de Sûreté Nucléaire (IRSN) www.sfrnet.org www.sfmn.org www.asn.fr www.irsn.fr

Talk 8: Referral Guidelines in Western Australia

Richard Mendelson, Western Australian Health Department

Dr. Richard Mendelson, Western Australian Health Department, Perth, Australia richard.mendelson@health.wa.gov.au

Diagnostic Imaging Pathways (DIP) is a suite of evidence-based and consensus based guidelines that has been developed over many years to assist clinicians to choose the most appropriate diagnostic examinations according to best practice and evidence. It is only published electronically and is freely available from the intranet within the public hospital system in Western Australia and from the internet: www.imagingpathways.health.wa.gov.au.

The intellectual property of DIP is owned by the Western Australian Health Department. Editorial control and management of DIP is based at Royal Perth Hospital, but Editorial Panel members, contributors and advisors are sourced from other public and private health institutions in WA and, indeed, from interstate and even overseas.

Within the public health system, the aim of DIP is to be a tool for quality control and demand management, through its guidance to clinicians to choose the appropriate imaging in common clinical scenarios.

DIP contains more than 150 pathways, which are relevant to all of the organ systems and common clinical scenarios. Each of the pathways is laid out as a diagnostic flowchart. Commencing with a presenting condition (e.g. low back pain) the user can step through various clinical possibilities (e.g. back pain +/- sciatica) and indications for investigation (e.g. 'red flags'), to receive advice on a sequence of examinations which is recommended according to broad consensus and the best available evidence. Access to supporting information and source references is provided. References are graded according to the Oxford system for levels of evidence. DIP is thought to be unique in its format; rather than the tabular form of recommendations used by other imaging guideline developers DIP uses an algorithmic or flow-chart structure. This allows for a 'layered" format for users to access

as much or as little background information as they wish. At the minimum level they can view the flowchart only, but behind the flow charts is accessible, referenced narrative text which forms the basis for the recommendations.

DIP also contains general information about diagnostic imaging, information for patients and carers, image galleries of normal anatomy and pathology, and teaching points for students.

The clinical and academic content is developed, continuously reviewed, and updated at least quarterly under the direction of an Editorial Panel. The panel obtains advice from a large network of 'provider' and 'referrer' contributors which includes imaging specialists with subspecialty interests, medical and surgical specialists, and general practitioners. The recommendations in DIP are therefore evidence and consensus-based.

The application is widely accepted and used and has achieved national and international acclaim. It receives about 7 million 'hits' per year from users worldwide.

DIP is endorsed by the Royal Australian & New Zealand College of Radiologists, is accredited by the Geneva based Health On The Net Foundation, and meets standards for partnership with HealthInsite and the Joanna Briggs Institute. DIP has been accepted as a member of the Guidelines International Network.

The Australian National Health & Medical Research Council (NHMRC) provides access to DIP via its Clinical Practice Guidelines Portal.

Importantly, DIP has achieved accreditation from NICE - National Health Service Evidence (UK). Effectively this means that DIP complies with the AGREE II criteria for development of guidelines.

DIP has been adopted into the curricula of several Australian medical schools including the University of Western Australia and the University of Notre Dame Australia.

The World Health Organisation (WHO) is collaborating with the International Radiology Quality Network (IRQN) on the development of imaging referral guidelines. Draft WHO/IRQN guidelines are based on three existing sets of diagnostic imaging guidelines from around the world, one of which is DIP.

Despite DIP's widespread use, there is evidence from our own studies and those of others that 'stand-alone' guidelines have limited utility in altering requesting behaviour among referring clinicians. Therefore, we are developing and evaluating an electronic request/decision support tool which integrates the academic content of DIP into the requesting process for diagnostic imaging so that imaging recommendations are a seamless part of the clinicians' work flow.

Talk 9: Referral Guidelines in Canada

Martin Reed, The Canadian Association of Radiologists (CAR)

Dr. Martin Reed, Chair, Guidelines Working Group, Canadian Association of Radiologists Department of Radiology, Children's Hospital, Winnipeg, Canada mreed@exchange.hsc.mb.ca

The Canadian Association of Radiologists (CAR) referral guidelines were initially developed as a result of a strategic planning process which was carried out in 2004. The first of three goals identified by that process was "to actively participate in health system cost control through control of inappropriate utilization". In order to achieve this, a guidelines working group was set up. Recognizing that the CAR did not have the resources to develop its own complete set of guidelines a search was undertaken to determine if any sets of radiology referral guidelines were available which we could adopt and adapt. The committee concluded that the Royal College of Radiologists guidelines, Making the Best Use of the Department of Clinical Radiology: Guidelines for Doctors (5th Edition) would be the most appropriate for our use. The Royal College of Radiologists kindly gave us permission to use these guidelines. The guideline committee reviewed all the guidelines. Each section was sent out to independent reviewers who were members of the CAR and had expertise in the appropriate specialty area. The guidelines were also sent to the Canadian Association of Nuclear Medicine. A presentation on the CAR referral guidelines was also made to the National Specialty Societies meeting which was held in conjunction with the annual meeting of the Canadian Medical Association (CMA) in 2005, and the guidelines were circulated to all the specialty societies for comments. The comments received from all these reviewers were all reviewed by the committee, and the guidelines were finalized. For the most part this involved only minor changes to adapt the guidelines to the Canadian context.

The guidelines were published in both English and French versions in booklet form in 2005. However, recognizing that a book of guidelines may not be the best way of ensuring their utilization the guidelines were also made available on the Internet through password protected websites including the CAR website, the CMA Infobase and the website of the College of Family Physicians. A PDF version was also made available on CD. The guidelines were quite widely circulated and the first English printing of one thousand copies was sold out and a second printing had to be made.

The CAR has recently undertaken and completed a revision of its guidelines which are now freely available on the website (http://www.car.ca/en/standards-guidelines/guidelines.aspx). The CAR is committed to continuing to improve and update their referral guidelines, to encourage their use as widely as possible in the physician community in Canada.

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Talk 10: Referral Guidelines in the USA

Michael Bettmann, American College of Radiology (ACR)

Michael Bettmann, MD, FACR, FAHA

Chair, ACR Appropriateness Criteria Oversight Committee, Co-Chair, ACR Task Force on Decision Support

Basic concerns in the utilization of imaging include its overuse, inappropriate use, increasing costs and radiation exposure. The American College of Radiology (ACR) Appropriateness Criteria® are based on the best-available clinical data. The intended uses of these criteria include education and clinical decision guidance. In a specific situation, if the healthcare provider is considering an imaging study they should ask the question what study, IF ANY, is most likely to provide the necessary information?

Some of the potential reasons for inappropriate imaging include:

- Patient expectations and demands for imaging
- Concerns of liability exposure if diagnosis is delayed
- Conflict of interest presented by physician ownership of imaging equipment (selfreferral)
- Lack of specific guidance from Radiologists
- Lack of knowledge by ordering physicians and other providers (increasing number of exams ordered by non-physicians)-e.g., "customary practice"

Table 1: Medical imaging procedures with largest contribution to cumulative effective dose.

Procedure	Average Effective Dose	Annual Effective Dose per Person	Proportion of the Total Effective Dose from All Study Procedures
	millisieverts		%
Myocardial perfusion imaging	15.6†	0.540	22.1
CT of the abdomen	8	0.446	18.3
CT of the pelvis	6	0.297	12.2
CT of the chest	7	0.184	7.5
Diagnostic cardiac catheterization	7	0.113	4.6
Radiography of the lumbar spine	1.5	0.080	3.3
Mammography	0.4	0.076	3.1
CT angiography of the chest (noncoronary)	15	0.075	3.1
Upper gastrointestinal series	6	0.058	2.4
CT of the head or brain	2	0.049	2.0
Percutaneous coronary intervention	15	0.043	1.8
Nuclear bone imaging	6.3	0.035	1.4
Radiograph of the abdomen	0.7	0.028	1.1
CT of the cervical spine	6	0.020	0.8
CT of the lumbar spine	6	0.018	0.7
Chest radiograph	0.02‡	0.016	0.7
Thyroid uptake	1.9	0.016	0.7
Intravenous urography	3	0.014	0.6
CT of the neck	3	0.014	0.6
Cardiac resting ventriculography	7.8	0.014	0.6

Some of the potential reasons for inappropriate imaging include:

- Patient expectations and demands for imaging
- Concerns of liability exposure if diagnosis is delayed
- Conflict of interest presented by physician ownership of imaging equipment (selfreferral)
- Lack of specific guidance from Radiologists

^{*} Average effective doses for these imaging procedures are based on data from Mettler et al. 10
† Calculation of the average radiation dose for myocardial perfusion imaging with the use of single-photon-emission CT relied on dose coefficients from a detailed review of radiation dosimetry of specific cardiac radiopharmaceuticals, 17 median injected radiopharmaceutical doses (millicuries) from the guidelines of the American Society of Nuclear Cardiology, 18 and distributions of the use of various protocols in the United States. 20
\$ This dose is the effective dose for a posteroanterior study of the chest.

• Lack of knowledge by ordering physicians and other providers (increasing number of exams ordered by non-physicians)-e.g., "customary practice"

<u>Ideal clinical imaging guidelines are:</u>

- Evidence-based
- Produced by experts in imaging and supplemented by others
- Consistent, with a transparent methodology
- Updated regularly (for example every 2 years)
- Widely accepted
- Readily available-on-line, as a database, as part of Computerised Physician Order Entry (CPOE) or Decision Support Systems (DSS)

ACR Appropriateness Criteria® were developed to provide data-based guidance to requesting physicians, radiologists, and radiation oncologists, in making initial decisions about diagnostic imaging and therapeutic techniques.

In conclusion, the ACR Appropriateness Criteria®:

- Provide a sound, transparent, reproducible methodology
- Are data-based, supplemented by expert opinion
- Must "translate" to achieve electronic medical record (EMR)usability
- Demonstrate that sound imaging guidelines, incorporated into EMRs, are necessary

Session 1: Summary and Conclusions

Rapporteur: Pete Cavanagh, The Royal College of Radiologists (RCR)

This session covered the drivers for the effective use of guidelines, followed by the experience from a number of countries who had developed and used their own referral guidelines. The key messages include:

Drivers for the effective use of guidelines

- There is European and International Legislation related to radiation protection that requires effective justification of imaging tests involving radiation based on evidence based guidance
- Increased per capita dose by medical imaging across Europe and internationally
- Earlier access to appropriate imaging is known to affect outcomes in a number of conditions

Production of Guidelines

- There was a similar process for the production and formatting of guidelines by those countries who presented their experience with the exception of Western Australia
- Most countries displayed the guidelines in a tabular form involving a grading system but in Western Australia the guidance was integrated into a decision making algorithm
- All countries reported that the production of evidence-based guidelines was resource intensive particularly in regard to radiologist input to the process.

- Thee was an acknowledgement that there was duplication of effort, with the same evidence being reviewed in each individual country reaching the same or similar conclusions
- The guidelines were radiologist initiated and owned and this may well have an impact on the adoption of guidelines by the end user

Challenges in Evidence

- The evidence base is often related to comparison of differing modalities in terms of accuracy, safety and efficiency but there is less robust data on the impact of the use of imaging to patient outcomes. Improvements in process are often considered as a proxy for outcome
- Evidence in many pathways is not always present and if present is not always robust
- A key factor should be the overall efficiency gains within the health system by the correct use of guidelines

Why don't guidelines work?

There were common challenges and barriers at the following stages: awareness, agreement, adoption and adherence.

Specific barriers that were discussed included:

- The total number of guidelines was seen as a potential barrier for adoption/adherence – often in excess of 300
- It was agreed that there had to be ease of access by the end user at the time of referral and for this reason paper versions were the least effective. Web- based or App-based should in principle improve this.
- Ideally guidelines should be free to recognised referrers but this requires a stable financial model for the production.
- Guidelines were often seen as owned by the radiology/radiologists with no real ownership by the referrer. In some instances certain clinical specialties had developed their own guidance as part of clinical pathways which had the potential to conflict with the radiology guidelines
- The increasing concern by referrers of the potential for litigation if they miss a diagnosis leads to unnecessary overuse of imaging
- Patient expectations are continuing to increase and their insistence on imaging can over-ride clinical judgement

Solutions

Potential solutions to the barriers and challenges were suggested as follows:

- European or International Collaboration on reviewing evidence
- Focussing on fewer guidelines which are likely to have the biggest impact to safe, quality and efficient care
- Involve referrer groups in the production and promotion of guidelines
- Integrating guidelines into the electronic referral process 'decision support' software
- Increasing dose awareness as part of the guideline process
- Improved communication/promotion
- Focus on improving the evidence base for the guidelines that are likely to have most impact

- Production of internationally agreed guidelines with the ability to customise to national/ local circumstances
- Education/training/audit

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Session 2: Specific Issues

Chair: Mario Bezzi, Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Rapporteur: Nick Ashford, Royal College of Radiologists (RCR)

Talk 11: Particular paediatric points

Jean-François Chateil, European Society of Paediatric Radiology (ESPR)

Jean-François Chateil MD, PhD Member of the board of the European Society of Paediatric Radiology, past president jean-francois.chateil@chu-bordeaux.fr

Imaging referral guidelines in Europe: Specific Aspects in Children

Why is there a need for specific recommendations for children? Children demonstrate a higher sensitivity to ionizing radiations. Pathology can be different in children relative to adults, and different imaging procedures can be carried out. Specific diagnostic reference levels are required, and, in addition, a need for specific guidelines for children has been expressed in a European survey.

Some of the difficulties associated with the establishment of specific recommendations for children include a lack of consensus between paediatricians, radiologists, and countries, heterogeneity of equipment and heterogeneity of formation.

There is a real need to control radiation level with paediatric imaging. The risks associated with medical irradiation are higher at a younger age, particularly the potential carcinogenic effect (see Figure 1.). Organs are particularly sensitive to radiation at younger age, cells are dividing faster, and the expected remaining lifetime is much longer than in older age.

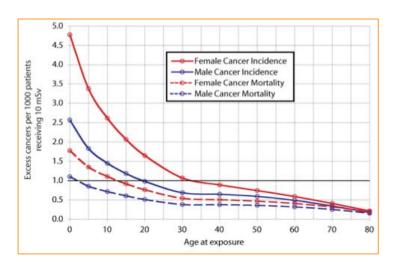


Fig. 1. Additional risk of cancer induction by ionising radiation at different ages.

What is the real risk with paediatric imaging?

In the United States, of approximately 600,000 abdominal and head CT examinations annually performed in children under the age of 15 years, a rough estimate is that 500 of these individuals might ultimately die from cancer attributable to the CT radiation.

Further, a paper was published in the Lancet in June 2012 which showed the relationship between radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours (Pearce et al. 2012). The paper concluded that Use of CT scans in children to deliver cumulative doses of about 50 mGy might almost triple the risk of leukaemia, and doses of about 60 mGy might triple the risk of brain cancer.

In conclusion:

- Radiation-induced effects are greater in children than they are in adults
- Conventional radiography may represent a low risk, however CT represents a real risk to children, in relation with relative delivered high dose, cumulative effect and longer expected lifetime.
- Some of the educational objectives for paediatric radiology include:
 - Strong justification of explorations with radiation
 - Use of substitutive imaging methods without radiation (US, MRI)
 - ALARA attitude every day: optimization
- Imaging Referral guidance specific for children is essential, with diffusion to general practitioners, paediatricians and radiologists.

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Talk 12: Referral guidelines and Interventional Radiology

Mario Bezzi, Cardiovascular and Interventional Radiological Society of Europe (CIRSE)

Mario Bezzi, MD Aggregate Professor of Radiology at the University of Rome Sapienza, Italy Mario.bezzi@uniroma1.it

Image-guided interventional procedures are performed in large numbers in Europe and in the United States and the number of procedures performed annually has increased over the past 20 years (1–3). While the benefits of Interventional Radiology (IR) to patients are

extensive and beyond dispute, there are also some procedure-related risks. One of these risks is that many IR procedures have the potential to produce patient radiation doses high enough to cause radiation effects and occupational doses to interventional radiologists high enough to cause concern. Management of radiation exposure is therefore essential for these procedures. This is achieved by education in radiation safety which is part of general radiology training and IR training.

The key issues in radiation exposure management can be summarized in: patient selection, procedure performance, patient monitoring, and appropriate documentation and follow-up. Patient selection is therefore the first key point in a strategy of dose reduction.

The decision to refer a patient to a specialist IR service is a crucial point in his/her management. Despite its importance, however, there has been little research in this area. Many retrospective evaluations of referrals seek to quantify the level of appropriateness, often from one stakeholder's perspective. Careful analysis reveals that referrals are more complex. They reflect the needs and expectations of individual patients and their families, the knowledge and experience of the individual practitioner, and the range, type and level of services available locally, as it is for Diagnostic Radiology.

There are several differences between Diagnostic Radiology (DR) and IR that we must consider when discussing any proposed Referral Guidelines for IR procedures. DR deals with diagnostic imaging investigations while IR deals with image guided treatments. Imaging investigations are carried out in all primary care centres while IR procedures are most often offered in secondary/tertiary centres. The radiation exposure for most diagnostic imaging tests is standardized, while the same IR procedure may cause different radiation doses in different patients depending on procedural complexity, standard of equipment and body habitus. Importantly, just like a surgical procedure, an IR procedure is a consultation between the Interventional radiologist and the patient where the procedure, risk benefit ratio and alternatives are discussed and consent obtained. Each consult is an individual transaction and generalizations are difficult to construct.

Concerns over patient radiation doses are valid. However, as IR procedures offer a therapeutic option, the risk of radiation exposure is usually outweighed by the benefit to the patient. IR procedures sometimes require clinically significant amounts of radiation, but the risk of radiation is low compared to other procedural risks such as haemorrhage or tissue ischaemia, while the benefits of imaging guidance are great. In fact, image-guided procedures often cause less morbidity and mortality than the equivalent surgical procedures. The potential harm due to radiation is less than the potential harm due to a procedure that is cancelled, incomplete, or clinically inadequate because of concerns over radiation.

So far, most of the process of patient selection and procedure justification in many European countries has been controlled by the Interventional Radiologists. The Interventional Radiologist is by nature committed to safety. As a professional and scientific society, the Cardiovascular and Interventional Radiological Society of Europe (CIRSE), is fully aware of its role in assuring patient safety. As a matter of fact, in its "Mission and Values" statements, CIRSE includes among its main values to be "Respectful and Safety Conscious".

As a further example, CIRSE is actively involved in an EU Research tender: the **MEDRAPET** (**MED**ical **Ra**diation **P**rotection **E**ducation and **T**raining) project (4). The primary aim of the

MEDRAPET project is the identification of needs in radiation protection training. An integrated approach to education and training with high-standard training programmes harmonised at EU level is a key prerequisite to ensure excellence in radiation protection and to implement programmes for dose optimization in medicine. CIRSE is convinced that it is essential that all stakeholders in radiation protection ensure that proper education and training are in place, in particular with regard to new technologies and complex medical exposure procedures that have been developed in the past years and that are introduced into clinical practice at a rapid pace. Correct patient referral and evaluation of alternative treatment options are the first important steps of radiation dose reduction.

Another important aspect of CIRSE commitment to safety is the "CIRSE IR Patient Safety Checklist" (5). The first three items in this list are relevant to the concept of referral and procedure planning:

- 1. Was the case-procedure discussed with the referring physician or within a MDT?
- 2. Were relevant previous imaging studies reviewed?
- 3. Was relevant medical history reviewed?

This concept is underlined in a recent review article on "Clinical Radiation Management for Fluoroscopically Guided Interventional Procedures" by Miller et al. (6). The authors note how pre-procedural radiation dose management starts with a multidisciplinary discussion on treatment options. It is important to realize that Interventional Radiology procedures are effectively surgical procedures and extra information is required, in terms of patient safety, than for diagnostic imaging. Coagulation status, relevant medical and past medical history, performance status, informed consent and patient and/or family expectations are all important issues that require attention before any IR procedure is scheduled.

It is during this multidisciplinary discussion that the Interventional Radiologist acts as a "gatekeeper" of referral. This may happen at multiple levels. The IR may be directly consulted by the referring physician, over the phone or during a joint review of clinical and imaging results. IRs are increasingly seeing patients in an outpatient setting to discuss the potential IR procedure, alternatives, risks and benefits. For more complex cases, the treatment options are discussed within Multidisciplinary Teams (MDTs) and the great majority of oncologic IR procedures are discussed during Tumour Board Panels. In addition, procedures are scheduled by the Interventional Radiologist and the administrative team in adherence to currently available Practice Guidelines and applying a Level 3 justification, where the application of the specific procedure to an individual patient must be justified.

Now the question that arises is: what kind of IR Referral Guidelines are available in Europe that may assist referring physicians and the Interventional Radiologist in everyday clinical practice?

Currently in Europe, IR procedures are usually included in Referral Guidelines developed for DR. This can happen in two ways. IR procedures may be listed in a dedicated section, as is the case for the guidelines of SIRM (Italian Society of Radiology) (7) and of the Société Française de Radiologie (8); in both guidelines there is an "Interventional Radiology" subsection which lists between 35 and 50 common IR procedures. For each clinical condition and relative IR procedure the level of recommendation is indicated, together with the level

of radiation dose involved (in a generic 1-4 grade scale) and a comment explaining the specific features of the procedure described.

In other Diagnostic Imaging Referral Guidelines, the IR procedures are most commonly listed as part of a diagnostic problem. This is the case, for example, of "Percutaneous Transhepatic Cholangiography" which is discussed and analyzed within the diagnostic problem "Jaundice" in the section "Gastrointestinal system", as reported in the Referral Guidelines developed by the Royal College of Radiologists (9). For each IR procedure, the level of recommendation, the level of radiation dose involved (in a 1-4 grade scale) and a comment on the specific features of the procedure are included.

In each of these two approaches, multidisciplinary knowledge was gathered in the preparation of the guidelines. Experts from several clinical specialties and several different scientific societies contributed to the creation of guidelines of member states of the European Union. Despite this effort, there is not full coverage of all the clinical conditions that can be encountered in everyday practice and the whole spectrum of IR procedures that can be performed is not analyzed in detail. We believe that a complete set of referral guidelines for IR is not possible because of the individual nature of each referral and consultation.

A different way to look at referral guidelines in IR, is to find them within multidisciplinary guidelines which are in most cases prepared through an intersociety consensus. These multidisciplinary guidelines are designed to assist physicians, patients, health-care providers, and health authorities in the decision-making processes according to evidence based data.

Several examples can be found in the literature. Management of hepatocellular carcinoma is discussed in the EASL–EORTC Clinical Practice Guidelines (10). Guidelines for the early management of the adults with ischemic stroke are given in an intersociety document prepared by North American cardiology and neurology associations (11), while guidelines for the management of peripheral arterial disease are described in the TASC-II document whose preparation involved several scientific societies from different disciplines in Europe and North America (12).

Multidisciplinary guidelines prepared through intersociety consensus, most of the times do not mention radiation exposure issues. It would be advisable that these issues be considered in future multidisciplinary guidelines and that agencies and societies involved in radiation protection be consulted before publication.

Conclusion

Practice guidelines for IR are not fully implemented in current DR guidelines. No member state of the European Union has independent guidelines created for IR by the national IR society. In most cases, in clinical practice, the Interventional Radiologists has the role of regulating the referrals (clinical gatekeeper). At the present state, it would be really difficult to try and create guidelines for all IR procedures as risks do not just relate to radiation dose and each referral is an individual contract between the patient and the Interventional Radiologist. In any case, multidisciplinary treatment guidelines should be preferred.

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Talk 13: Referral guidelines and Nuclear Medicine

Fred Verzijlbergen, European Association of Nuclear Medicine (EANM)

Prof. Fred Verzijbergen President of the European Association of Nuclear Medicine j.verzijlbergen@erasmusmc.nl

The European Association of Nuclear Medicine (EANM) is comprised of 3600 individual members, 39 national societies, and has 16 affiliated members (countries outside Council of Europe). The governance structure for EANM is shown in the figure below:

Executive Secretariat Executive in Vienna with In-House Committee Congress Management **Advisory Council** Members Delegates Assembly Assembly 12 Committees 1 Task Group **Educational Facility at** the Executive European School of Secretariat in Vienna **Nuclear Medicine**

EANM - Governance and Bodies

Of the twelve EANM committees, the **Dosimetry Committee** has published several documents, including:

- A Series on Standard Operational Procedures for Pre-Therapeutic Dosimetry II. Radioiodine Test Prior to Radioiodine Therapy of Benign Thyroid Disease (revision 2012 in progress)
- 2. A guidance document on good practice of clinical dosimetry reporting (publication: 2010)
- 3. Guidelines for bone marrow and whole-body dosimetry (publication: 2010)
- 4. A series on standard operational procedures for pre-therapeutic dosimetry: blood and bone marrow dosimetry in differentiated thyroid cancer therapy (publication: 2008)

The **Paediatrics Committee** has published the following guidelines:

- 1. Guidelines for standard and diuretic renogram in children (publication: 2011)
- 2. Guideline for radioiodinated MIBG scintigraphy in children (publication: 2011)
- 3. Guidelines for paediatric bone scanning with 99mTc-labelled radiopharmaceuticals and 18F-fluoride (publication: 2010)
- 4. Guidelines on 99mTc-DMSA Scintigraphy in children (publication: 1st version 2001, revised version 2009)
- 5. Guidelines for lung scintigraphy in children (publication: 2007)
- 6. Guidelines for 18F-FDG PET and PET-CT imaging in paediatric oncology (date of publication not-available)

The Cardiovascular Committee has published the following:

- Hybrid cardiac imaging: SPECT/CT and PET/CT. A joint position statement by the European Association of Nuclear Medicine (EANM), the European Society of Cardiac Radiology (ESCR) and the European Council of Nuclear Cardiology (ECNC) -(publication: 2010)
- 2. EANM/ESC guidelines for radionuclide imaging of cardiac function (publication: 2008)
- 3. EANM/ESC procedural guidelines for myocardial perfusion imaging in nuclear cardiology (publication: 2005, currently under revision)

The **Oncology Committee** has published the following:

- 1. PET in radiotherapy planning: Particularly exquisite test or pending and experimental tool? (publication by EANM and ESTRO 2010)
- 2. EANM-EORTC general recommendations for sentinel node diagnostics in melanoma (publication: 2009)
- 3. Joint practice guidelines for radionuclide lymphoscintigraphy for sentinel node localization in oral/oropharyngeal squamous cell carcinoma (publication: 2009)
- 4. FDG PET and PET/CT: EANM procedure guidelines for tumour PET imaging: version 1.0 (publication: 2009)
- 5. Sentinel node in breast cancer procedural guidelines (publication: 2007)

Do the guidelines work?

- Most European NM physicians check the request the day before the actual study Pharmacists and Physicists are members of the team
- Working according to guidelines is a constant issue during audits
- Further improvement is required on the clinicians' side

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Talk 14: Radiation dose issues and risk

Reinhard Loose, German Commission on Radiological Protection (SSK)

Reinhard Loose MD PhD German Commission on Radiological Protection (SSK) German Roentgen Society (DRG) loose@klinikum-nuernberg.de

Justification is the first step in diagnostic radiology before applying ionizing radiation to an individual patient. This first step should always be a balance between the expected benefit and the risk of radiation. Depending on the type of imaging procedure the dose is variable in a range of more than 1:1000. Typical dose values for X-ray examinations are listed in Table 1.

EU (RP 118)					
Radiographic examinati	ons:	# chest exams	# days natural background		
Limbs and joints (except hip)	<0.01	<0.5	<1.5 days		
Chest (single PA film)	0.02	1	3 days		
Skull	0.06	3	9 days		
Thoracic spine	0.7	35	4 months		
Lumbar spine	1.0	50	5 months		
Hip	0.4	20	2 months		
Pelvis	0.7	35	4 months		
Abdomen	0.7	35	4 months		
IVU	2.4	120	14 months		
Barium swallow	1.5	75	8 months		
Barium meal	2.6	130	15 months		
Barium follow through	3	150	16 months		
Barium enema	7.2	360	3.2 years		
CT head	2.0	100	10 months		
CT chest	8	400	3.6 years		
CT abdomen or pelvis	10	500	4.5 years		

Table 1: typical effective doses for radiography, fluoroscopy and CT examinations, comparison with number of single PA chest examinations and comparison with natural background exposure (EU – RP 118) [1].

The next question is how reliable our data are and where they come from?

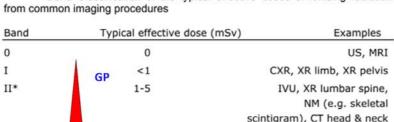
Table 2 shows dose values for radiographic chest examinations in different countries. It cannot be explained with the physical patient properties why the ratio of pa/lat view in Switzerland is 1:2 and in Belgium 1:8 (blue) or why the DAP for a pa view in Germany is about 20% of Norway (green). Hence, in future a more standardized approach for data acquisition is mandatory.

SOURCES AND EFFECTS OF IONIZING RADIATION United Nations Scientific Committee on the Effects of Atomic Radiation UNSCEAR 2008 Report to the General Assembly with Scientific Annexes How reliable are our data? •Questionnaires? •Health insurance companies? •National reporting systems?

VOLUME I

Country		Che	est
	Chest PA	Chest LAT	T.
A.conton En	0.16	0.73	<u> 1</u>
Australia	0.1.0		<u></u>
Belgium	0.15	1.23	ratio pa/lat 1:8.2
Czech Republic	0.40	1.20	_
Germany	0.13	0.46	DAP pa 20% of Norway
Greece	0.50		
Hungary	0.52	0.91	
Iceland	0.57		
Japan	0.33	0.44	
Lithuania	0.44	1.60	
Malta	0.20	0.45	
Netherlands	0.04		
Norway	0.64	0.82	DAP pa 0.64 μGy cm^2
Romania	1.30	3.50	
Slovenia	0.29	0.96	
Spain	0.17	0.49	
Sweden	0.40	0.40	T
Switzerland	0.10	0.20	ratio pa/lat 1:2.0
United Kingdom	0.16		

Table 2: Dose comparison for chest radiography in different countries. Regular type values are entrance air kerma in mGy, bold type values are for DAP in Gy cm² (UNSCEAR 2008).



Band Classification of the typical effective doses of ionising radiation

st The average annual background dose in most parts of Europe falls in band II.

Level of justification

Table 3: Dose bands for different groups of radiological examinations (UNSCEAR 2008)

Due to the wide dose range of all available radiological examinations it is helpful for justification to define dose bands from 0 (US and MRI), I (simple radiographic images) up to III and IV with CT of the trunk, PET-CT and some nuclear medicine studies. Dose band I is the range of natural radiation dose or below and needs a simple individual justification, which is in most cases included in the medical question of the referring physician. Examinations within the dose bands III and IV require a careful individual justification by a radiologist. In some cases it may be necessary to contact the referrer and change the requested procedure.

The associated risks of most medical X-ray examinations are comparable with other risks of daily life like smoking, car driving, sports and many others.

A significant difference between risks of daily life and medical imaging is the distribution of dose as a function of age and severity of disease. Figure 1 shows the dose distribution of 403 randomized patients in a large teaching hospital (Nuremberg). About 50% of patients get no X-ray examinations whereas in the exposed group 44 patients receive 90% and 10 patients 50% of the collective dose [3]. This demonstrates clearly that a minority of patients with high disease related risks receive the predominant portion of dose.

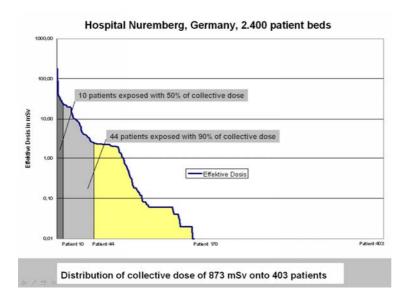


Figure 1: Distribution of collective X-ray dose on 403 randomized patients

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Talk 15: Imaging referral guidelines and implementation issues

Steve Ebdon-Jackson, Radiation Protection Division, UK HPA

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Euratom Directives establishing frameworks for radiation protection have been, for many years, the basis for regulations in European Member States. These have laid down the basic measures for the health protection of individuals against the dangers associated with ionising radiation. It is perhaps surprising therefore that Medical Exposure Directive 84/466/Euratom¹ made no reference to referrers or to referral guidelines. As a consequence, national regulations such as the UK's POPUMET regulations² made no reference to them either.

This did not prevent professional bodies and organisations taking a lead in these matters. In 1989, the Royal College of Radiologists (RCR) produced the first of a series of guidelines "Making the Best Use of a Department of Clinical Radiology"³, the latest of which was issued in 2012⁴.In 1990, the RCR, in conjunction with the UK's National Radiological Protection Board (NRPB) issued its document "Patient dose reduction in diagnostic radiology"⁵ which highlighted that up to 20% of radiology procedures in the UK might be clinically unhelpful.

The Department of Health (DH) in England was broadly supportive of the RCR's approach, but recognised the costs and logistics involved in production and dissemination. Nevertheless, such was the importance of the initiative, DH began to consider ways in which the need for referral guidelines could be incorporated into regulations.

The basis for doing so was provided by Directive 97/43/Euratom⁶ which required Member States to ensure that recommendations concerning referral criteria were available to those who referred patients for medical exposures and in Great Britain this was implemented in the Ionising Radiation (Medical Exposure) Regulations 2000⁷.

This was accepted by professions and hospital management without opposition; the RCR guidelines were already in their 4th edition. These guidelines were in use in every UK hospital and provided a standard of care. This has continued and in the edition of 2012, the change of name to "iRefer" demonstrates a maturity of development and confidence of the importance of such guidelines.

Inevitably, questions have been raised as to use rather than availability and value of guidelines within the referral and justification processes. Inclusion within a regulatory package should ensure implementation, but evidence of this is best provided through local and national audit. One such study in Sweden⁸ has demonstrated that the impact of guidelines might be less than expected, with the conclusion that 20% of CT examinations are not justified. Further examination of the situation however shows that the guidelines in place at that time were those produced by the European Commission in 2001⁹. Lack of up to date and locally derived guidelines may have influenced local practice.

Experience of use of guidelines does show that their use takes time and professional resolve. It might be easier to agree to referrals without question and to ignore the guidelines in place.

This is a matter of professional integrity. Experience of production of guidelines has shown that the process in expensive and time consuming, if it is done well and if guidelines are to have an acceptable level of evidence base. Nevertheless, despite these issues, there remains a role for referral guidelines, as long as they are up to date and auditing shows their use. The costs may not be trivial, but the potential impact is significant and it is important that funding is secured to ensure the continuing development and evolution of referral guidelines.

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Talk 16: Imaging referral guidelines and radiography

Graciano Paulo, European Federation of Radiographer Societies (EFRS)

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Since Roentgens' discovery professionals have obtained medical images for clinical diagnostic purposes. This can be accounted to be the origin of Radiographers' profession: a health professional that acts as the interface between patient and technology. In November 2011, the EFRS General Assembly approved a definition for the term "Radiographer" to be used in all international documents, to avoid further confusion and misinterpretation arising from the fact that there are several names referring to the same profession across Europe.

Therefore and according to the approved definition, Radiographers are recognised as being medical imaging and radiotherapy experts who:

- Are professionally accountable to the patients' physical and psychological well being, prior to, during and following examinations or therapy;
- Take an active role in the justification and optimization of medical imaging and radio therapeutic procedures;
- Are key-persons in the radiation safety of patients and third persons in accordance with the "As Low As Reasonably Achievable" (ALARA) principal and relevant legislation.

It is expected that the radiographer will have professional autonomy and accountability, develop good professional relationships, develop personal and professional skills and

demonstrate an ethical and knowledgeable understanding of the profession. It is considered vital that professional advancement arises out of evidence-based practice and is informed through focused research.

To guide these expectations EFRS has created a European Code of Ethics for Radiographers, focused on the radiographers' professional life, relation with the patients and personal and professional standards.

The outstanding evolution of imaging technology gave health systems, the capability to produce more and faster imaging procedures. Behind this "more and faster" concept, a progressive increase of patient dose and exam frequency (especially those delivering higher dose, such as CT and interventional procedures) is unfortunately verified.

Published data indicates reasons for this phenomenon, such as: lack of dose exposure awareness by referring practitioners; defensive medicine practice; out-dated information regarding new modalities or technological solutions; lack of a centralized patient data center policy implementation by the National Health Service (NHS) of each country, to avoid exam repetition; major cultural and organizational differences between each country NHS; patient pressure to perform more procedures; etc.

Health systems are complex socio-technical environments sustained on multi-professional teams, affecting and be affected by several variables that dramatically influence daily practice, such as:

- asymmetric knowledge (even within the same profession);
- some working in primary care units and others at highly technical equipped hospitals;
- some with easy access to all kind of technology and others limited to basic diagnostic tools and with difficulties in referring;
- some working in a "pure" NHS model (with almost 100% of health care delivery in public institutions) and others working simultaneously in public and private practice;

It's in this complex environment that solutions must be found to develop, create, disseminate and audit the implementation of EU imaging referral guidelines (IRGL). EFRS supports that IRGL are an important tool to drive clinical practice towards effective, efficient and safe patient care delivery, according to evidence-based standards.

It's important to be aware that IRGL are not only about Patient Radiation Protection, but also about prescribing (if necessary) the most adequate medical imaging procedure, according to the patient's clinical signs, symptoms and needs. These guidelines, once implemented, will certainly contribute to decrease medical imaging procedures and consequently decrease exposure, health expenditure and patient waiting list.

IRGL will help to build a bridge between science and daily practice. However, professional societies should be aware that one of the most important tools for the success of its implementation is the development of a perfect communication tool to deliver information to its members.

A more effective regulation of health systems and professional practice is also needed for the success of the implementation of IRGL, as well as a combined strategy to implement an effective clinical audit system, as a tool for promoting patient safety culture and improve the quality of care.

Therefore, there are several challenges for European IRGL. They have to adapt to professional daily practice and to each national health system model and be creative in finding a mechanism that avoids conflicts between health professionals, in regard to justification processes in medical imaging, due to:

- different professional opinions;
- economical impact of those opinions;
- patient rights

Due to the role of Radiographers' in a modern health care system, daily base practice demonstrates that they play a key role in medical imaging procedures, acting as an interface between patient and technology.

Radiographers are the pivot between referrers, patients and radiologists, and therefore a key player in the implementation of IRGL.

Being the final point of contact for the patient, Radiographers have the responsibility to guarantee the correct procedure to the right patient while ensuring maximum optimization of the procedure.

EFRS, as representative of European Radiographers, is ready for the challenge and available to be part of the solution to develop a better health system for EU citizens.

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Talk 17: Imaging referral guidelines for general practitioners

Wolfgang Spiegel, Austrian Society of General Practice and Family Medicine

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What GPs imagine radiological reports to be and what they wish from radiologists

Keep it clear and short:

- The referral question should be clearly addressed.
- Always give a brief summary of the radiological findings at the end of the report.

• State opinion about the dignity or clinical relevance of the main radiological findings.

What makes life easier for GPs:

Radiologists, please kindly:

- Give a first interpretation of the radiological test to the patient (if the referring GP likes you to do that) but do not address treatment options or patient management which is the duty of the GP.
- Get in contact with GP if immediate action is needed (e.g. a fracture) to coordinate patient management.
- Get in contact with GP if bad news needs to be broken to patient.
- Do not use abbreviations (acronyms).
- Do not say "due to gas in intestine assessment of the pancreas not possible". Assure quality.
- If quality of examination is not given (e.g. gas in intestine) reschedule and improve patient preparation.

What GPs would like radiologists rather not to do:

- Do not make any routine statement about when the test should be repeated!
- Do not recommend additional radiological imaging methods (e.g. MRI) in test report unless really unavoidable.
- If additional radiological imaging is indicated consider personal communication (e.g. telephone) with physician who referred patient.
- Do not tell the patient to which specialist he/she needs to go. Refer patient back to GP.

What radiologists are entitled to expect from GPs/FPs:

GPs/FPs:

- have to assess the need (indication) for radiological testing carefully.
- have to clearly state the clinical question.
- need to evaluate risk (e.g. radiation) and possible benefit (if available according to guidelines).

Radiologists can expect GPs/FPs:

- to inform them about the patient's clinical conditions and physical findings (referral letter or form).
- that they inform their patient about the sense of proposed radiological testing.
- that they interpret radiological findings to the patient with care and assure optimal patient management in the given setting.

What makes life easier for radiologists – a GP's view:

GPs/FPs:

- should brief radiologists about their practise style and possible spectrum of care.
- should inform radiologist beforehand about desired patient management when immediate action might be required after imaging is done.

What GPs should rather not do:

GPs/FPs:

• should not give in to patients' demands on radiological testing without clear indication (reason for radiological testing).

Summary and conclusion:

Good communication between GPs and radiologists is essential for efficient and patientoriented use of imaging methods. Both GPs and radiologists have professional principles and needs and expect each other to take them into account in professional interactions.

Guidelines and recommendations

Council Directive 97/EURATOM ARTICLE 3, JUSTIFICATION

1. Medical exposure referred to in Article 1 (2) shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation.

Council Directive 97/EURATOM ARTICLE 5, RESPONSIBILITIES

- 1. The prescriber as well as the practitioner shall be involved as specified by Member States in the justification process at the appropriate level.
- 2. Member States shall ensure that any medical exposure referred to in Article 1 (2) is effected under the clinical responsibility of a practitioner.

Conclusions

Introduction of radiological guidelines together with feedback on referral rates was effective in reducing the number of requests for spinal examinations over one year. Wider use of GP-orientated guidelines with regular updating and feedback might save costs and reduce unnecessary irradiation of patients.

Summary

- Communication between GPs and radiologists is essential for patient-oriented use of imaging methods.
- Both GPs and radiologists have professional needs and expect each other to take them into account in professional interactions.
- It improves coordination of care if GPs brief referral radiologist of possible patient management strategies in case of critical findings.

Talk 18: The patient's perspective

Alison Meyric-Hughes, Patient Liaison Group, The Royal College of Radiologists (RCR)

A.H.Meyric-Hughes@city.ac.uk

Many people are anxious when going to an imaging unit, both about the procedure itself and what it might reveal. Information about what happens before, during and after a procedure, including when and how the results will be given, helps allay patients' fears.

Referrers must check how patients will receive the necessary information. It is the imaging service that is responsible for creating and sending up-to-date, patient friendly guidelines and information. This needs to be written in clear, plain language without the use of acronyms. It should be available in a variety of formats, including, for example, Braille, and in the various languages appropriate to the location of the service.

Patients need to be told by the referrer why a service has been chosen, which is sometimes not the local hospital, and why the particular procedure has been selected.

Citing the referral guidelines can be useful in gaining patients' confidence and in reducing the feeling of lack of control. This, and the points made above, should help patients understand their conditions and give them a measure of sense of control. Referrers should remember the mantra "no decision about me without me".

Session 2: Summary and Conclusions

Rapporteur: Nick Ashford, The Royal College of Radiologists (RCR)

This session gave an excellent overview of referral guidelines from the perspectives of varying and diverse stakeholders in respect to guidelines with input from:

- Paediatric radiology
- Interventional radiology
- Nuclear medicine
- Radiological protection, both dose issues and risk as well as implementation issues
- Radiography and the radiographer
- General practitioners
- The patient's perspective

Not surprisingly all were strongly in favour of guidelines although each speaker saw and described their structure, design and use with differing perspectives.

The key presentation relating to paediatrics stressed the greater radiation induced effects in children, these risks being far greater with CT which is the real risk rather than conventional radiology. Education is essential and the development and provision of specific guidelines for children is essential. Discussion centred as to whether these should be stand-alone guidelines or separate guidelines integrated into a unified guideline publication.

Interventional radiology is a rapidly changing field hence the need for frequent updates with practice guidelines for IR not fully implemented in current diagnostic radiology guidelines.

Interventional radiologists act as clinical gatekeepers the design of guidelines to involve multidisciplinary practice, collaboration of a large number of diverse stakeholders and robust education, not only across the healthcare community, but also to patients, the public and media.

It was noted that procedural risks in interventional radiology were often far higher than radiation related risks.

Nuclear medicine benefits from fewer procedures, guidelines are committee driven and jointly written with clinical specialities. Interestingly technologists prepare parallel guidelines. All requests are routinely checked and there is a strong culture of audit.

Radiation dose and risk particularly the risk of medical exposure is in the range of day to day activities.

The balance between risk and benefit is pivotal, the assessment of dose alone is not helpful and justification requires knowledge of clinical circumstances. The wording of guidelines must be carefully chosen especially related to possible risk of misuse, criteria and appropriateness.

Key points of implementation are that guidelines are legally required but more importantly they are useful, they should be kept up to date they should be used, audited and their development funded.

Radiographers were portrayed as having the key role at the interface between patient and technology being the pivot between referrers, patients and radiologists. They are therefore key player in the implementation of referral guidelines.

The general practitioner presentation stressed that excellent communication between patient and GP and radiologist is essential. This will be facilitated by clear referral guidelines.

The patient's perspective stressed the need for dose information, clear communication (no acronyms), the need to be sensitive to the patient's needs and that the patient is a member of the team. "No decision about me without me".

The varying and diverse interpretation of "Specific issues" demonstrated the need for a broad base of knowledge expertise and experience when designing and implementing guidelines.

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Session 3: Survey Feedback

Chair: Jean-François Chateil, European Society of Paediatric Radiology (ESPR) Rapporteur: Steve Ebdon-Jackson, Radiation Protection Division, UK HPA

Talk 19: Guidelines survey development

Nick Ashford, The Royal College of Radiologists (RCR)

Dr. Nick Ashford, Treasurer of the Royal College of Radiologists, UK Nick.Ashford@wsht.nhs.uk

A questionnaire was developed by the RCR during December and January 2011-2012 following submission of the proposal for the project "Implementation of Council Directive 97/43/Euratom requirements concerning referral criteria for medical imaging in the European Union" as submitted as a consortium in June 2011.

A web-based survey was used to assess the availability of imaging referral guidelines, developmental methodology, preferences for future initiatives for European community action to facilitate justification and appropriate use of radiological diagnostic procedures An Initial draft was devised by the RCR, by a team which included: Denis Remedios, Pete Cavanagh, Hazel Beckett, Bethan Seymour and Nick Ashford, and this was presented at the Referral Guidelines Tender Project Kick-Off Meeting on 19th January 2012 in Luxembourg;

- Implementation of Council Directive 97/43/Euratom requirements concerning referral criteria for medical
- Imaging in the European Union
- EC Tender Contract no. ENER / 11 /NUCL/S12.60691 5

The draft was subsequently developed further in WP1 with input from all the members of the project consortium:

- European Society of Radiology (ESR), Project Coordinator
- The Royal College of Radiologists (RCR)
- Société Française de Radiologie (SFR)
- Cardiovascular and Interventional Radiological Society of Europe (CIRSE)
- European Society for Paediatric Radiology (ESPR)
- European Commission, DG Energy

The individual members were:

- Georgi Simeonov, European Commission
- Denis Remedios, ESR
- Philippe Grenier, SFR
- Mario Bezzi, CIRSE
- Karen Rosendahl, ESPR
- Maria Del Rosario Perez, WHO, external expert
- Madan Rehani, IAEA, external expert
- Monika Hierath, Project Manager, ESR
- Nick Ashford and Pete Cavanagh RCR

The survey design was presented at the EC referral Guidelines Workshop September 21st in Vienna. Important points included:

- Guidelines Design of survey
- Methodology of guidelines
- Guideline availability and distribution
- Funding of guidelines
- Audit
- Barriers
- Solutions
- Bonus questions
- Future wishes

The design of the study was illustrated by discussing a number of the key survey questions and points.

The web based survey, compiled in SurveyMonkey™, was distributed to national radiological societies, national nuclear medicine societies and national radiological protection competent authorities. The survey was designed to be easily understood with carefully chosen simple terminology, easy to analyse statistically with few free text answers, and easy to complete with seamless design leading responders only through the relevant questions. A Likert scale was used to quantify the answers and to explore the way forward.

The questionnaire was meticulously tested and further discussed in Vienna on March 5th before being distributed by the ESR and then kindly analysed by the SFR.

A selection of the survey questions including the core questions were presented at the Final Workshop to demonstrate the content, style, aims and methodology of the survey.

In conclusion, the intention of this presentation and summary was to clearly demonstrate how a complex and comprehensive survey, designed by the RCR with support from the Project Consortium, could also be easy to complete.

Talk 20: Guidelines survey and analysis of questionnaire

Valérie Vilgrain, the Société Française de Radiologie (SFR)

Dr. Valerie Vilgrain is Chair of the Department of Radiology at the University Beaujon Hospital, Clichy, Paris 7 University, France valerie.vilgrain@bjn.aphp.fr

A web-based survey was used to assess the availability of imaging referral guidelines, development methodology, and the preferences for future initiatives for European community action to facilitate justification and appropriate use of radiological diagnostic procedures. A questionnaire devised by the RCR together with other members of the project consortium was distributed to representatives of national radiological and nuclear medicine societies as well as national radiological protection competent authorities in 30 European countries including 27 European Union member states, Croatia (the candidate country) and countries using European legislation viz. Norway and Switzerland. Responses were collated by the ESR and analysed by the SFR together with the Steering Committee.

Analysis of responses to the questions 1 to 12

Thirty countries responded and 80 responses were received. Of these:

- 32 were from national radiological societies
- 20 were from national nuclear medicine societies
- 28 were from national competent authorities

From the national radiological societies, no response was received from Cyprus, two responses were received from the Netherlands and three from Romania.

From the national nuclear medicine societies, no response was received from Bulgaria, Estonia, Finland, France, Ireland, Lithuania, Luxembourg, Norway, Poland, Portugal, Slovakia or Slovenia. Three responses were received from the Netherlands.

From the national competent authorities, responses were received from all countries, except Italia, Hungary, Latvia and two responses were received from Spain.

In the analysis, all the responses received were taken into account as it was impossible to select or to merge the different responses coming from the same countries.

61% of responders said "yes: There is a legal requirement for imaging in referral guidelines including radiation dose". Interestingly, 5 responders said: "I don't know whether such a legal requirement exists or not".

Surprisingly, there were some disagreements between national societies and competent authorities' responses to the question about the transfer responsibility for making guidelines availability. 17 national societies answered "I don't know" versus one competent authority.

In the great majority of responses, the responsibility for making guidelines has been transferred to department/ministry of health, or professional organizations.

The great majority of states have recommended European or national guidelines.

The great majority (76%) of responders answered "No" to the question concerning the insurance requirements stating that a guideline must exist in order for there to be a payment for an imaging investigation (10% answered "I don't know").

Regarding which professionals make requests, most of them are made by medical doctors. Among the medical doctors, General Practitioners differed from emergency dept. Clinicians and specialist/hospital doctors as the former essentially make requests for plain radiography, contrast radiography, and ultrasound. According to national societies' responses, GPs more rarely make requests for CT, MRI, IR and nuclear medicine examinations.

Analysis of responses to the questions 13 to 41

20 radiology societies and 12 nuclear medicine societies, and surprisingly only 8 competent authorities, responded that there are nationally recognized imaging referral guidelines including radiation dose available.

Only the responses from the national societies were taken into consideration as the number of competent authorities which responded was relatively small. The responses from the competent authorities to this question were often incomplete and sometimes discordant with those of national societies.

Only 12 of the 20 radiological societies and 9 of the 12 nuclear medicine societies having nationally recognized imaging referral guidelines including radiation dose answered the subsequent questions concerning specifically the content of these guidelines. These guidelines were issued from a single source for 4 national societies and from multiple sources for 11.

The guidelines were nationally developed in half of the countries and modified or adopted with modifications from another source in the others. There was a good correspondence between radiology and nuclear medicine societies taking into account two countries (France and UK) which have delivered radiological and NM guidelines in the same document.

The year of the first edition varied from 1989 to 2005 for radiological societies and from 1998 to 2011 for nuclear medicine societies. The approximate duration of the review cycle has varied between countries from 3-4 years to > 6 years.

In the majority of countries (67% for radiology and 90% for nuclear medicine), the source of funding was departments or ministries of health or other governmental departments.

The radiating imaging modalities (RX and nuclear medicine) were included in the great majority of the guidelines (83-92%) whereas the non radiating imaging modalities (US, MRI) were only present in 75% of the guidelines.

The majority of guidelines have produced separate guidance for children (67-80%) and pregnant women (83-78%).

Almost all radiological societies' guidelines have covered all groups of medical conditions. It has been often less covered in nuclear medicine guidelines.

Only 7 of 12 guidelines of radiological societies and 2 of 11 nuclear medicine societies have been based on clinical presentations and their imaging investigations.

Radiation dose, strength of evidence and grading of recommendations were considered in all or almost all guidelines. Cost effectiveness and availability of equipment or expertise were much less often considered.

Very few guidelines have included recognized evidence levels (6 radiology, 3 nuclear medicine) and grading recommendation using a recognized system (4 radiology, 1 nuclear medicine).

Delphi process was used in 3 radiological societies' guidelines (Finland, France, UK). Expert meeting for consensus was used by 4 radiological societies and 5 nuclear medicine societies.

Radiation dose was obtained from recognized source in 8 radiological and 9 nuclear medicine societies.

The radiological societies' guidelines included between 200 to 500 clinical conditions or diagnostic problems, and the nuclear medicine societies guidelines between 16 and 300.

Two radiological societies graded their recommendations (France and UK). The vast majority of recommendations were either B or C.

Almost all guidelines are available on downloaded digital version. The great majority of guidelines are available in a web version. Very few have a PDA/tablets or smart phones application.

The majority of guidelines routinely circulate to providers of the service, general practitioners, emergency department clinicians and specialists / hospital doctors. Only few of these guidelines routinely circulate to non healthcare professional, medical students, funders and public.

Reinforcement of guidelines is made by periodic reminders in half of guidelines and by educational message in most of the radiological societies.

Only two national societies have incorporated their guidelines into clinical decision support systems (CDSS) (Finland, Italy).

Guidelines have been mainly used for education and academic/research purposes.

Analysis of responses to the questions 42 to 47

28 responses were received from the radiology societies, 18 for NM societies and 27 from competent authorities, and all responses were taken into account. The percentage of responses rated 5-7 with a threshold of 75% were considered.

82% of radiology societies and 78% of competent authorities support European guidelines developed by combination of multiple national guidelines agreed by consensus. This is also supported to a lesser extent by nuclear medicine societies (61%). 75% of radiology societies support Pan-European guidelines developed centrally.

Most societies and competent authorities support tabular and flowchart format for the guidelines.

Most societies and competent authorities support web version (not password protected) for distribution mode. 75% of radiology societies support provision of guidelines through electronic requesting systems as a future development.

No potential barriers, or challenges to the availability of guidelines, exceed the threshold of 75% in responses rated 5-7.

Education and involvement of referring clinicians are mostly proposed by competent authorities to solve barriers limiting the availability of guidelines.

Competent authorities strongly support local internal and external clinical audits to monitor guideline use.

Key Points

- 1. The results of this survey might not be completely accurate as some countries responded several times and others have pooled results with radiological societies and nuclear medicine societies.
- 2. This survey shows that few countries have developed national guidelines including radiation dose.
- 3. Not all national guidelines available are based on clinical indications.
- 4. No significant barriers or major challenges to the development of guidelines have been raised by national societies or competent authorities.
- 5. The majority of responders are supporting the development of European guidelines either developed by combination of multiple national guidelines agreed by consensus or Pan-European developed centrally.
- 6. There is a trend to support the concept of integrating guidelines into clinical decision support systems.

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Talk 21: Good practices in Europe

National radiology societies, competent authority representatives

A number of presentations of good practice were made by competent authorities and members of professional societies including Finland, Croatia, Germany, Greece and Norway. These provided examples of different approaches, support and content including the availability of national guidelines for paediatric examinations, better and improving coordination between professional bodies and government, the value of finance from government, with acknowledgement that some States had managed to produce guidelines without national funding and the importance of a multi-disciplinary approach, including the end user.

Session 3: Summary and Conclusions

Rapporteur: Steve Ebdon-Jackson, UK HPA

Session 3 addressed survey feedback and included three distinct sections:

- 1. guidelines survey development
- 2. guidelines survey analysis
- 3. good practices in Europe

There followed an enthusiastic discussion and question session.

The survey feedback summarised the survey. It was web based and involved multiple organisations from 30 countries. These included radiology and nuclear medicine societies and competent authorities. The questions were comprehensive and related to

responsibilities, format, circulation and purpose of the referral guidelines. In addition, barriers to implementation and solutions were addressed. In establishing the survey, consideration was given to ease of understanding, completion and subsequent analysis.

The analysis provided a wealth of data. More significant information related to awareness of the legal requirement for guidelines (60%) and the difference between this requirement and actual availability. There was variation as to the origin of the guidelines in each of the countries – some were based on practice within the Member State while others were heavily or entirely based on the publications from organisations external to their country (eg translation of RCR guidelines). The guidelines provided information on a number of key elements and factors of the guidelines including the evidence base, the grading of procedures and the associated radiation dose.

Session 4: Innovations

Chair: Guy Frija, European Society of Radiology (ESR)

Rapporteur: Fred Verzijlbergen, European Association of Nuclear Medicine (EANM)

Talk 22: Innovations for improving Guideline use

Myriam Hunink, European Society of Radiology (ESR)

MG Myriam Hunink, MD, PhD Radiology, Clinical Epidemiology, Decision Sciences, Erasmus University Rotterdam & Harvard University Boston m.hunink@erasmusmc.nl

Background and Rationale

Given the rapid pace of technological advances, the wide variety of diagnostic and therapeutic possibilities, and the continual changing evidence, the modern physician is faced with a huge amount of information that needs to be assimilated in order to make wise diagnostic and therapeutic decisions. The information overload can form an insurmountable obstacle to the individual physician. Referral guidelines can guide the physician in making smart choices and can streamline clinical practice. This is particularly true for decisions regarding imaging procedures.

Nevertheless, physicians are reluctant to use guidelines. Changing physician behaviour is notoriously difficult. Is it because they cherish their autonomy? Are they set in their ways? Is it financial incentives? Are the guidelines unavailable at the point-of-care? Or do they feel that a one-size-fits-all guideline simply does not fit their unique patient?

State-of-the-art

A systematic review of interventions to improve outpatient referrals from primary care to secondary care [1] demonstrated the paucity of rigorous evaluations in the field. Seventeen studies involving 23 separate comparisons were included in the review. Nine studies (14 comparisons) evaluated professional educational interventions.

Interventions that were ineffective included:

- passive dissemination of local referral guidelines
- feedback of referral rates
- discussion with independent medical adviser

Generally effective interventions included:

- dissemination of guidelines with structured referral sheets
- involvement of consultants (secondary care specialists) in educational activities

Promising interventions were:

- organizational interventions (examples: patient management by family physicians instead of internists, physiotherapist incorporated in general practice, a new slot system for referrals requiring a 'in-house' second opinion prior to referral)
- financial incentives (example: mixed capitation and fee-for-service system with an element of risk sharing for secondary care services)

Shortcomings

Guidelines are commonly:

- inconsistent and complex
- not integrated with other diagnostic procedures
- time-consuming to produce
- costly
- difficult to implement
- not available at the point of care
- not personalized / not patient tailored
- not setting specific
- quickly outdated

Innovations

Clinical decision support Solutions

Osheroff (2006) [2], defines it as "Clinical decision support (CDS) systems provide clinicians, staff, patients, and other individuals with knowledge and person specific information, intelligently filtered and presented at appropriate times, to enhance health and health care." Knowledge-based CDS systems consist of:

- a knowledge base
- an inference engine
- a communication tool

Non-Knowledge-based CDS systems include:

- artificial intelligence
- machine learning
- artificial networks

Radiology order entry with decision support: initial clinical experience [3,4,5]

- "Computerized order entry with decision support can be widely accepted by clinicians and can have an impact on ordering practices." (MGH Experience)
- Radiology order entry handles 90% of all pre-scheduled outpatient exams
- 95% of primary care physicians either use radiology order entry directly or have their clinical staff do it for them
- 80% of general Internal Medicine orders come directly from physicians
- ER CT pulmonary angiography utilization decreased by 20% whereas the yield increased from 6% to 10%.

Prediction rules

- Clinical prediction rules (prior to performing an imaging test) estimate the probability
 of disease conditional on clinical parameters and can thus be useful in justifying the
 need for an imaging procedure
- Diagnostic prediction rules (after the imaging test has been performed) estimate the probability of disease conditional on clinical parameters combined with the imaging findings and can thus be useful in guiding treatment choices based on the integrated information from all diagnostic procedures

Vision

A clinical decision support system to optimize the use of imaging would have to fulfil the following criteria:

- online clinical decision support system
- available at the point-of-care
- integrated in radiology order entry system and hospital information system
- integrated with other diagnostic procedures and diagnostic information
- linked to electronic patient record
- provides evidence-based information
- includes individual patient-tailored decision support
- both pre-test and post-test decision support
- Web 2.0 / wiki-type environment to get input from multiple stakeholders
- setting specific
- continually and dynamically updated
- adaptive Bayesian design
- self-learning

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Talk 23: Innovations for improving Guideline use

Francesco Sardanelli, European Society of Radiology (ESR)

Francesco Sardanelli, EuroAIM Director University of Milan School of Medicine, IRCCS Policlinico San Donato, Milan, Italy f.sardanelli@grupposandonato.it

The role of radiologists and nuclear physicians in the authorship of systematic reviews on diagnostic and interventional imaging. Summary of a report of the EuroAIM working group

The relative delay of evidence-based medicine application to diagnostic and interventional imaging and the anecdotic finding of secondary studies on typical radiological procedures written by groups of "experts" not including radiologists or nuclear physician (imaging specialists) raised the idea to systematically investigate about the authorship of secondary imaging studies. This was carried out by a working group of the European Network for Assessment of Imaging in Medicine (EuroAIM) initiative.

We searched for systematic reviews (SRs) regarding diagnostic and interventional procedures, published in 2001-2010. Selection was initially based on Title/Abstract; only eligible SRs were fully assessed. SRs concerning procedures mainly performed by non-imaging specialists were excluded. Each SR was attributed to one of 11 subspecialties and one of 15 study categories.

Of 3,258 retrieved citations, 875 SRs entered analysis. A nearly-linear increase in the annual number of overall SRs was observed, from 26 in 2001 to 169 in 2010. A similar trend was observed for the SRs with at least one imaging specialists as an author, from 9 to 61, respectively. As a consequence, the rate of SRs with at least one imaging specialist as an author significantly (but more slowly) increased during the decade, reaching a peak of 44% in 2008; unfortunately, this trend declined in the last two years to 36%.

Neuroimaging was the most represented subspecialty (28%), followed by Gastrointestinal/Abdominal (12%). Diagnostic performance was the most represented category (41%), followed by Neurological Morphometry/Function (14%). Publication rate in imaging journals was 26%, from 6% (Pediatric) to 45% (General Oncology) and from 6% (Diagnostic Performance of a Non-imaging Test) to 75% (Technical Performance of an Imaging Test).

On average during the decade, only 20% of these secondary studies have an imaging specialist as first author, 19% as last author, 38% as an author in whatever position. Thus, there is an under-representation of imaging specialists in the authorship of SRs regarding imaging. This low proportion is alarming if we consider that imaging procedures mainly performed by non-imaging specialists were excluded from analysis. For a quick comparison, consider that the evaluation of first author's affiliation for 100 consecutive SRs published in 2010 attributable to a medical specialty of primary interest resulted in 85 SRs clearly authored by clinical experts of the investigated field (PubMed, accessed on September 3, 2012), while the rate of imaging specialists who authored in whatever position SRs on imaging in same year was only 36%

The balance between radiologists and nuclear physicians in the authorship resulted 138/39 (3.5:1) for the first position and 130/32 for the last position (4.1:1). Thus, radiologists overall contributed for about 80% of relevant positions of imaging specialists in authorship. Obviously, nuclear physicians contributed for 57% of relevant positions in authorship for General Oncology, as expected considering the relevance of radionuclide imaging in this field. Moreover, this almost balanced situation happens in the subspecialty with the far highest percentage of SRs with at least an imaging specialist in the authorship (88%).

The median journal impact factor of SRs published in 2009-2010 with at least one imaging specialist in the authorship (3.207) was lower than that of SRs without (4.327).

In conclusion, only 38% of SRs on imaging published from 2001 to 2010 has at least one radiologist or nuclear physician as an author. Imaging specialists are under-represented in the authorship of secondary evidence for procedures they daily perform and discuss with patients, referring physicians, healthcare providers, and decision makers. Policies to counteract this trend should be adopted.

Suggested reading

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Talk 24: Innovations for improving Guideline use

Pete Cavanagh, The Royal College of Radiologists (RCR)

Dr. Pete Cavanagh Vice President Royal College of Radiologists, UK Peter.cavanagh@southwest.nhs.uk

Despite the significant effort and rigour involved in the production of referral guidelines in the UK there is still a significant challenge to ensure their effective usage. Although justification of a request by a radiologist has the potential for intervention after the referral has been made, the aim must be to influence decision-making by the referrer at the time of referral. A number of actions may facilitate this:

1. Ease of access at the point of referral

For example, the RCR has developed an App version of its guidance which is now available for smart phones and tablets. This could be further improved by being able to customise guidelines by user profile so that only the guidelines relevant to an individual practice are stored in active mode.

2. Decision support software

As electronic requesting becomes the norm, there is an opportunity to embed the guidelines into these software programmes, prompting the referrer to make the right decision. This will only work if it does not impede the ease of referral.

3. Education and training

Although there may be a role for education and training for the current and next generation of referrers, this in itself is unlikely to be a solution. Current Guideline documents contain hundreds of individual guidelines and although these will not all be relevant, it will require on-going re-enforcement. However more knowledge of this in the undergraduate curriculum should be pursued.

4. Incentives or Sanctions

In the current model of healthcare delivery in the UK there are opportunities to reimburse primary care doctors (general practitioners) for delivering certain aspects of quality care such as checking blood pressure and cholesterol screening. It is possible that this type of approach could be extended to correct use of imaging for certain conditions.

The reimbursement in England for healthcare is based on a system termed Payment by Results. The concept is that providers get paid for certain interventions, tests, or episodes of care. It may be possible to agree on withholding payment for certain diagnostic test that fall outside accepted guidance. However, the 'policing' of such a system could be difficult to implement across the whole of the guidelines.

5. Benchmarked information feedback

Referrers may be challenged to improve their referral patterns if accurate and timely feedback of their practice could be provided to them with indications of which guidelines may be relevant to their particular referral pattern.

It is unlikely that any one of these potential interventions will provide the solution in isolation. It would be important to test their potential benefit on a small scale where applicable to gain more information as to their potential benefit.

Talk 25: Innovations for improving Guideline use

Richard Mendelson, Western Australian Health Department

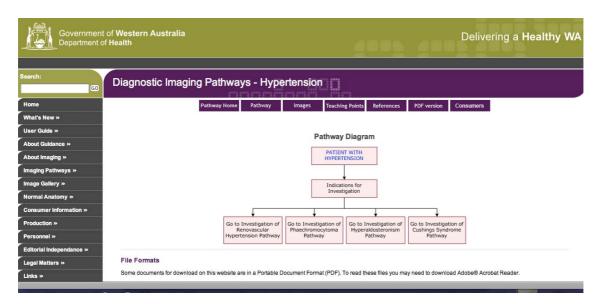
Prof. Richard Mendelson, Royal Perth Hospital, Perth, Western Australia Richard.mendelson@health.wa.gov.au

There is evidence from our own studies and those of others that 'stand-alone' guidelines have limited utility in altering requesting behaviour among referring clinicians. Therefore, we

are developing and evaluating an electronic request/decision support tool which integrates the academic content of DIP into the requesting process for diagnostic imaging so that imaging recommendations are a seamless part of the clinicians' work flow.

The application's opening electronic page shows the icons for the various organ systems. If, say neurological, is chosen the sub menu is displayed indicating the various neurological clinical scenarios. 'Suspected stroke' will be used to demonstrate the application.

Each scenario uses a flow chart or algorithmic format based on the content of the Western Australian "Diagnostic Imaging Pathways" (DIP) website.



Each page has a drop down legend - showing the meaning of the abbreviations used in the flow chart, such as 'i' for general information 'ri' for radiology information and 'ci' for clinical information. Clicking on these icons either results in a succinct "pop-up" take-home message or a link to more detailed information in DIP and the full functionality of the DIP website, including referenced narrative text, teaching points, the full DIP pathways, etc. The legend also indicates the meaning of the ionizing radiology icons used in the pop-up messages in terms of relative dose from 'none' to 'high'.

So, for example, returning to the stroke flowchart, there is some pop up clinical information indicating the role of imaging in this condition. Green boxes in the flow chart indicate the recommended imaging - in this case an urgent head CT scan. The user has the option of accepting or overriding the recommendations. If the recommendation is accepted, clicking the tick icon allows the user to request just that test or to add other tests. Perhaps in the case of suspected stroke a chest x-ray would be appropriate. Clicking 'request test' takes the user to the imaging service request form.

In a real-life situation the application would be linked to the Hospital Information System and Radiology Information System so all of the demographics and other information for that patient would be pre-populated on the form. However a patient can be selected manually from a drop-down work-list. Similarly, the radiology provider to which the request is directed can be automatically or manually entered.

The "clinical information" section of the request form has been populated with details that have been recorded by documenting the previous mouse clicks and how the point of request has been achieved. The referrer can sign the form electronically and, when ready, send the request electronically by internal or external secure messaging to the imaging provider. Obviously, the form that arrives at the other end can be customised by the practice. Some fields can be made mandatory, for example the "is the patient pregnant?" field.

Returning to the flow chart, the next step depends on the result of the initial CT Scan. Further imaging may be required contingent on the CT result and clinical situation.

Returning to the original scenario and considering that the referring doctor may believe that for his patient a MRI scan is more appropriate than a CT scan as the initial test and wishes to override the recommendation for CT. By clicking on 'override' the user is prompted to enter a justification for the override, which appears on the imaging request form. The user must then complete their choice of modality manually.

The imaging provider can customise the application so that some overrides can be allowed through, without consultation with an imaging specialist, while others may require consultation prior to acceptance. Of course, the application lends itself to extensive auditing of referrals, and in particular, the frequency and reasons for overriding of recommendations by individual clinicians.

Other examples of clinical scenarios use check boxes to determine whether imaging is required. For example, for ankle injury (accessed from the musculoskeletal trauma menu), initially the user is prompted to choose which side of the body has been injured and then is aided in applying the Ottawa ankle rule. Checking for example the 'inability to weight bear' leads to the process of requesting a plain ankle x-ray series. From then on this leads to a similar process we have already seen with CT in stroke. However if no parameters exist for indicating an x-ray, the user is informed of this, but has the option to override, but is required to provide justification for doing so.

In summary, the application is a potentially powerful audit tool. Of course, not all requests require decision support, for example a request for clavicle x-ray goes straight to the request form after the side of injury is selected.

Talk 26: Innovations for improving Guideline use

Martin Reed, The Canadian Association of Radiologists (CAR)

Dr. Martin H. Reed, Chair, Guidelines Working Group, Canadian Association of Radiologists Department of Radiology, Children's Hospital, Winnipeg, Canada MReed@exchange.hsc.mb.ca

The Canadian Association of Radiologists (CAR) referral guidelines were published in both English and French versions in booklet form in 2005. The guidelines were also made available on the Internet through password protected websites including the CAR website, the CMA Infobase and the website of the College of Family Physicians. A PDF version was also made available on CD. The guidelines were quite widely circulated and the first English printing of one thousand copies was sold out and a second printing had to be made.

However, the CAR also recognized that making guidelines available in all these formats did not guarantee their utilization. Believing that integrating the guidelines into the physician's workflow would be the best method of ensuring their uptake and utilization, a software company, Medicalis, based in Waterloo, Ontario, was approached. They had developed a computerized order entry (CPOE) system for diagnostic imaging and they were willing to incorporate the CAR guidelines into that CPOE. Two projects were undertaken to assess the effectiveness of incorporating the CAR guidelines into a CPOE. The initial project was carried out at the Children's Hospital in Winnipeg between October 2006 and August 2007. Seventyseven pediatricians and twenty-seven pediatric residents and Fellows participated in that project. Almost nine thousand orders were placed using the software (Table) and of these approximately 11% were considered inappropriate according the CAR referral guidelines. However, the advice to change the order was only accepted in 2% of cases. The second project was carried out with a group of family practitioners at the Steinbach Family Medical Centre between November 2008 and February 2009. This was a smaller project with only nine hundred orders being placed using the software (Table). A similar percentage of orders (14%) were considered inappropriate according to the CAR referral guidelines, but in this case the advice to change the order was accepted in 25% of cases.

Table: Results of studies

Project	Total orders	Inappropriate orders	Advice accepted
Children's Hospital	8757	957 (10.9%)	19 (1.9%)
Steinbach	904	123 (13.6%)	31 (25.5%)

A third project was undertaken at the Children's Hospital in Winnipeg between February 2010 and July 2012 to try to use several interventions to improve physicians' ordering patterns. The original Medicalis software had been used on a regular basis at the Children's Hospital up until the beginning of this new project. Unfortunately, however, Medicalis had changed their software in the interval and for various reasons the new software had to be implemented in order to carry out the new project. This new software had been designed without consultation with users at the Children's Hospital and it turned out to be very different from the software that they were used to using. It was also found to be less user friendly and slower to use. Numerous problems were encountered in attempting to improve the software from the users' point of view, to integrate it into the Radiology Information Management System at Children's Hospital and to improve its speed. Because of the rather limited funding and other priorities for both Medicalis and the IT Department at the Children's Hospital all these problems were never completely solved during the lifetime of the project. As a result the interventions could not be tested and assessed.

The CAR believes that a number of lessons have been learned from the various projects that the organization has undertaken to assess the value of incorporating referral guidelines into a CPOE for diagnostic imaging. These lessons include:

- Any software program incorporating decision support into a CPOE has to be simple, fast, and transparently integrated into existing electronic systems.
- Any project designed to introduce CPOE with decision support must have the resources to allow adequate time for the project and to provide adequate IT support for the project.
- These projects cannot be simply implemented by administration. They require leadership by physicians respected in the community.
- Initially the software should be tested with a group of interested physicians who have IT expertise and can provide constructive advice about any deficiencies in the software.
- Because decision support does to some extent interfere with physicians" workflow, only a limited number of important referral guidelines should be integrated into the software. The decision about which guidelines should be used should be made in consultation with both referring physicians and radiologists on site.

The CAR is committed to continuing to improve and update their referral guidelines, to encourage their use as widely as possible in the physician community in Canada and to study the best methods of incorporating referral guidelines into CPOE's and to assess the effectiveness of this approach to implementing referral guidelines.

Talk 27: Innovations for improving Guideline use

Michael Bettmann, American College of Radiologists (ACR)

Michael Bettmann, MD, FACR, FAHA Chair, ACR Appropriateness Criteria Oversight Committee, Co-Chair, ACR Task Force on Decision Support

Challenges to the use of imaging in the US

- Inappropriate use, for many reasons
- Attempts at external controls add cost, delay
 - o Radiology Benefit Managers,
 - Insurance company hurdles and constraints
- Guidelines in format usable in Electronic medical records, EMRs are sparse, poor and/or hard to use.

Challenges to the ACR Appropriateness Criteria

- Usability of guidelines: format, scope
- Availability in electronic format
- Buy-in: Users individually,
 - Health-care organizations,
 - o EMR vendors,
 - Other medical societies
- Process for revision, addition, validation

Current ACR Effort: Creation of a useable imaging clinical imaging decision support tool

- ACR Select-collaboration with National Decision Support Company, NDSC
- Content is ACR Appropriateness criteria, supplemented as needed
- Content as a fixed data-base will be sold by NDSC

Content owned by ACR. Cannot be altered by users

Aim of ACR Select

- Serve as on-line CDS tool, to improve the appropriate use of imaging-decrease inappropriate exams, decrease unnecessary radiation exposure
- Through feedback from users, continual improvement of the coverage, usability and validity of the ACR AC
- Through analysis of use by individuals, groups and healthcare organizations, collect and analyze data on utilization and utility of imaging
- Eliminate unnecessary hurdles

ACR Select

- Sold to vendors of CPOE/ EMR systems
- Sold directly or secondarily to health care organizations or Decision Support System, DSS creators
- Key considerations are:
 - methodological soundness,
 - o ongoing feedback with users and vendors,
 - o sound, web-based IT format

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Session 4: Summary and Conclusions

Rapporteur: Fred Verzijlbergen, European Association of Nuclear Medicine (EANM)

Need to improve/increase Guidelines, with a specific emphasis on the level of Evidence (currently at least 30% not evidence-based!). Guidelines should be based on secondary research described in Systematic Reviews. We need European guidelines, either a synthesis of several national guidelines or developed by European bodies.

Written as algorithms and in the publication of every guideline an imaging specialist should be one of the authors. Presented not only to the referrers, but also to the patients/public. Implemented in the medical training of undergraduates and residents.

The basis for the future should be computerized patient order entry (CPOE) in connection to clinical decision system (CDS). The referral data need to be structured and one question is who is responsible for gathering the primary data: patients/family/ PA/Radiographer?

Selective guidelines-building, only high-impact usable guidelines, constructed with simple, fast and transparent software, under the leadership of physicians and validated in small integrated patient groups by motivated physicians.

Web-based, A	ipps, and adequate	e resources are required	l.	

Session 5: Workshop conclusions and recommendations

Denis Remedios, European Society of Radiology (ESR) Project Lead

Dr. Denis Remedios Faculty of Medicine Centre, Imperial College London, UK denis.remedios@imperial.ac.uk

Following presentations from over 30 speakers and lengthy discussions at the European Workshop, Work Package 2 of the EC Guidelines Project, a clearer picture of the current situation has emerged with a coherent message as to the way forward.

Guideline availability and use in Europe

Data to inform the availability of referral guidelines are not as straightforward as hoped. The survey has shown discordance of responses between some national competent authority and professional society representatives, possibly related to issues of awareness of guideline existence and the legal requirement for guidelines; as well as issues of access to national guidelines which may be in format or media which are difficult to find.

In the European survey, respondents in 2/3 of European countries know of legal requirement for guidelines nationally, and in these countries 2/3 of these have guidelines available. Of the 1/3 of European countries where there is no awareness of a legal requirement, only 1/3 has guidelines available. Discussion at the Workshop identified that several countries had work in progress to update or adopt guidelines, with considerable progress since the survey took place, 4 months previously.

A further, brief, follow-up survey to ascertain the up-to date status of guideline availability was planned following the Workshop to enable the current work in progress to be reflected in the final report.

Guideline implementation

Workshop participants agreed that availability of guidelines did not equate with use. As guidelines cannot encompass all clinical scenarios, adherence can only be expected in up to 90% of clinical scenarios. Participants at the Workshop reported that even where guidelines are available, their uptake and use is limited. Reasons for this may include: sub-optimal clinician buy-in, conflicting advice from other (often clinical) guidelines, and the difficulty monitoring and encouraging guideline use.

Tools which can encourage guideline use include:

- **Education** at all levels of training and continuing professional development. Webbased, training courses and inclusion in curricula as well as educational reminders. These initiatives are already in progress.
- Clinical decision support systems (CDS), particularly those with flexible architecture
 to fit existing requesting systems. Examples of CDS were available from many
 speakers and there was great interest amongst participants, radiological and
 regulatory.
- Management systems e.g. Radiological benefit management
- **Governmental incentives** e.g. Payment for performance, Quality Outcome Framework.

Monitoring of Guidelines

Measures for reinforcement of guidelines were considered essential to provide encouragement for use and to ensure sustained benefit. The European survey identified non-mandatory models, particularly external clinical audit as the preferred means, with a secondary role for local internal audit. Mandatory self-regulation and inspection had less support.

Guideline development

Areas of agreement for guideline development methodology which have been identified from the European survey and consolidated at the Workshop are:

- Preference for European imaging referral guidelines which may best be adapted and amalgamated from mature, trusted, nationally-developed evidence-based guidelines. This option was considered more practical and expeditious than centralised development of European guidelines de novo. Later iterations of European Guidelines should encompass a more inclusive methodology with consensus from experts from multiple European countries.
- Need to include dose information in a form understood by referrers and patients
- Separate section for imaging of children
- Stakeholders including referrers and patient representatives should be involved
- Recommendations based on evidence of efficacy, radiation safety and cost.

Recommendations for future Community action

- 1. Clearer guidance should be given by the EC for making imaging referral guidelines available **and** used in all EU member states,
- 2. Evidence-based Guidelines with separate guidance for children should be issued or endorsed by a trusted European organisation,
- 3. Clinical decision support systems and other tools such as educational initiatives are needed for implementation of Guidelines.
- 4. Monitoring of Guideline implementation and use could be by clinical audit, particularly external audit and but also local / internal audit.

APPENDIX 6 Consultation: Questionnaire

IMPORTANT INFORMATION. PLEASE READ FOLLOWING BEFORE STARTING SURVEY.

Stakeholder consultation on Draft Conclusions Document

Imaging referral guidelines (Guidelines) have been available in Europe for over 20 years and are an accepted tool for ICRP level 2 justification for diagnostic imaging. The European Commission-sponsored project EC Tender ENER/11/NUCL/SI2.606915 aims to assess current availability and implementation of Guidelines and strategies to improve future use.

One main task of the project is to produce conclusions and recommendations regarding the need for national and/or Community action in this area.

The first two tasks –conduct of a European survey on the availability, development and implementation of referral guidelines for radiological imaging in Europe and the organisation of a Workshop with representatives from European national radiological and regulatory organisations– form the basis for project's conclusions.

The Draft Conclusions Document is attached to the email you have received on December 17, 2012 together with the link to the following survey on surveymonkey.

As you review the Draft Conclusions Document, please use the following questions to guide your feedback. The more specific your recommendations are, the better the writing team of the project office will be able to address your concerns.

When referring to specific items in the document, please note the subtopic (e.g., CONCLUSIONS/ RECOMMENDATIONS), the bullet (e.g., 2.) and/or the specific achievement level (e.g., proficient) and use the comments field.

You will be asked to reply to each question.

Technical instructions:

- The survey does not have to be completed in one sitting; it can be saved and re-accessed via the link provided in the invitation email at any point of time until the closing date. Please complete the survey at the SAME WORKPLACE (same IP address) and within the SAME BROWSER in which it was started. This is necessary to identify you correctly as the same participant.
- Every given answer is saved immediately, therefore no replies will be lost if the survey is not completed in one sitting
- Answers can be amended until the closing date of the survey; please just re-enter the survey and select the new answer for the concerned question(s).
- Square check boxes stand for questions that allow multiple answers to be selected; round radio buttons only enable the selection of 1 answer per question.
- Starred questions (*) are mandatory.
- For navigation, please use the two buttons (PREV or SAVE AND NEXT) at the bottom of the page, NOT the arrows on the browser".

Please fill in all full-text answers in English.

The closing date of the survey is January 14, 2013.

If you have any questions or difficulties, please contact Ms. Angelika Benkovszky, Project Manager (angelika.benkovszky@myesr.org).

Thank you very much in advance for your support!

Respondent Det	ails	
≭1. Please give t	he following respondent details:	
Name Email		
Affiliation (Name of the organisation on whose behalf you are completing the survey)		
*2. Please indica	ate your Member State / Country:	

Draft Conclusions I	Document	
*3. Have you identif	fied any factual errors	s?
☐ Yes	-	
□ No		
If yes, please specify		

Draft Conclusions Document	
*4. Do you have additional references to add to the draft?	
☐ Yes	
□ No	
If yes, please specify	
	v

Draft Conclusions Document	
★5. Do you have any concerns about the conclusions?	
☐ Yes	
□ No	
If yes, please specify	
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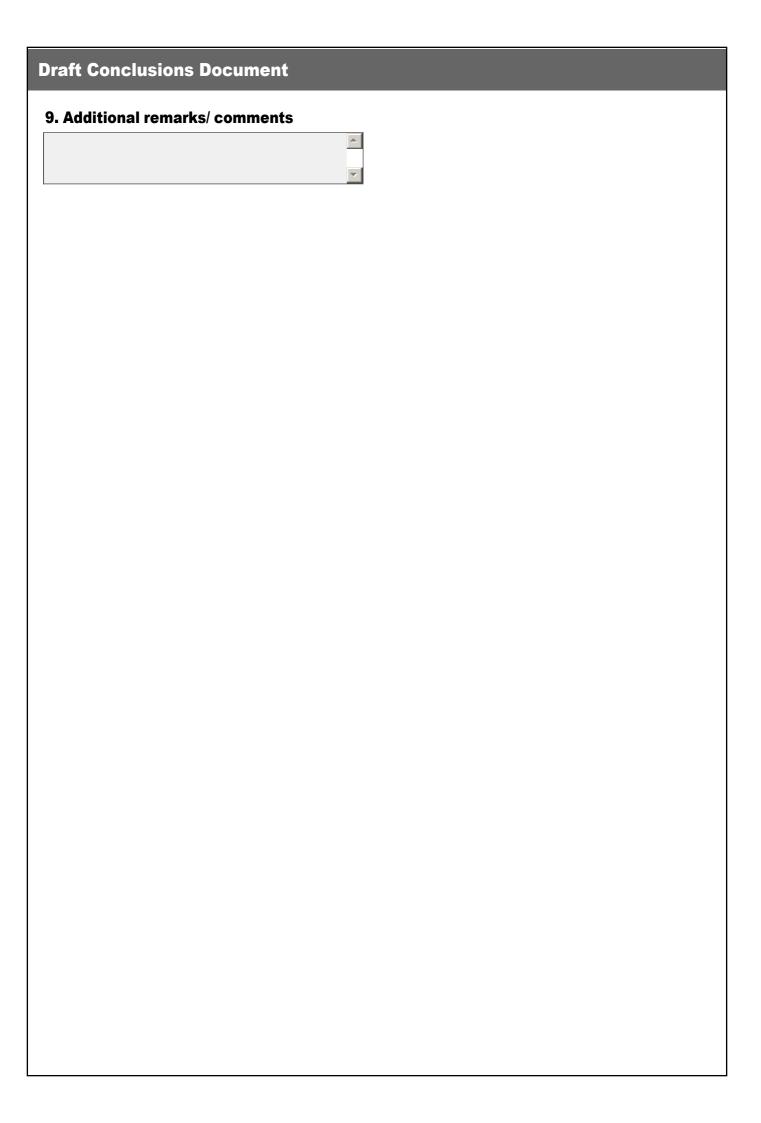
Draft Conclusions Document	
*6. Do you have any concerns about the recommendations?	
☐ Yes	
□ No	
If yes, please specify	
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Draft Conclusion	ns Document				
≭ 7. Please give y					
				Agree	
a. conclusions b. recommendations	Strongly disagree C	Disagree	Neutral	Agree	Strongly agree

Draft Conclusions Document

8. Please give your level of agreement with the following recommendations:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
 Clearer and stronger European measures to encourage both and use availability of referral guidelines. 	•	O	•	6	•
European Imaging Referral Guidelines.	C	0	O	O	O
3. Integration of Clinical Decision Support (CDS) with existing electronic requesting systems.	O	С	O	С	O
4. Encourage educational initiatives.	O	0	0	O	O
5. Encourage monitoring through clinical audit.	O	0	O	O	O



Thank you very much for your time!
Please note: Answers can be amended until the closing date of the survey; please just re-enter the survey and select the new answer for the concerned question(s).
The closing date of the survey is January 14, 2013. If you have any questions or difficulties, please contact Ms. Angelika Benkovszky, (angelika.benkovszky@myesr.org).

APPENDIX 7 Consultation: Invited Organisations

Country	Organisation	Affiliation
Austria	Austrian Roentgen Society	Radiology Society
Austria	Cardiovascular and Interventional Radiological	Imaging Referral Guidelines
	Society of Europe (CIRSE)	Partner Organisation
Austria	European Association of Nuclear Medicine (EANM)	Imaging Referral Guidelines
		External Expert Advisor
Austria	European Society for Magnetic Resonance in	External Stakeholder
Austria	Medicine and Biology (ESMRMB) European Society of Breast imaging (EUSOBI)	External Stakeholder
Austria	European Society of Cardiac Radiology (ESCR)	External Stakeholder
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Austria	European Society of Radiology (ESR)	Imaging Referral Guidelines Partner Organisation
Austria	Federal Ministry of Health	Health Authority
Austria	Federal Ministry of Health	Competent Authority
Austria	International Atomic Energy Agency (IAEA)	Imaging Referral Guidelines
Austria	international Atomic Energy Agency (IALA)	External Expert Advisor
Belgium	European Academy of Paediatrics	External Stakeholder
Belgium	European Brain Council (EBC)	Patient Group
Belgium	European Cancer Leagues (ECL)	Patient Group
Belgium	European Cervical Cancer Association (ECCA)	Patient Group
Belgium	European Federation Crohn's and Ulcerative Colitis	Patient Group
3	Associations (EFCCA)	·
Belgium	European Federation of Families of People with a	Patient Group
	Mental Illness (EUFAMI)	
Belgium	European Federation of Nurses Associations	External Stakeholder
Belgium	European Heart Network (EHN)	Patient Group
Belgium	European Liver Patients Association (ELPA)	Patient Group
Belgium	European Men's Health Forum	Patient Group
Belgium	European Multiple Sclerosis Platform (EMSP)	Patient Group
Belgium	European Myeloma Platform (EMP)	Patient Group
Belgium	European Patients' Forum (EPF)	External Stakeholder
Belgium	Federal Agency for Nuclear Control	Competent Authority
Belgium	Federal Public Service Public Health	Health Authority
Belgium	International Diabetes Federation - Region Europe	Patient Group
Belgium	(IDF Europe) Rare Diseases Europe (EURORDIS)	Patient Group
Belgium	Royal Belgian Radiological Society	Radiology Society
Belgium	Werkgroup Hersentumoren Brain Tumor Working	Patient Group
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Bulgaria	Bulgarian Association of Radiology	Radiology Society
Bulgaria	Ministry of Health	Health Authority
Bulgaria	Radiation Protection Agency	Competent Authority
Croatia	Croatian Society of Radiology	Radiology Society
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Croatia	State Office for Radiological and Nuclear Safety	Competent Authority
Cyprus	Cyprus Radiological Society	Radiology Society
Cyprus	Ministry of Labour and Social Insurance, Department of Labour Inspection, Radiation Protection Sector	Competent Authority
Cyprus	Thalassaemia International Federation (TIF)	Patient Group
Czech Republic	Czech Radiological Society	Radiology Society
Czech Republic	State Office for Nuclear Safety	Competent Authority
Denmark	Danish Society of Radiology	Radiology Society
Denmark	National Institute of Radiation Protection	Competent Authority
Estonia	Estonian Society of Radiology	Radiology Society
Estonia	Ministry of Social Affairs	Health Authority
Estonia	Radiation Safety Department of the Environmental Board	Competent Authority
European	EAMDA	Patient Group
European	EPOS	Patient Group
European	WONCA Europe	External Stakeholder
European Affairs Officer	TIF	Patient Group
Finland	Radiation and Nuclear Safety Authority	Competent Authority
Finland	Radiological Society of Finland	Radiology Society
France	European Society of Paediatric Radiology (ESPR)	Imaging Referral Guidelines Partner Organisation
France	French Radiological Society (SFR)	Imaging Referral Guidelines Partner Organisation
France	Nuclear Safety Authority (ASN)	Competent Authority
France	Société Française de Radiologie	Radiology Society
Germany	Bundesamt für Strahlenschutz (BfS)	Imaging Referral Guidelines External Expert Advisor
Germany	Cystic Fibrosis Europe	Patient Group
Germany	European Ass. Patients Org. Sarcoidosis Granulomatous Disorder (EPOS)	Patient Group
Germany	European Congenital Heart Disease Organisation (ECHDO)	Patient Group
Germany	Federal Office for Radiation Protection (BfS)	Competent Authority
Germany	German Radiological Society	Radiology Society
Germany	Myeloma Euronet (ME)	Patient Group
Germany	Rare Cancers Europe (RCE)	Patient Group
Germany	Bundesministerium für Gesundheit (BMG)	Health Authority
Greece	Greek Atomic Energy Commission	Competent Authority
Greece	Hellenic Radiological Society	Radiology Society
Hungary	Frédéric Joliot-Curie - National Research Institute for Radiobiology and Radiohygiene (NRIRR)	Competent Authority
Hungary	Hungarian Society of Radiologists	Radiology Society
International	World Health Organization (WHO)	Imaging Referral Guidelines
		External Expert Advisor

Ireland	Department of Health	Competent Authority
Ireland	European Federation of Neurological Associations (EFNA)	Patient Group
Ireland	European Kidney Patients' Federation (CEAPIR)	Patient Group
Ireland	Faculty of Radiologists, Royal College of Surgeons in Ireland	Radiology Society
Ireland	St James's Hospital	Health Authority
Italy	EuropaDonna - The European Brast Cancer Coalition	Patient Group
Italy	Institute for Environmental Protection and Research (ISPRA)	Competent Authority
Italy	Società Italiana di Radiologia Medica	Radiology Society
Latvia	Latvian Association of Radiologists	Radiology Society
Latvia	Radiation Safety Centre of the State Environmental Service	Competent Authority
Lithuania	Lithuanian Radiologists' Association	Radiology Society
Lithuania	Radiation Protection Centre	Competent Authority
Luxembourg	Alzheimer Europe	Patient Group
Luxembourg	Ministry of Health, Radiation Protection Department	Competent Authority
Luxembourg	Société Luxembourgeoise de Radiologie	Radiology Society
Malta	Maltese Association of Radiologists	Radiology Society
Malta	Occupational Health & Safety Authority (OHSA), RADIATION PROTECTION BOARD	Competent Authority
Netherlands	Foundation of Epilepsy Centres in the Netherlands (SEIN)	Patient Group
Netherlands	Ministry of Health, Welfare and Sport	Competent Authority
Netherlands	Ministry of Health, Welfare and Sport, The Health Care Inspectorate (IGZ)	Health Authority
Netherlands	Radiological Society of the Netherlands	Radiology Society
Netherlands	SEIN	Patient Group
NL / BE	European Cancer Patient Coalition (ECPC)	Patient Group
Norway	Norwegian Radiation Protection Authority	Competent Authority
Norway	Norwegian Society of Radiology	Radiology Society
Poland	Ministry of Health	Health Authority
Poland	National Centre for Radiation Protection in Health Care	Competent Authority
Poland	Polish Medical Society of Radiology	Radiology Society
Portugal	Direcção Geral da Saúde / Ministério da Saúde (General Directorate of Health / Ministry of Health)	Health Authority
Portugal	European Federation of Radiographer Societies (EFRS)	External Stakeholder
Portugal	European Society of Gastrointestinal and Abdominal Radiology (ESGAR)	External Stakeholder
Portugal	Instituto Tecnológico e Nuclear (ITN), Radiological Protection and Safety Unit	Competent Authority
Portugal	Portuguese Society of Radiology and Nuclear Medicine	Radiology Society

Romania	National Commission for Nuclear Activities Control (CNCAN)	Competent Authority
Romania	National Institute of Public Health, Radiation	Health Authority
	Hygiene Laboratory	
Romania	Romanian Society of Radiology and Medical Imaging	Radiology Society
Slovakia	Regional Public Health Authority	Competent Authority
Slovakia	Slovak Radiological Society	Radiology Society
Slovenia	European Alliance of Neuromuscular Disorders Associations (EAMDA)	Patient Group
Slovenia	Ministry of Health	Health Authority
Slovenia	Slovenian Association of Radiology	Radiology Society
Slovenia	Slovenian Radiation Protection Administration	Competent Authority
Spain	Nuclear Safety Council	Competent Authority
Spain	Sociedad Española de Radiología Médica	Radiology Society
Sweden	Swedish National Board of Health and Welfare	Health Authority
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Sweden	Swedish Radiation Safety Authority (SSM)	Competent Authority
Sweden	Swedish Society of Medical Radiology	Radiology Society
Switzerland	European Society of Neuroradiology (ESNR)	External Stakeholder
Switzerland	Health Authority	Health Authority
Switzerland	Swiss Federal Office of Public Health	Competent Authority
Switzerland	Swiss Society of Radiology	Radiology Society
UK / BE	European Parkinson's Disease Association (EPDA)	Patient Group
United	British Heart Foundation	Patient Group
Kingdom	2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
United	Cancer Research UK	Patient Group
Kingdom United	Chartered Society of Physiotherapy	External Stakeholder
Kingdom	Chartered Society of Physiotherapy	External Stakeholder
United	European Chiropractors' Union	External Stakeholder
Kingdom	European eniropractors officin	External Stakenoider
United	European Federation of Societies for Ultrasound in	External Stakeholder
Kingdom	Medicine and Biology (EFSUMB)	
United	European Paediatric Association (EPA/ UNEPSA)	External Stakeholder
Kingdom		
United	European Society for Emergency Medicine	External Stakeholder
Kingdom		
United	Global Lung Cancer Coalition (GLCC)	Patient Group
Kingdom		
United	International Alliance of Patients Organizations	Patient Group
Kingdom		
United	International Alliance of Patients Organizations	Patient Group
Kingdom	(IAPO)	Dation Co.
United	International Brain Tumour Alliance (IBTA)	Patient Group
Kingdom	Padiation Protection Division Haalth Brotastics	Compotent Authority
United	Radiation Protection Division, Health Protection	Competent Authority
Kingdom	Agency Royal College of Radiologists (RCR)	Imaging Referral Guidelines
United	Royal College of Radiologists (RCR)	Imaging Referral Guidelines

Kingdom		Partner Organisation
United	Stroke Alliance for Europe (SAFE)	Patient Group
Kingdom		
United	The Royal College of Radiologists	Radiology Society
Kingdom		
United	UK Department of Health (UK DH)	Health Authority
Kingdom		
United	UK Health Protection Agency	Imaging Referral Guidelines
Kingdom		External Expert Advisor

APPENDIX 8 Consultation: Comments & Action Points

Consultation : Comments & Action Points

1. Participating Organisations

Organisation	Country	Affiliation
Austrian Roentgen Society	Austria	Radiology Society
Cardiovascular and Interventional Radiological Society of Europe (CIRSE)	Austria	Imaging Referral Guidelines Partner Organisation
Croatian Society of Radiology	Croatia	Radiology Society
Danish Society of Radiology	Denmark	Radiology Society
Department of Health	Ireland	Competent Authority
European Federation of Radiographer Societies (EFRS)	Portugal	External Stakeholder
European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB)	United Kingdom	External Stakeholder
European Society for Emergency Medicine	United Kingdom	External Stakeholder
European Society of Breast imaging (EUSOBI)	Austria	External Stakeholder
European Society of Cardiac Radiology (ESCR)	Austria	External Stakeholder
European Society of Gastrointestinal and Abdominal Radiology (ESGAR)	Portugal	External Stakeholder
European Society of Radiology (ESR)	Austria	Imaging Referral Guidelines Partner Organisation
Federal Agency for Nuclear Control	Belgium	Competent Authority
Federal Ministry of Health	Austria	Competent Authority
Federal Office for Radiation Protection (BfS)	Germany	Competent Authority
Federal Public Service Public Health	Belgium	Health Authority
French Radiological Society (SFR)	France	Imaging Referral Guidelines Partner Organisation
German Radiological Society	Germany	Radiology Society
Greek Atomic Energy Commission	Greece	Competent Authority
Hellenic Radiological Society	Greece	Radiology Society
Lithuanian Radiologists' Association	Lithuania	Radiology Society
Maltese Association of Radiologists	Malta	Radiology Society
Ministry of Health, Radiation Protection Department	Luxembourg	Competent Authority
National Centre for Radiation Protection in Health Care	Poland	Competent Authority
Norwegian Radiation Protection Authority	Norway	Competent Authority
Portuguese Society of Radiology and Nuclear Medicine	Portugal	Radiology Society
Radiation Protection Centre	Lithuania	Competent Authority

Appendix 8 Consultation : Comments & Action Points

Radiation Protection Division, Health Protection Agency	United Kingdom	Competent Authority
Radiation Safety Department of the Environmental Board	Estonia	Competent Authority
Radiological Society of Finland	Finland	Radiology Society
Regional Public Health Authority	Slovakia	Competent Authority
Royal College of Radiologists (RCR)	United Kingdom	Imaging Referral Guidelines Partner Organisation
Slovak Radiological Society	Slovakia	Radiology Society
Slovenian Association of Radiology	Slovenia	Radiology Society
Slovenian Radiation Protection Administration	Slovenia	Competent Authority
Società Italiana di Radiologia Medica	Italy	Radiology Society
Société Française de Radiologie	France	Radiology Society
State Office for Nuclear Safety	Czech Republic	Competent Authority
Swedish Radiation Safety Authority (SSM)	Sweden	Competent Authority
Swedish Society of Medical Radiology	Sweden	Radiology Society
Swiss Federal Office of Public Health	Switzerland	Competent Authority
Swiss Society of Radiology	Switzerland	Radiology Society
Romanian Society of Radiology and Medical Imaging	Romania	Radiology Society

2. Consultation: Comments & Action Points

Type of comment and number	Comment	Response / Action
Comments re Factual error		
F1	On page 24, conclusions numbering starts at 5. Are conclusions 1 to 4 missing?	Apologies, typo, already corrected.
Comments re		
Conclusions		
C2	Conclusions bullet 10) The text is long and not easy to read. Consider to split in two sentences.	Agreed. ACTION: split sentence.
С3	Conclusion. Add the following: Guidelines must include specific advice for shielding on patient during medical X-Ray diagnostic procedures.	Patient protection important but outside the scope of this project. Imaging referral guidelines are for clinicians and justification.
C4	Conclusions bullet 10) The text is long and not easy to read. Consider to split in two sentences.	Editorial changes.
C5	Conclusions,14. Education of dentists Education of cardiologists, orthopaedists, urologists (included in "specialist"?)	All specialists who refer for imaging and many more- too many to mention individually.
C6	8. "Stakeholders" seems not to be the right wording for those who are the main actors in a diagnostic or interventional imaging process like radiologists, cardiologists and other authorized physicians	8. No term is perfect but "stakeholder" is accepted.15. Agree CDS is important. House style

		Τ
C7	applying ionized radiation to patients. 15. A CDS system was one of the recommendations of the workshop. Highlighting this point with bold text suggests a too urgent time schedule for development and introduction. Due to the heterogeneous IT solutions in the European member states and also within a single member state, a CDS implementation will take several years more than setting up harmonized referral criteria. CONCLUSIONS/13 It would be helpful to be aware	will be used to show this. 13. Additional measures currently
	of any proposals at this stage concerning the additional measures needed to be taken in order to reinforce the use of Guidelines.	undertaken are largely educational eg MEDRAPET
C8	Country guidelines sometimes are not based on evidence based practices but more on opinions and practices that certain professionals do not want to change or abandon. At least from the point of view of emergency medicine imaging, we face certain problems in Romania having different guidelines than those accepted by the radiologists in certain centers. There is no national guideline to approach certain issues like abdominal blunt trauma CT which some centers refuse to do it using contrast whilst others do it with contrast, as an example. So I believe that the future guideline must be looking on evidence based practices and if consensus is sought where no evidence based practices are available, we need to have involved practitioners from several specialties as is mentioned by you in the document.	Agreed. Current and future imaging referral guidelines are and will be evidence-based where such evidence exists. In the absence of evidence, consensus based guidance is given.
C9	In general: it is not clear why some of the text is bold typed. To avoid confusion no bold typing should be used. 15. When considering the implementation of CDS systems, it is important to underline that these systems are not intended to replace the role and responsibility of the radiological practitioner with respect to justification. It is very helpful that this is made clear in the draft conclusions.	House style will be used in the final document. 15.Agree, CDS must not replace role and responsibility of radiological practitioner. ACTION- amend wording.
C10	Item 8. I recommend to use instead of other professionals the list of professionals: family doctor, cardiologist, pediatricians etc.	List of professionals in the main body of report / appendices.
C11	Nowhere in the conclusions is there a reference with regard to the need for very regular ("continuous")updating of the guidelines. Because this process is laborious, it is a further argument for trans-border collaboration AND for guidelines to be made available electronicaly, easily allowing for updates in CDS, via apps, etc.	Agree regular review of guidelines is essential. This is covered in the original survey in Work Package 1 and concurs with your comments and AGREE criteria. http://www.agreetrust.org/
C12	Proposal: There is no clear statement that Guidelines should be updated regularly.	Agree regular review of guidelines is essential. This is covered in the original survey in Work Package 1 and concurs with your comments and AGREE criteria. http://www.agreetrust.org/
C13	Just one regarding updating the final document of Imaging Referral Guidelines. Auditing is foreseen in your document but a defined strategy would in my	The EC has published guidance for External Clinical Audit. Publication 159

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	opinion be welcomed.	
C14	There is an agreement that Guidelines must include radiation dose information - does this mean reference dose levels for each imaging procedure? Paragraph 16: National professional societies should	Dose information is for informing the choice of imaging procedure. Diagnostic reference levels may inform dose estimations and have done so but quoted doses are usually effective doses not exposure. Audit arrangements are essential but
C14	have a leading role in these audits. Also funds for financing have to be assigned	outside the scope of this project.
C15	Regarding conclusion number 8. Who represents the patients?	Patient representation is through recognised patient groups, European and national. Patients representatives are involved in guideline development and took part in the Guidelines Workshop.
C16	De novo development of European guidelines may be tedious and time consuming. Would it not be easier and faster to adopt existing guidelines that have proven their validity and thoroughness (such as the RCR ones)?	Agreed. Likely mechanism is to adopt and adapt initially.
Comments re Recommendations		
R1	concerning the point 4 of the Recommendations it should be very useful to strengthen the requirement of basic radiation protection knowledge during the general medical education (using the word "mandatory", instead of "should be" implemented in the curricula). In Slovakia is only very small support for this implementation in the official education system	Individual member states will decide how to interpret European Directives but in general a mandatory recommendation of this nature will be difficult to enforce.
R2		Style matters will be addressed in the
R3	3. No bold typed text In general: it is not clear why some of the text is bold typed. To avoid confusion no bold typing should be used.	final draft in House style. Style matters will be addressed in the final draft in House style.
R4	I would suggest to change the following in the bullet point 4 of recommendations text:" Referrers, radiological practitioners and radiographers"	Agreed. ACTION: insert radiographer.
R5	In recommendation 4, it is stated that "Both referring and radiological practitioners will benefit". That is undoubtfully true, but benefits go way beyond these two categories of persons specified. Other people professionally involved, such as radiographers, nursing staff could also benefit, as could -in fine- the patients through the provision of better health care	Agreed. ACTION: insert radiographer.
R6	Item 1. The second sentence: Such measures should be made centrally or through European or through European radiological competent authorities. I recommend to take out the followingor through European radiological competent, because the authority body is not only under the Ministry of Social Affairs but also under the Ministry of the	Agreed. ACTION: Omit <i>radiological</i> .

	Fordermont College II I I I I	
	Environment. So, based on the above mentioned the item 1 could be: Such measures should be made centrally through European competent authority. Item 2, second sentence:must contain dose information, shielding on patient and must include	Patient shielding is important within a department of radiology but the not really relevant as advice given to referrer and outside the scope of this study.
R7	Reffering to RECOMMENDATIONS/2 where it is mentioned that "European Guidelines must contain dose information and must include separate advice for children, the pregnant women and the unborn child.", it is suggested to exclude the term "unborn child" since the justification of the examination refers to the pregnant women and the urgency of the exam and not separately to the unborn child.	As 2 patients (mother and foetus) are being radiated potentially, the justification applies to both.
Additional remarks/ comments		
A1	Although we have no objections whatsoever with the idea of European guidelines (which would be an improvement as compared to "national guidelines" which differ from one country to another, for a number of clinical conditions (eg cranial trauma patients) the guidelines should be applicable worldwide, so we should aim at "global" guidelines. Only if disease patterns differ considerably is there a need for specific guidance taking these difference into account. The availability of imaging equipment and techniques may be very different, that is why one should have "second best", "third best", in the guidelines	Global guidelines are an ideal situation and one being addressed by the WHO. Latitude in recommendations is essential in all guidelines to allow for differences in equipment and expertise, even within a single member state.
A2	For many medical indications or illnesses global guidelines are perfectly possible. These global guidelines can always be adapted on a national level based on national differences, for example availability of medical imaging equipment. The making and updating of national guidelines is a difficult process. European (or even global) guidelines could help to facilitate this process. Guidelines should be used as active decision support. They should always be easy to access and free for the users (in order to improve compliance).	Agreed, global guidelines and CDS are ideals, CDS may be more achievable in the short to medium term.
A3	Good conclusions and recommendations	Thank you.
A4	I would like to thank dr Remedios and Ms Monika	Thank you.
	Hierath	
A5	Important conclusions and recommendations	Thank you.
A6	Integration of Clinical Decision Support (CDS) with existing electronic requesting systems is a good idea but the information systems used in different hospitals are variable and the implementation CDS might be a technical problem.	Agreed, interface essential for information systems.
A7	J think it's very important to trainer the staff and inform patients about the risks of radiation in	Agreed, MEDRAPET seeks to address training issues in radiation protection.

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	accordance with the principles of radiation protection	
A8	Key points are following: 1) European guidelines and 2) Development of clinical decision support systems	Agreed, they are in the top 3 recommendations.
A9	None, except thank you for your good work.	Thank you.
A10	Nothing to add	Thank you.
A11	Thanks for the opportunity to comment.	Thank you.
A12	The ESR should take care of the translation of these guidelines in the different national languages.	Translation issues will be dealt with once broad agreement has been made to progress with European Guidelines.
A13	The European Workshop on imaging referral guidelines was a wonderful and useful meeting. Thank you for all the nice presentations and conclusions	Thank you.
A14	We would like to thank the ESR for kindly leading on this study and delivering clear conclusions and recommendations. The RCR has many years of experience in providing internally acknowledged guidelines and is strongly committed to the future development and delivery of such guidelines in Europe.	Thank you.

APPENDIX 9 Abbreviations

Appendix 9: Abbreviations

BfS	Bundesamt für Strahlenschutz (German Federal Office for Radiation Protection)
CDS	Clinical Decision Support
CIRSE	Cardiovascular and Interventional Radiological Society of Europe
EANM	European Association for Nuclear Medicine
EMAN	European Medical ALARA Network
EC	European Commission
EC DG Energy	European Commission, Directorate-General for Energy
ESPR	European Society of Paediatric Radiology
ESR	European Society of Radiology
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
MED	Medical Exposures Directive (see Reference [1])
MEDRAPET	Medical Radiation Protection in Education and Training
RCR	Royal College of Radiologists
SFR	La Société Française de Radiologie (French Radiology Society)
UK HPA	United Kingdom Health Protection Agency
WHO	World Health Organization
WP	Work Package. The Guidelines project is divided into 4 Work Packages (WP0 – WP3)