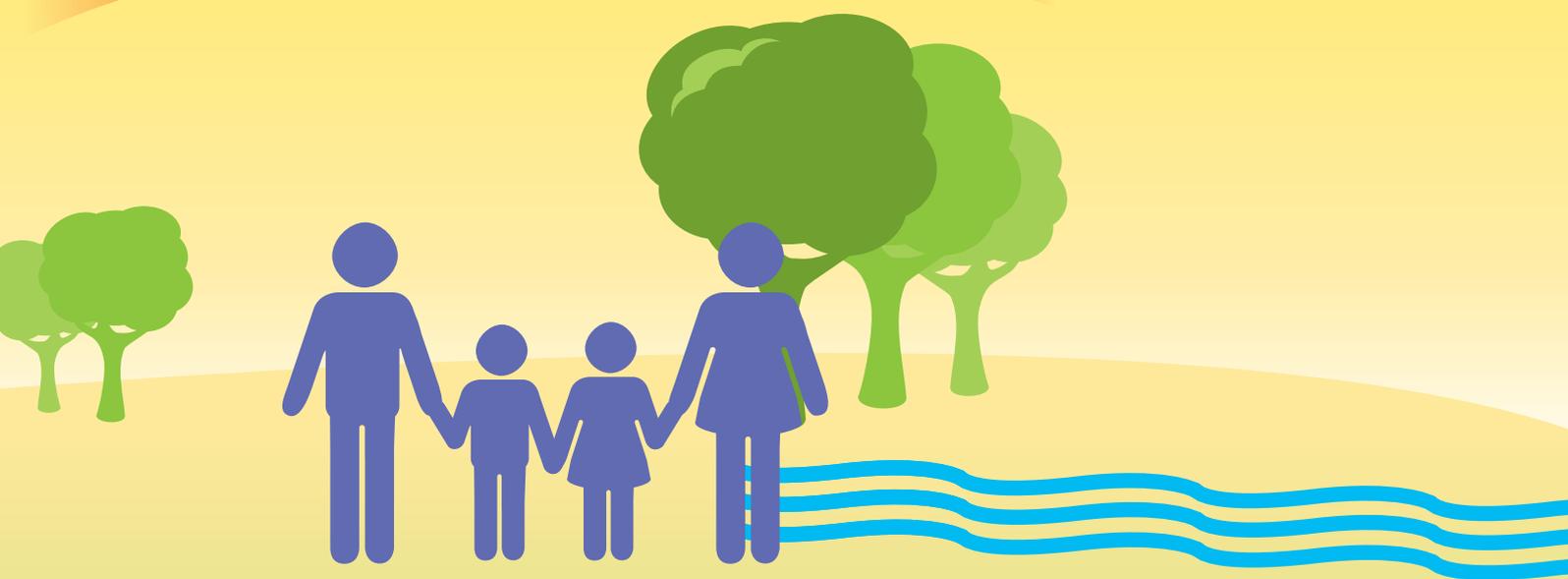




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*Referral Guidelines for Medical Imaging
Availability and Use in the European Union*

Energy

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**Referral Guidelines for Medical Imaging
Availability and Use in the European Union**

Directorate-General for Energy
Directorate D — Nuclear Safety & Fuel Cycle
Unit D3 — Radiation Protection
2014

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FOREWORD

Luxembourg, January 2014

Imaging referral guidelines are intended to help physicians decide when an imaging study would be useful and identify the most appropriate examination for a particular patient. They were developed in the United Kingdom in the late 1980s and were found to be an effective tool for reducing the number of radiology referrals and improving the use of the clinical radiology departments. Referral guidelines provide numerous other benefits which would ultimately improve the quality of health care.

The potential of imaging referral guidelines in radiation protection of patients led to their introduction in the Medical Exposure Directive of 1997 as a legally-binding requirement for EU Member States. Subsequently, the European Commission launched a project to develop European referral guidelines, which were published in 2000 and, having been updated only once (in 2003), are now considered outdated. The European referral guidelines were intended to help Member States with the adoption of national guidelines which, as stated above, is their legal responsibility.

The period following the first publication of imaging referral guidelines has been marked by important changes in medicine, particularly in the area of medical imaging. Advances in imaging technology have allowed physicians to address a higher number of more specific clinical questions but also require up-to-date expertise in the area. Medical imaging was influenced by, and played a part in, the development of evidence-based medicine. As a result, imaging referral guidelines are now needed more than ever and, at the same time, their development requires specialized skills and considerable resources.

In recent years, imaging referral guidelines received much attention from the radiation protection community and international organisations. Notwithstanding these developments, there was no clear picture of the availability and implementation of referral guidelines in Europe. To address this deficiency, the European Commission launched a project in 2011, aimed at collecting information from national authorities and professional societies. A workshop was held in Vienna in September 2012 to facilitate the exchange of experiences and views between these stakeholders. The work was carried out by a consortium led by the European Society of Radiology. This report summarises the main project results.

The situation in Europe, as described on the following pages, is diverse and demonstrates the transformative power, but also the limitations, of common legal requirements. On the one hand, all EU countries have enacted legislation requiring imaging referral guidelines, which, in a large majority of cases, are either already available or under development. On the other hand, robust development methodologies and inclusion of all 'good practice' features were demonstrated in only two countries and the use of guidance in clinical practice was identified as major issue. The report makes specific recommendations for further action to improve the availability and use of guidelines and, while a lot can be achieved at a national level, the need for European co-operation in many areas is evident.

The European Commission is actively participating in the ongoing discussion among the European scientific community, national authorities and professional bodies on advancing radiation protection and, where necessary, takes action in accordance with its mandate and powers. The adoption of the revised European Basic Safety Standards at the end of 2013 provides a rare opportunity for revising current practice and redefining priorities and programmes. I believe that the information, conclusions and recommendations contained in this report will make a valuable contribution to this process.

Ivo Alehno
Head of Radiation Protection Unit
Directorate General for Energy

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1 EXECUTIVE SUMMARY

The European Council Directive 97/43/Euratom requires 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]). The Project ENER/D4/315-2011 aims to assess the current status of the availability of imaging referral guidelines (Guidelines) in European Union member states and those countries enacting European legislation.

The proposal for the project “Implementation of Council Directive 97/43/Euratom requirements concerning referral criteria for medical imaging in the European Union” was submitted as a consortium of several partners in June 2011. 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:

1. The conduct of an EU-wide study on the availability, development and implementation of referral guidelines for radiological imaging in the EU Member States. This web-based survey took place in the spring of 2012.
2. The organisation of a European Workshop with relevant representatives from the EU Member States. This workshop was held in Vienna on 20-21 September 2012.
3. The formulation of conclusions and recommendations for national and/or Community action.

Conclusions and recommendations for the EC Guidelines Project are based on the Workshop conclusions together with those from the survey of 30 European countries carried out in the spring of 2012, with refinement through the Steering Committee, taking into account information from expert advisors, feedback from stakeholder organisations and further correspondence with national organisations participating in the survey.

1.1 Availability of Guidelines

1. Survey respondents in 21/30 countries were aware of legal requirements for Guidelines. Subsequent to the survey the legal requirement has been confirmed in all EU countries.
2. Survey respondents in 18/30 countries were aware of the availability of Guidelines nationally. In the later stages of the project, respondents in a further 7 European countries have reported availability of referral guidelines mostly through work in progress to make such guidelines available. This takes the total number of countries with Guidelines available or in preparation to 25/30.
3. Respondents from 17 countries gave reference to 24 sets of national Guidelines, several countries having separate guidance for diagnostic radiology and nuclear medicine. Of the 24 sets of Guidelines, 10 were reported to be “nationally developed”, 8 adopted and modified, and 6 adopted without modification.

1.2 Guidelines development methodology

1. In both the Survey and Workshop there was agreement that European imaging referral guidelines (Guidelines) are essential.
2. A single set of European Guidelines is preferred. This was made clear at the European Workshop in Vienna (the Workshop).

3. National Guidelines, either developed de novo through accepted methodology or adopted, adapted and translated are alternatives.
4. Good practices were demonstrated in several countries which included some of the important methodological features shown below. Guidelines developed in 2 countries included all of these features:
 - radiation dose information
 - specific advice for imaging children
 - specific advice for the pregnant woman/ unborn child
 - an evidence-based process
 - formal consensus for recommendations
5. Stakeholders should include patients and their carers in addition to referrers, radiological practitioners, radiographers, regulators and other professionals involved in the process.
6. Responses to survey questions concerning Guideline methodology may not be fully representative of the whole EU as only 23 respondents (out of 80 in total) from 17/30 countries replied to this section.

1.3 Use of Guidelines

1. In both the Survey and Workshop there was agreement that additional measures were needed to reinforce the use of Guidelines.
2. Educational initiatives are in place but further measures would be helpful. Such measures include: radiation protection awareness in undergraduate and post-graduate training curricula; lifelong learning (continuing professional development) for referrers; and also through educational messages in reports with radiation dose.
3. Clinical Decision Support (CDS) systems to facilitate access, use and compliance were highly favoured both in the Survey and at the Workshop. An “add-on” system interfacing with existing radiology information systems and electronic requesting systems was preferred. A CDS system should not replace the role and responsibility of the radiological practitioner with respect to justification.
4. Clinical audit should be used for monitoring of Guidelines’ availability, their use and implementation. Although recommendations from such audits are not binding, they enable considerable quality improvement. Both external audit and local internal audit are needed.

1.4 Recommendations

1. Clearer and stronger European measures to encourage both availability and use of referral guidelines. Such measures should be made centrally or through European competent authorities.
2. European Guidelines. These may be produced initially by a combination of existing national Guidelines, developed using accepted methodology, under the auspices of a European professional organisation. European Guidelines must contain dose information and must include separate advice for children, and the pregnant woman/ unborn child.
3. Development and integration of Clinical Decision Support (CDS). This should interface with existing electronic requesting systems (computerised physician order entry systems) and radiology information systems.

4. Encourage educational initiatives. Such initiatives should complement European Medical ALARA Network (EMAN) [2] and Medical Radiation Protection in Education and Training (MEDRAPET) [3]. Referrers, radiologists and radiographers will benefit. Initiatives such as life-long-learning should be encouraged.
5. Both external audit and local internal audit are needed for monitoring. External audit has been addressed in EC guidelines on clinical audit [4], but further measures to promote local internal audit are needed.

2 INTRODUCTION

2.1 Background

The proposal for the project “Implementation of Council Directive 97/43/Euratom requirements concerning referral criteria for medical imaging in the European Union” was submitted as a consortium of several partners in June 2011. 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.

Many Member States have developed or adopted national imaging referral guidelines for clinical imaging principally to support the referring practitioner in selecting and justifying radiological procedures. The selection of the appropriate investigation promotes good medical practice and radiation safety of patients. 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” [5]. The Radiation Protection 118: Referral Guidelines for Imaging (RP 118) [6] 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, “Guide du bon usage des examens d'imagerie médicale” [7]. 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 ICRP level 2 [8] and reduction of unhelpful medical exposures was shown in early studies [9, 10]. Such guidance is also helpful to promote good medical practice and may improve cost effectiveness by encouraging the best test first.

The full project comprises 3 main tasks:

1. 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 representatives of relevant organisations from EU Member States, and
3. the development of conclusions from the workshop regarding the need for national and/or Community action.

2.2 Project Overview

In addition to Project Management, Work Package 0 (WP0), the project was broken down into 3 technical Work Packages (WPs) and each work package covers specific tasks contributing to achieve the common objective of reviewing the situation in the EU Member States regarding the fulfilment of their obligations under MED Article 6.2.

Work Package 1

The conduct of an EU-wide study on referral guidelines for radiology imaging in EU Member States is the task of Work Package 1. This WP comprised: developing the methodological approach for the study, carrying out the study as well as developing a structured evaluation/summary document of the study as a basis for the European Workshop under WP2. This work package was chaired by the RCR.

Work Package 2

The organisation of a European Workshop on referral guidelines for radiology in EU Member States and the discussion of the findings of the survey was the main task of Work Package 2, which was chaired by the ESR.

Work Package 3

The development of conclusions from the survey and workshop regarding the need for national and/or Community action was the main task of Work Package 3, chaired by the ESR.

2.3 Project Members

2.3.1 Steering Committee

Denis Remedios, ESR, Chair
Monika Hierath, ESR, Project Manager
Peter Cavanagh (alternate Nick Ashford), RCR
Philippe Grenier (alternate Valérie Vilgrain), SFR
Mario Bezzi, CIRSE
Jean-François Chateil (alternate Karen Rosendahl), ESPR
Georgi Simeonov, EC representative

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3 STUDY ON THE DEVELOPMENT AND IMPLEMENTATION OF REFERRAL GUIDELINES FOR RADIOLOGICAL IMAGING IN THE EU MEMBER STATES

3.1 Introduction

The objective of this WP was to devise and implement an EU-wide study on referral guidelines for radiological imaging in the EU Member States in order to identify major issues, important differences between Member States and good practices. For this project, it was agreed to include the 27 European Union countries, Croatia (the acceding state) and countries enacting European legislation (Norway and Switzerland), hereinafter called “European Countries”.

A web-based survey was used to assess the availability of imaging referral guidelines: the 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 acceding state) and countries using European legislation, namely, Norway and Switzerland. Responses were collated by the ESR and analysed by the SFR together with the Steering Committee.

3.2 Methods, approach and questionnaire

The main task was to establish the overall status, the legal provisions and the practical arrangements in the Member States regarding the implementation of the MED’s requirements on referral guidelines for imaging. This work package involved the development, distribution and analysis of a questionnaire (see Appendix 1). This questionnaire was specifically distributed to reach heads of designated representatives of national radiological and nuclear medicine societies in addition to competent authorities of European countries dealing with radiation safety. Due attention was paid to ensure delivery to the most appropriate representative, to avoid duplication and to encourage response to the questionnaire.

3.2.1 Identification of addresses for the questionnaire

National radiological societies, national nuclear medicine societies, and competent authorities (including regulatory / advisory radiation protection body, governmental authority or other official agency) were contacted. Lists of addresses were obtained from the ESR, EC Directorate General for Energy, or through the EANM. Addresses were double-checked before inviting participation in the completion of the questionnaire. The EC DG Energy kindly assisted in ensuring completeness of distribution and encouraging completion of the questionnaire by competent authorities.

3.2.2 The approach and matrix of the study

The decision was made to include the acceding state, Croatia and those countries enacting European legislation, Norway and Switzerland. The use of a balanced 7-point Likert scale was agreed to strengthen analysis. For consensus a 75% level of agreement was considered to be appropriate.

3.2.3 Development of the structure of the questionnaire, elaboration of the questions

The design of the questionnaire was based on three sections:

- Information regarding Guideline availability, legal requirements and imaging requesting issues,
- Methodology for development and distribution of Guidelines, and
- Preferences for future Guideline development, format, distribution, tools for reinforcement and monitoring.

The complete survey questionnaire can be found in Appendix 1.

3.2.4 Analysis of responses

Responses to the questionnaire were plotted and analysed to identify major issues, important differences between Member States and good practices in regard to referral guidelines for radiological and nuclear medicine imaging. Consensus as to the preferred future measures for Guideline development, distribution, implementation and monitoring was identified for key questions.

3.3 Survey Results

3.3.1 Availability, Development and Use of Imaging Referral Guidelines in European Countries

Representatives in 30 countries were surveyed and responses were received from all countries.

Eighty responses were received (see Table 1):

- 32 from national radiological societies (some countries had more than 1 national society)
- 20 from national nuclear medicine societies
- 28 from national competent authorities

From the national radiological societies, we did not receive response from Cyprus. We received 2 responses from the Netherlands and 3 from Romania.

From the national nuclear medicine societies, we did not receive response from Bulgaria, Estonia, Finland, France, Ireland, Lithuania, Luxembourg, Norway, Poland, Portugal, Slovakia and Slovenia. We received 3 responses from the Netherlands.

From the national competent authorities, we received responses from all countries, except Italia, Hungary and Latvia. We received 2 responses from Spain.

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

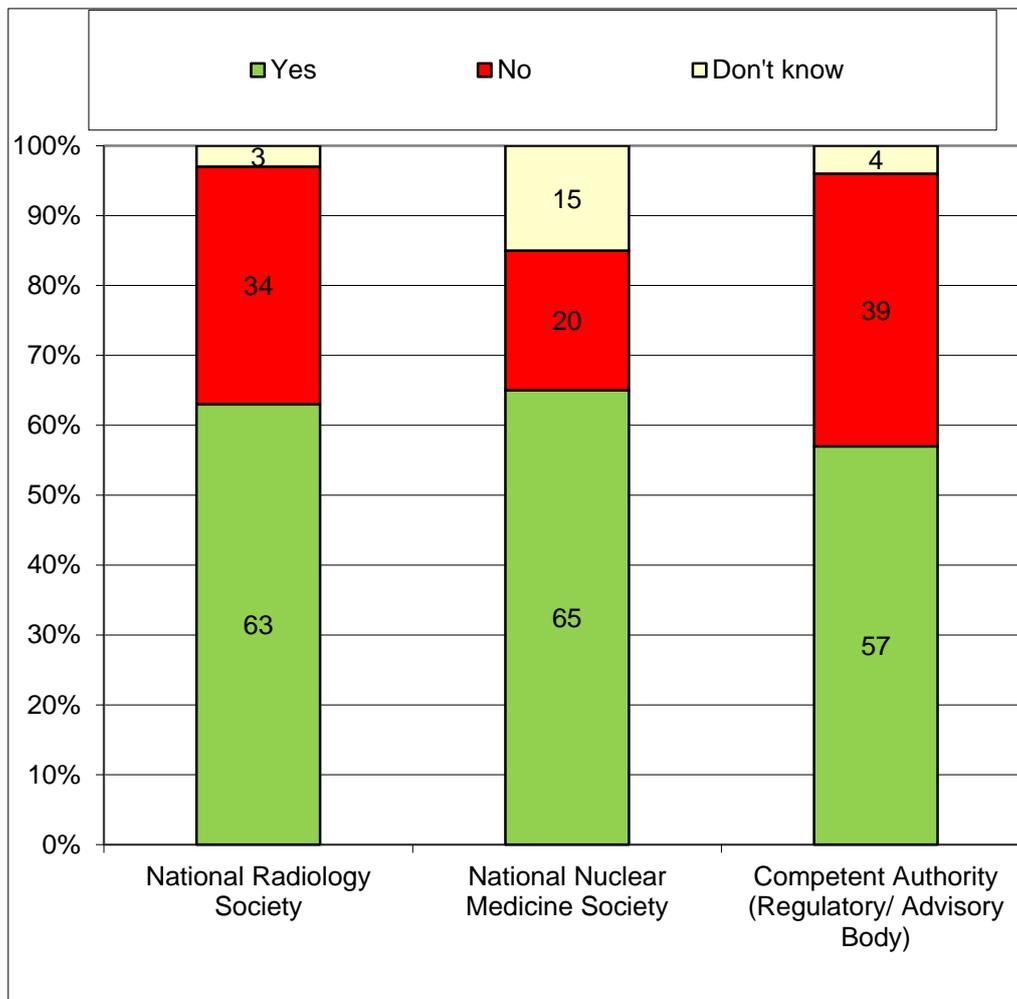
Table 1: Guidelines Survey: Participation by European radiological competent authorities and professional societies. Thirty European countries took part in the survey, including 27 EU member states, one acceding state* and 2 countries enacting EU legislation†

Member State	National Radiology Society	National Medicine Society	Nuclear Society	Competent Authority (Regulatory/ Advisory Body)
Austria	1	1		1
Belgium	1	1		1
Bulgaria	1	0		1
Croatia*	1	1		1
Cyprus	0	1		1
Czech Republic	1	1		1
Denmark	1	1		1
Estonia	1	0		1
Finland	1	0		1
France	1	0		1
Germany	1	1		1
Greece	1	1		1
Hungary	1	1		0
Ireland	1	0		1
Italy	1	1		0
Latvia	1	1		0
Lithuania	1	0		1
Luxembourg	1	0		1
Malta	1	1		1
Netherlands	2	3		1
Norway†	1	0		1
Poland	1	0		1
Portugal	1	0		1
Romania	3	1		1
Slovakia	1	0		1
Slovenia	1	0		1
Spain	1	1		2
Sweden	1	1		1
Switzerland†	1	1		1
United Kingdom	1	1		1
Total replies	32	20		28

3.3.1.1 Availability of Imaging Referral Guidelines in European Countries

Sixty-one percent of responders said that there was a legal requirement for Guidelines including radiation dose (see Fig. 1). Five responders said: "I don't know whether such a legal requirement exists or not".

Figure 1: Guidelines Survey: Responses (by national societies or competent authorities) as to the legal requirement for imaging referral guidelines in 30 European countries



Most respondents report that the responsibility for making Guidelines available has been transferred to ministries of health, or professional organisations. There was some discordance between national societies and competent authorities' responses to the question about the transfer responsibility for making guidelines availability.

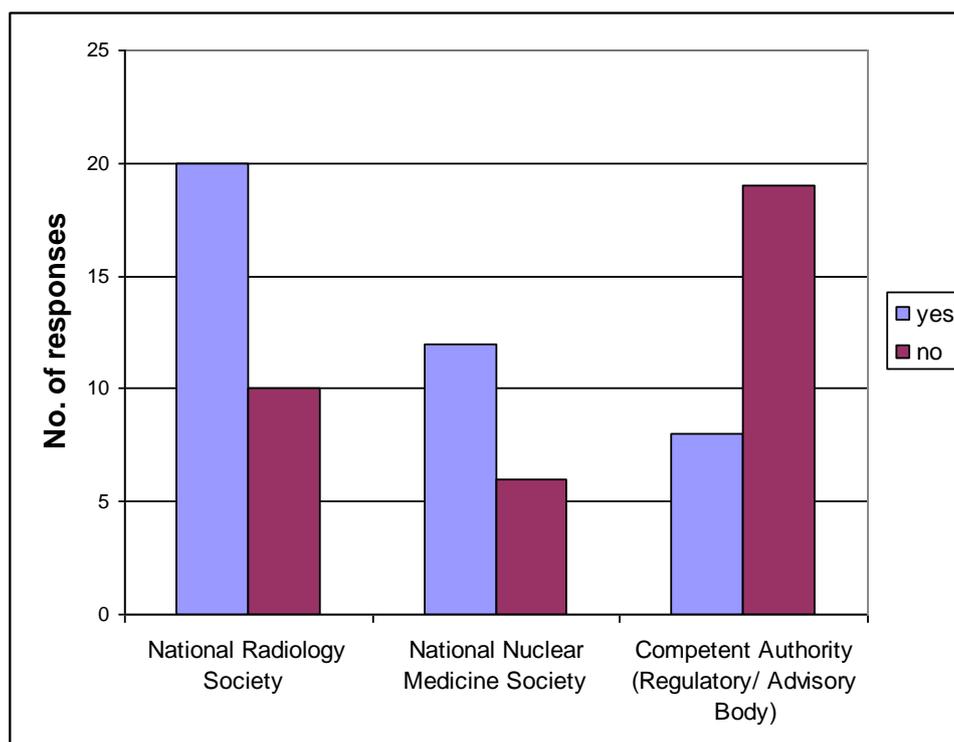
The majority of respondents (76%) did not think that Guidelines must exist in order for insurance companies in their country to pay for an imaging investigation. Respondents indicated that most imaging requests are made by medical practitioners. Respondents report that General Practitioners make more requests for plain radiographs, contrast radiography, and ultrasound (US) and fewer for computed tomography (CT), magnetic resonance imaging (MRI), interventional radiology (IR) and nuclear medicine (NM) examinations compared with hospital specialists.

Respondents indicated that the most common modality for which a patient could self-present was US, followed by plain radiography and MRI.

3.3.1.2 Availability of nationally recognised imaging referral guidelines (appropriateness or referral criteria) including radiation doses

Twenty radiology societies and 12 nuclear medicine societies, and 8 competent authorities, responded that there were nationally recognised imaging referral guidelines including radiation dose available (see Fig. 2).

Figure 2: Guidelines Survey: Availability of nationally recognised imaging referral guidelines reported by professional societies and competent authorities



Analysis by country took into account the majority response by the national radiology society, nuclear medicine society and competent authority, rounding up fractions (see Table 2 and Appendix 2. National Guidelines).

Only 12 of the 20 radiological societies and 9 of the 12 nuclear medicine societies which have nationally recognised 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.

Table 2: Guidelines Survey: National radiology and nuclear medicine society and competent authority responses to the availability of and legal requirements for imaging referral guidelines including radiation doses. Thirty European countries took part in the survey, including 27 EU member states, one acceding state* and 2 countries enacting EU legislation†.

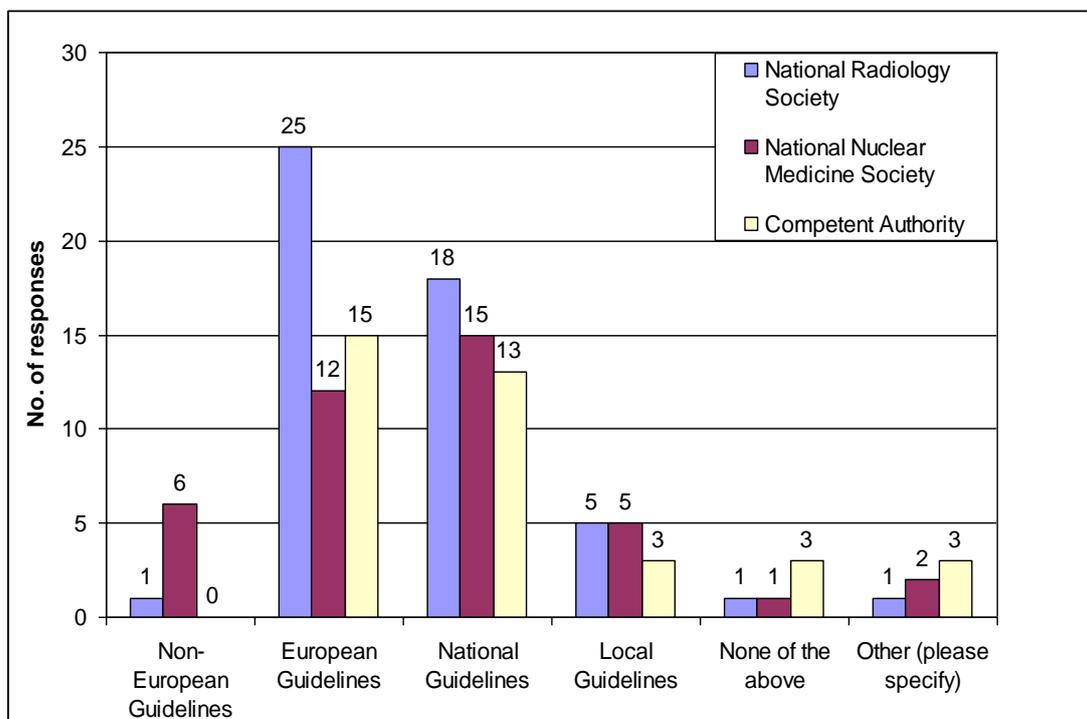
Subsequent to the survey, all EU countries have confirmed that they have a legal requirement for referral guidelines

Country	Does your Member State: have a legal requirement for imaging referral guidelines including radiation doses ("Guidelines")				In your Member State, are there nationally recognised imaging referral guidelines (appropriateness or referral criteria) including radiation doses available?			
	Comp auth	NM Soc.	Rad Soc.	Majority response#	Comp auth	NM Soc.	Rad Soc.	Majority response
Austria	yes	yes	yes	yes	yes	yes	yes	yes
Belgium	yes	yes	no	yes	yes	yes	yes	yes
Bulgaria	yes	-	no	no	yes	-	yes	yes
Croatia*	no	no	yes	no	no	no	yes	no
Cyprus	yes	yes	-	yes	no	no	-	no
Czech Republic	yes	yes	yes	yes	yes	yes	no	no
Denmark	yes	don't know	yes	yes	no	yes	yes	yes
Estonia	no	-	yes	no	no	-	yes	no
Finland	yes	-	yes	yes	yes	-	yes	yes
France	yes	-	yes	yes	yes	-	yes	yes
Germany	yes	yes	yes	yes	yes	yes	yes	yes
Greece	yes	yes	yes	yes	yes	no	yes	yes
Hungary	-	yes	no	yes	-	yes	no	yes
Ireland	yes	-	yes	yes	yes	-	-	no
Italy	-	yes	yes	yes	-	yes	yes	yes
Latvia	-	yes	yes	yes	-	yes	yes	yes
Lithuania	no	-	no	no	no	-	no	no
Luxembourg	yes	-	no	yes	yes	-	yes	yes
Malta	no	yes	yes	yes	no	no	no	no
Netherlands	no	yes	yes	yes	no	yes	yes	yes
Norway†	no	-	no	no	yes	-	no	no
Poland	yes	-	yes	yes	no	-	yes	yes
Portugal	no	-	yes	yes	no	-	no	no
Romania	yes	yes	yes	yes	no	yes	yes	yes
Slovakia	yes	-	yes	yes	yes	-	yes	yes
Slovenia	yes	-	no	yes	no	-	yes	no
Spain	No	no	no	no	no/ -	yes	yes	yes
Sweden	yes	no	yes	no	yes	no	no	no
Switzerland†	yes/ no	yes	no	no	no	yes	-	no
United Kingdom	yes	don't know	yes	yes	yes	no	yes	yes
Overall yes	19	13	22	21/30	14	12	23	18/30
Overall no	9	4	10	9/30	13	6	7	12/30

3.3.1.3 Preference for source of Guidelines to be used in Europe

The great majority of states have recommended European or national Guidelines. (See Figure 3)

Figure 3: Guidelines Survey: Preference for source of imaging referral guidelines to be used in Europe



Where “other” was chosen as the question response, the specified other options for the preference of the source of Guidelines included:

“The professional societies are responsible for drawing up the referral guidelines.”

“Our government would most probably accept competent international guidelines and the Croatian Society of Radiology is currently trying to introduce Royal College of Radiologists’ guidelines in our clinical practice modified according to our situation.”

“Current regulation does not but new draft regulation and guidelines recommend European Guidelines.”

“European guidelines are to be recommended in new legislation.”

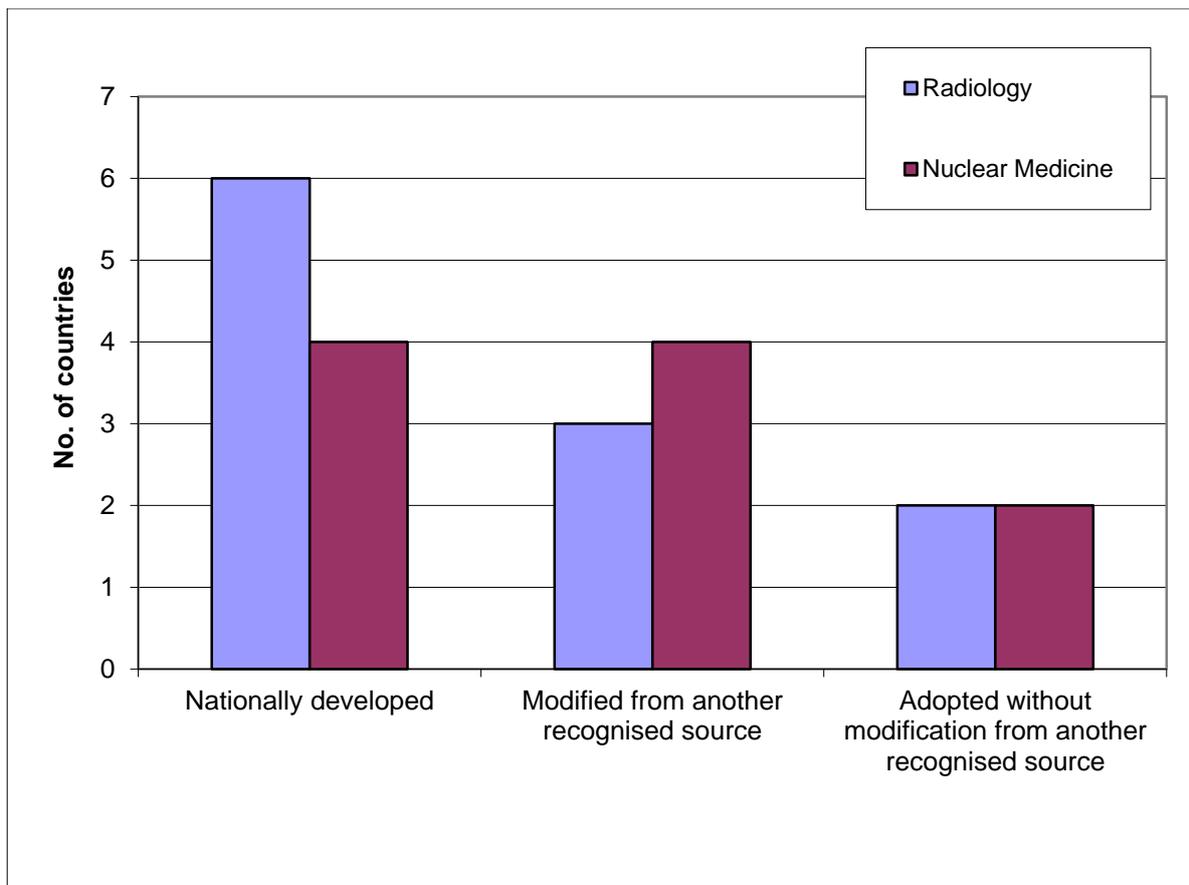
“If National guidelines are not available then European ones are implemented.”

“American guidelines (US).”

3.3.1.4 Development of Imaging Referral Guidelines

Guidelines were reported to be developed nationally in half of the countries and modified or adopted with modifications from another source in the others (See Figure 4). The replies for this section on guideline methodology may not be fully representative of all of the EU as only 23 responses from 17 countries were received out of 52 professional society representatives (and a total of 80 respondents including competent authority representatives).

Figure 4: Guidelines Survey: Guidelines are either developed de novo nationally, adopted and adapted from other sources or adopted without adaptation from other sources. 22 responses from 14 countries were received out of a total of 52 professional organisations



There was a good concordance between radiology and nuclear medicine societies for two countries (France and UK), which provided radiological and NM guidance within the same publication.

Regarding the organisations involved in the development of the Guidelines, there was a broad range of responses. Whilst most countries only responded with one organisation, some countries listed multiple organisations. In a few countries, speciality groups also took part in the development of the National Guidelines.

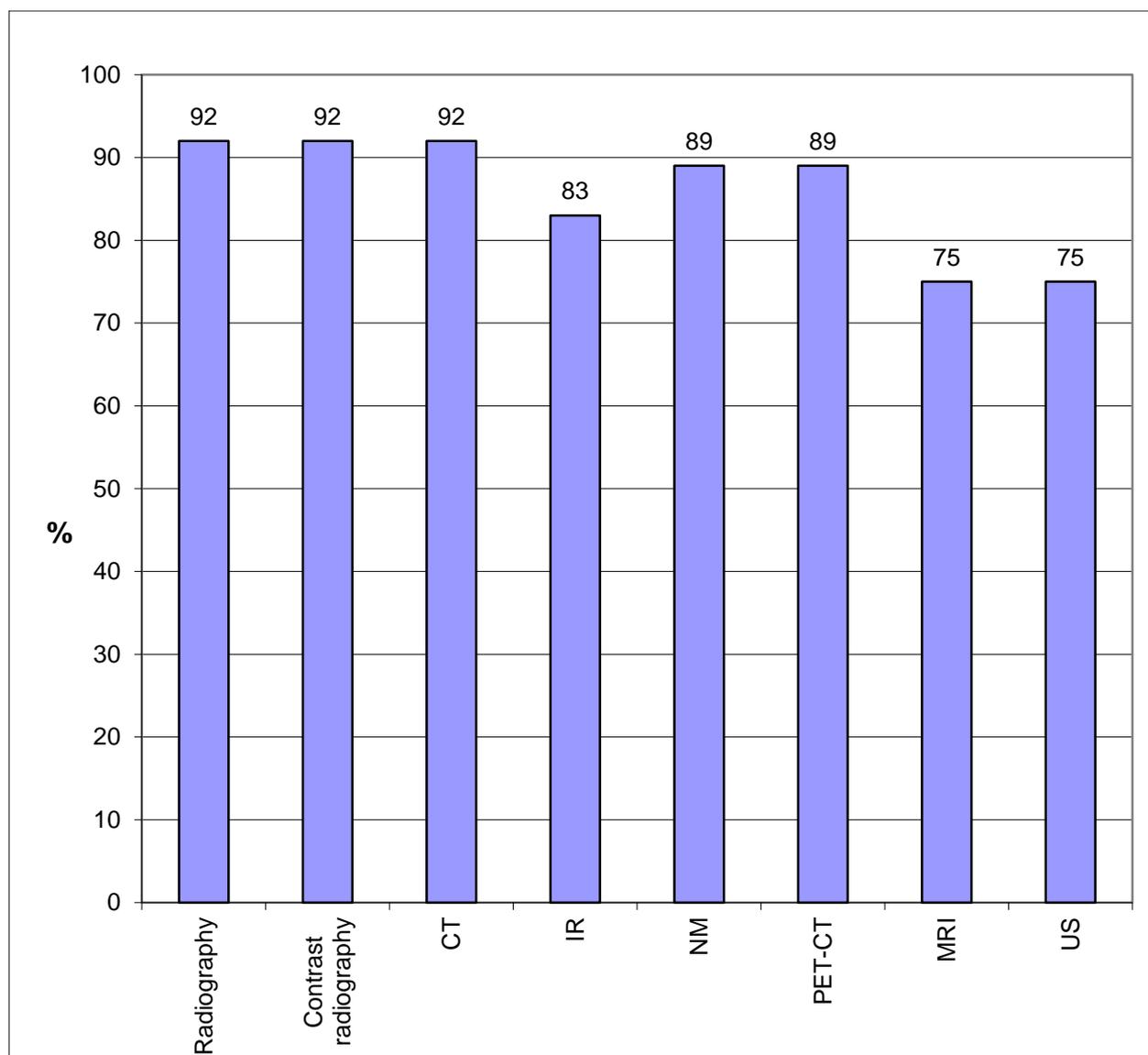
The year of the first edition of the Guidelines varied from 1989 to 2005 for radiological societies and from 1998 to 2011 for nuclear medicine societies. The approximate duration of the review cycle has varied between countries from 3-4 years to > 6 years.

In the majority of countries (67% for radiology and 90% for nuclear medicine), the source of funding for the development of the Guidelines was the Ministry of Health or other governmental department.

3.3.1.5 Imaging modalities included in Guidelines

The imaging modalities involving ionising radiation (radiography and nuclear medicine) were included in the great majority of the Guidelines (83-92%) whereas the non-ionising radiology modalities (US, MRI) were only present in 75% of the Guidelines (see Fig. 5).

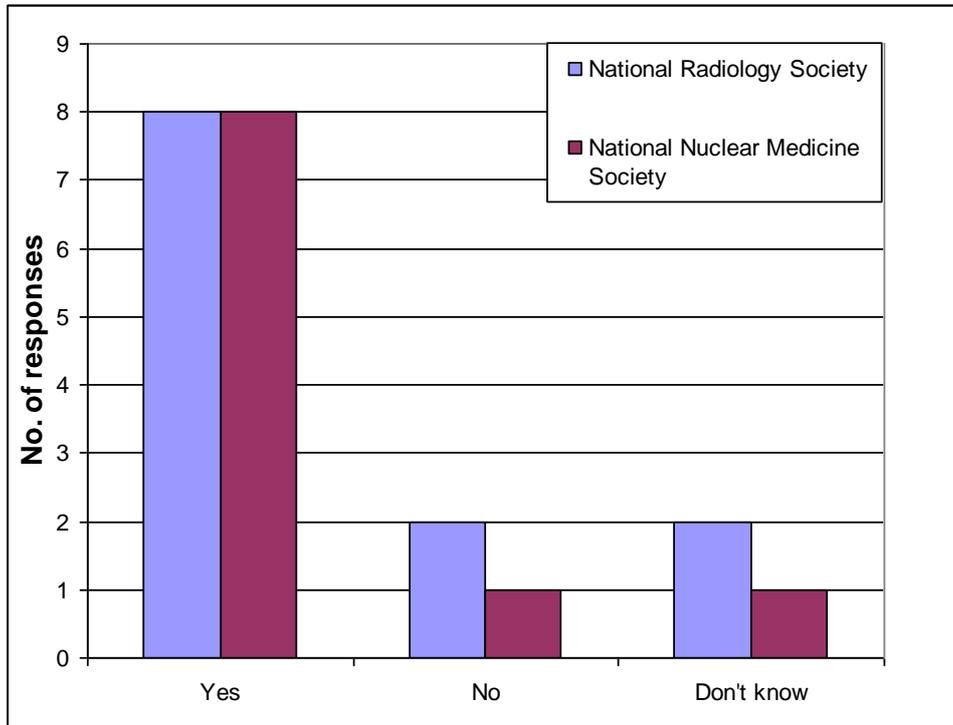
Figure 5: Guidelines Survey: Imaging modalities included in Guidelines. (CT= computed tomography, IR= interventional radiology, NM= nuclear medicine, PET-CT= Hybrid positron emission tomography with computed tomography, MRI= magnetic resonance imaging, US= ultrasound.)



3.3.1.6 Guidance for children

The majority of Guidelines include separate guidance for children (67-80%). (See Fig. 6.)

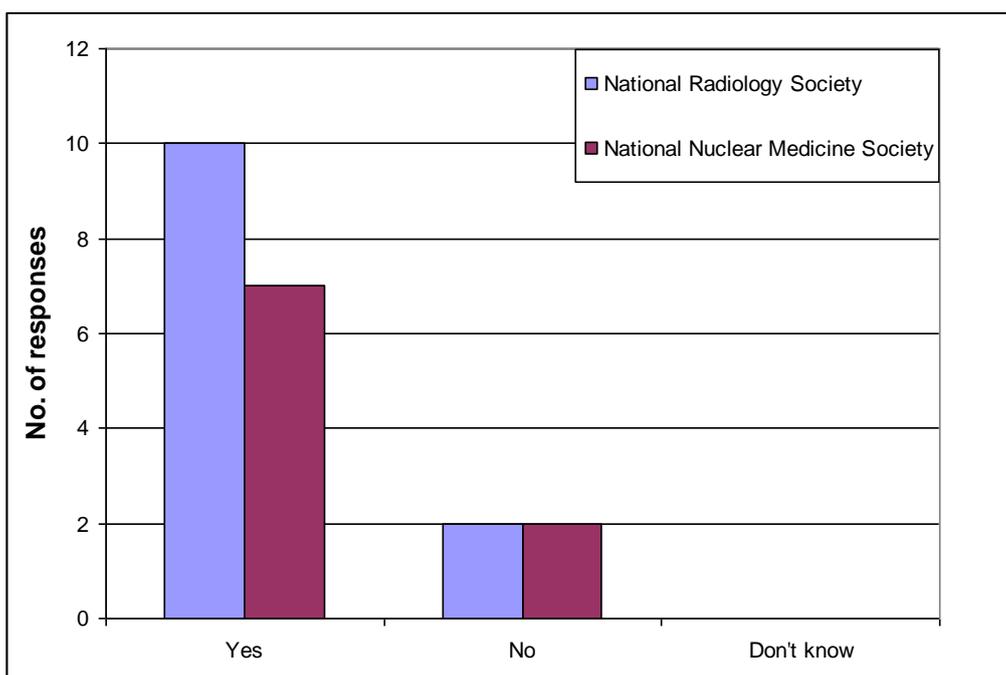
Figure 6: Guidelines Survey: Availability of separate guidance for children. Most national radiological and nuclear medicine guidelines include separate guidance for children



3.3.1.7 Guidance for pregnant women

The majority of Guidelines include guidance for the pregnant woman / unborn child (78-83%). (See Fig. 7.)

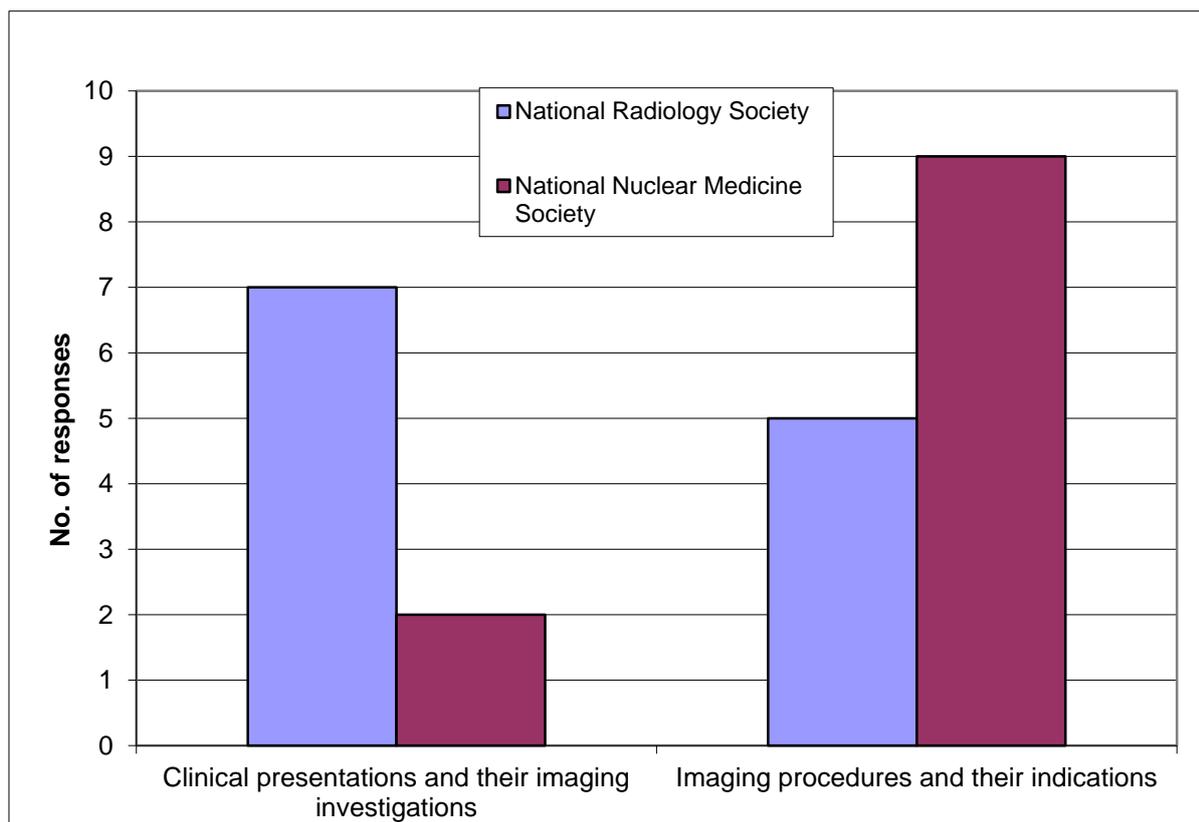
Figure 7: Guidelines Survey: Availability of guidance for pregnant women. Most national radiological and nuclear medicine societies include guidance for the pregnant woman / unborn child



3.3.1.8 Focus of Guidelines on clinical presentations or indications for procedures

Most radiological Guidelines focus on clinical presentations whereas most nuclear medicine guidelines focus on indications for procedures. (See Fig. 8.)

Figure 8: Guidelines Survey: Focus of Guidelines on clinical presentations or indications for procedures. Clinical presentations are used more commonly as the approach for radiological guidance whereas indications for procedures are more commonly the approach for nuclear medicine Guidelines. For this question there were 23 responses from 14 countries out of a total of 52 professional organisations



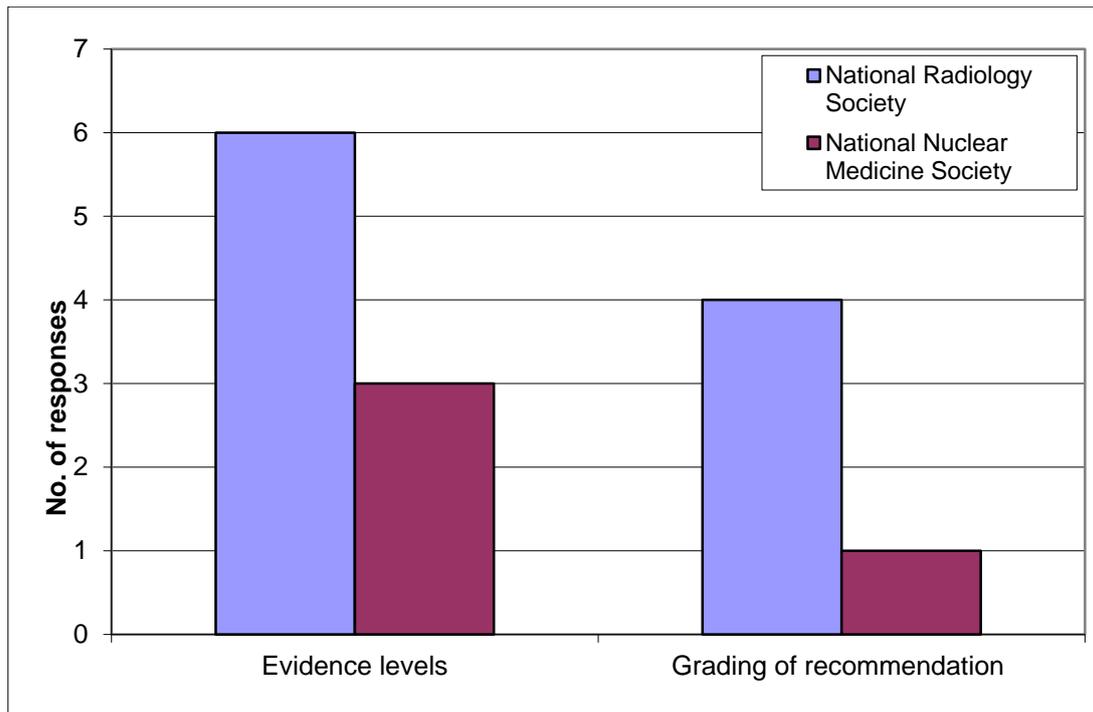
Most of the radiological societies' Guidelines and the nuclear medicine societies' Guidelines cover multiple groups of diseases and medical conditions for adults, including: breast, cancer, cardiovascular, chest, gastrointestinal, neurological, trauma and urogenital. Guidelines for children cover fewer clinical conditions.

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

3.3.1.9 Use of evidence levels and recommendations

Very few Guidelines have included recognised evidence levels (6 radiology, 3 nuclear medicine) and grading recommendation using a recognised system (4 radiology, 1 nuclear medicine). (See Fig. 9.)

Figure 9: Guidelines Survey: Use of evidence levels and grading of recommendations. Few Guideline developers use recognised evidence levels and fewer grade recommendations. For this question there were 14 yes responses (and 4 no responses – not shown in the chart) from 12 countries out of a total of 52 professional organisations



Radiation dose, strength of evidence and grading of recommendations were considered in most Guidelines. Cost effectiveness and availability of equipment or expertise were far less frequently taken into consideration.

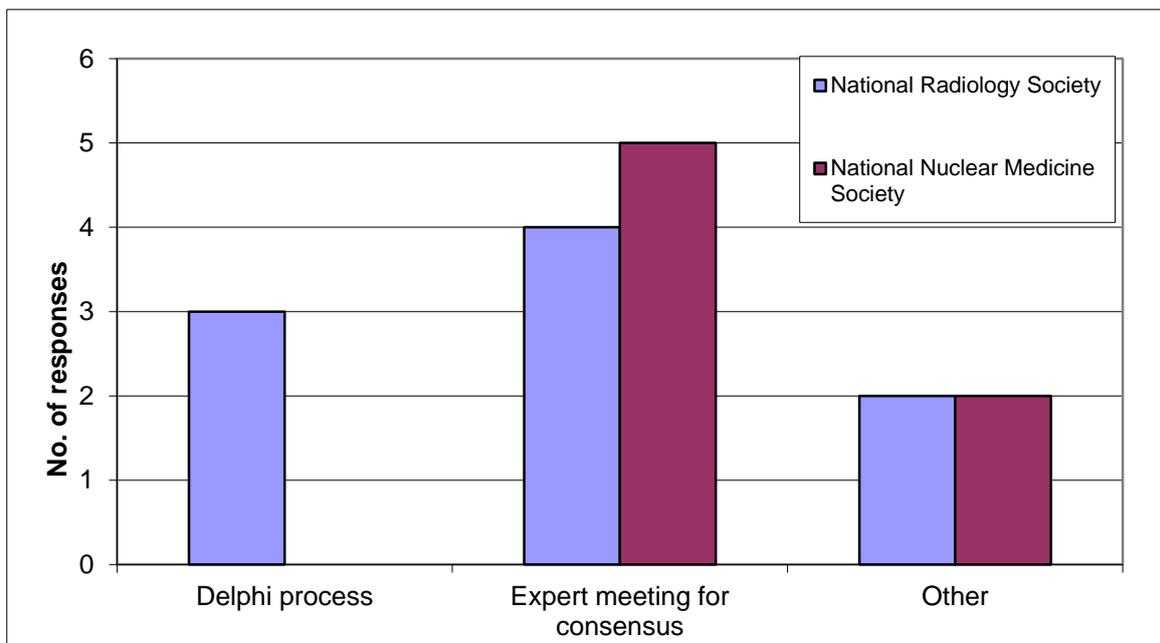
As an example, two radiological societies which graded their recommendations (France and UK):

- In the French Society of Radiology Guidelines there were 62 grade A recommendations, 618 grade B recommendations and 209 grade C recommendations;
- In the RCR Guidelines from the UK there were 74 grade A recommendations, 633 grade B recommendations and 166 grade C recommendations.

3.3.1.10 Use of a recognised process of consensus

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. (See Fig.10)

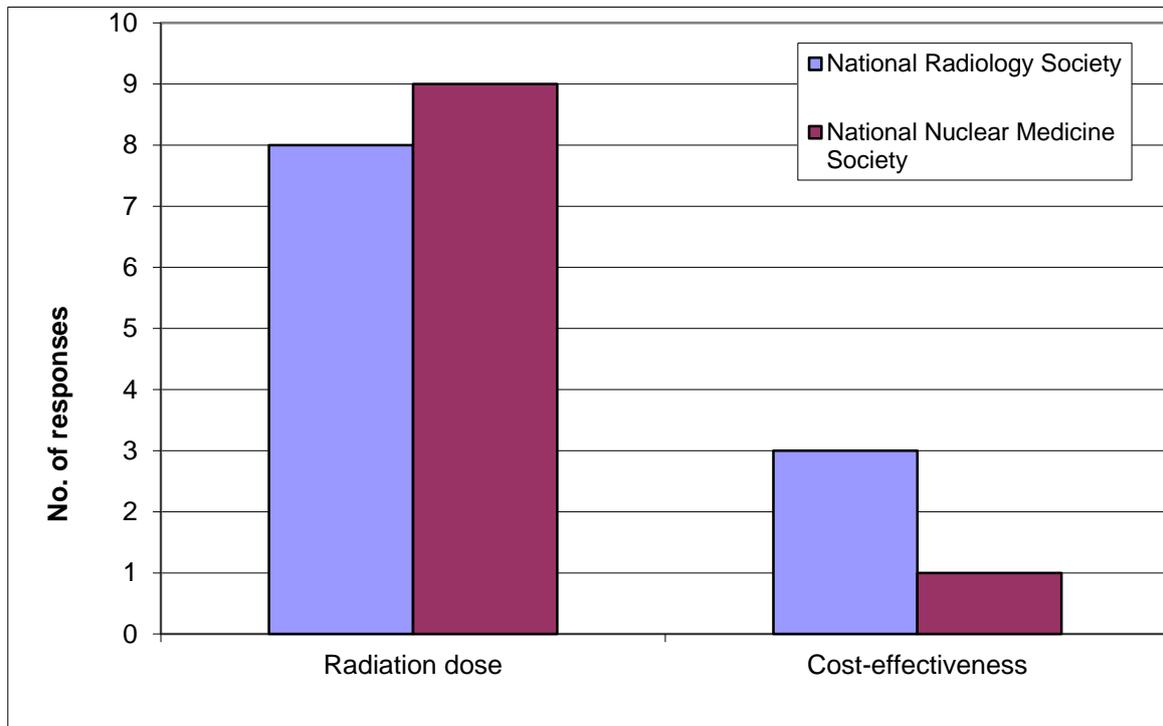
Figure 10: Guidelines Survey: Use of a recognised process of consensus. Consensus meetings are more frequently used than a Delphi iterative process for agreement. For this question there were 16 responses from 10 countries out of a total of 52 professional organisations



3.3.1.11 Use of recognised sources for radiation dose and costs

Radiation dose was obtained from recognised sources in 8 radiological and 9 nuclear medicine societies. (See Fig. 11.)

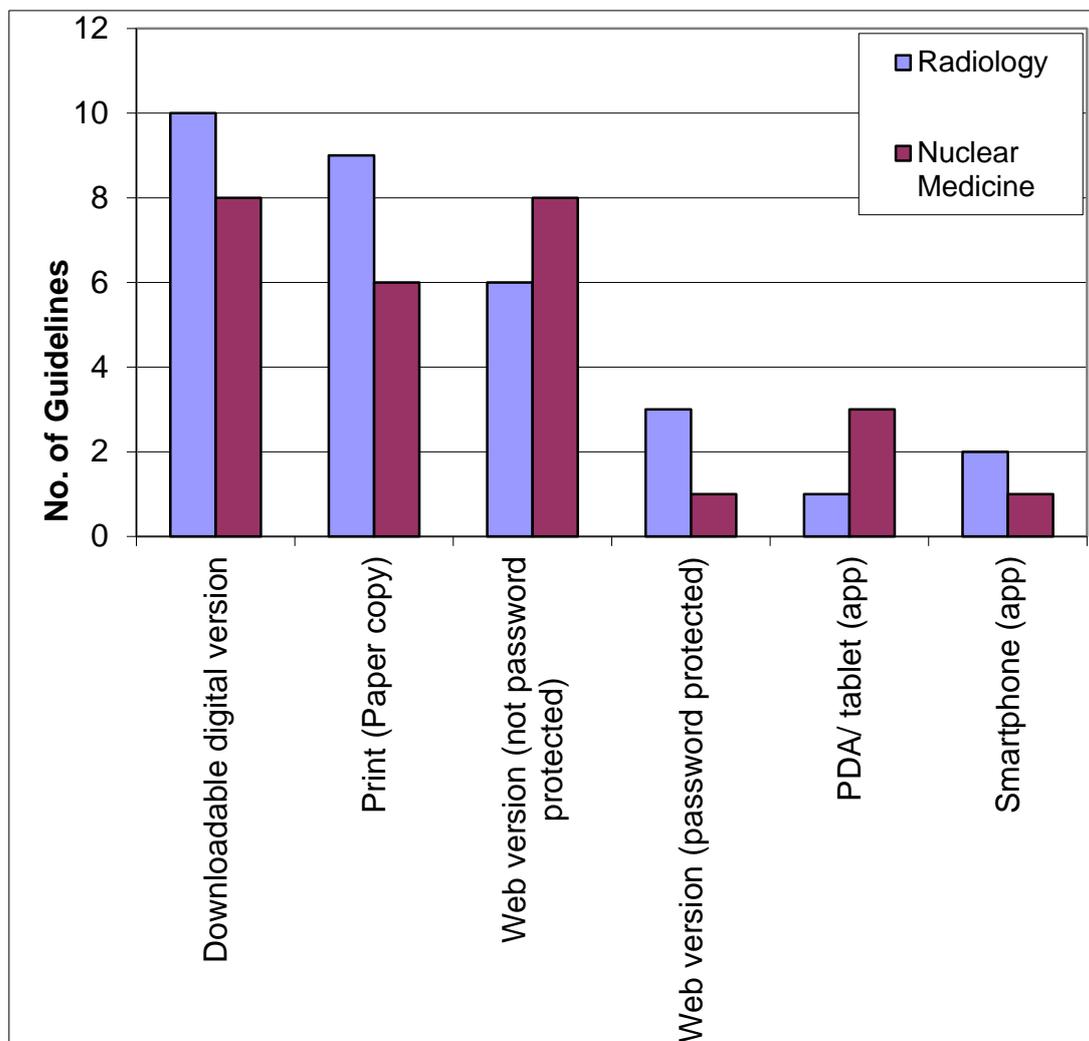
Figure 11: Guidelines Survey: Use of recognised sources for radiation dose and costs. Most Guidelines use a recognised source for radiation dose but few use recognised sources for costs. For this question there were 21 responses from 12 countries out of a total of 52 professional organisations



3.3.1.12 Format of Guidelines

Almost all Guidelines are available in a downloadable digital version. The great majority of Guidelines are available in a web version. Very few have a tablet or smart phone version. (See Fig. 12.)

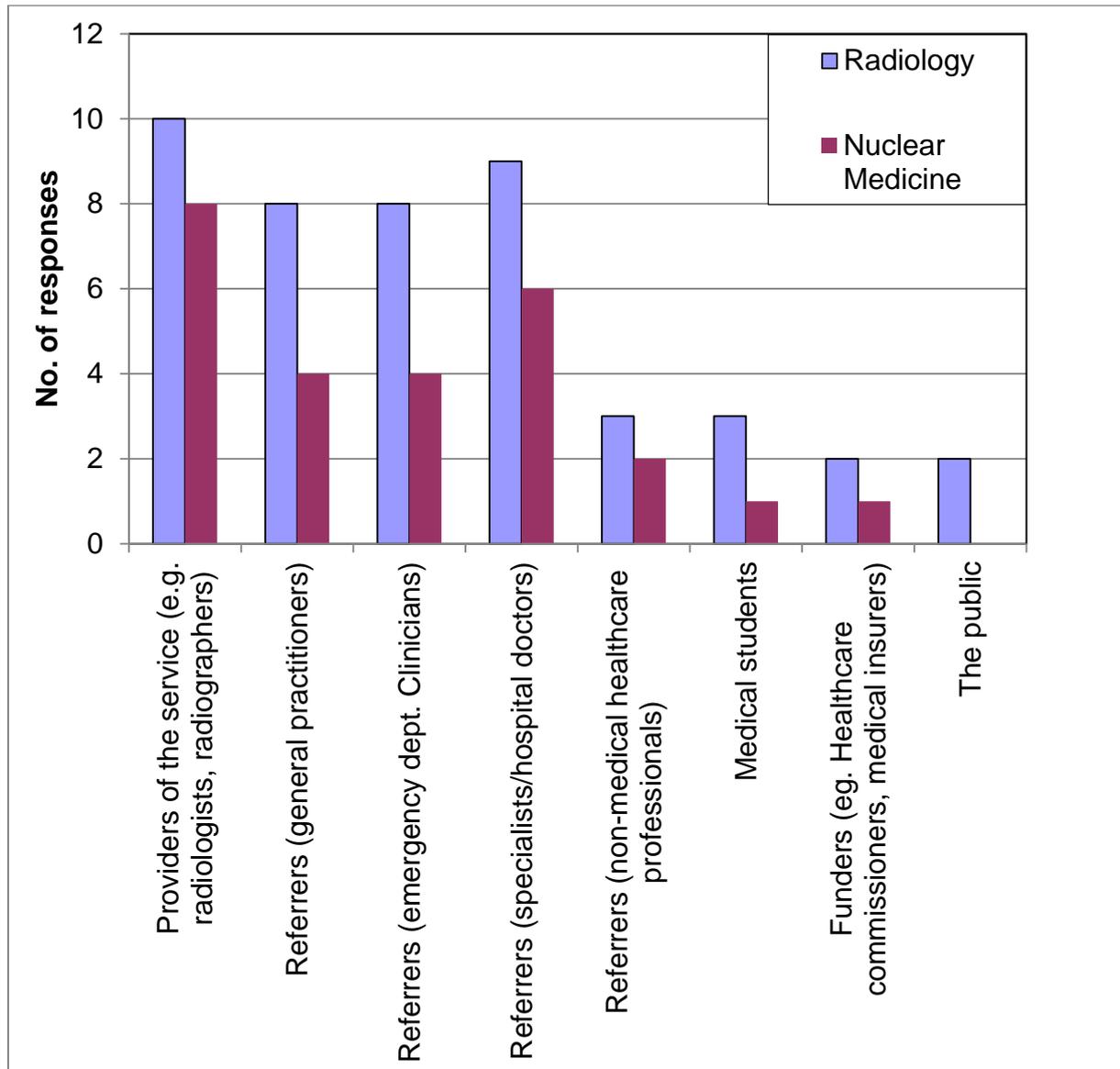
Figure 12: Guidelines Survey: Formats. Most Guidelines are available in downloadable digital, print and web versions



3.3.1.13 Distribution of Guidelines

The majority of Guidelines are routinely circulated to providers of the service, general practitioners, emergency department clinicians and specialists / hospital doctors. Only a few of these Guidelines are routinely circulated to non-healthcare professionals, medical students, funders and the public. (See Fig. 13.)

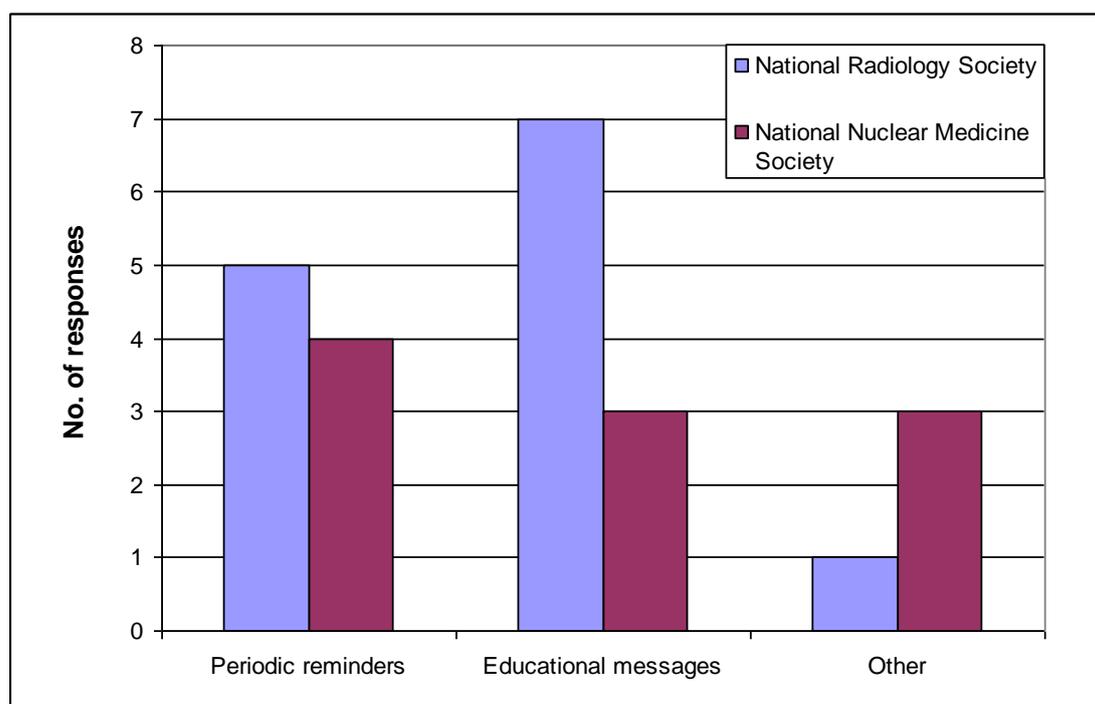
Figure 13: Guidelines Survey: Distribution of Guidelines to various user groups. Most Guidelines are distributed to referrers, radiologists and radiographers



3.3.1.14 Reinforcement of Guidelines

Reinforcement of Guidelines is advocated through periodical reminders in half and through educational message by most of the radiological societies. (See Fig. 14.)

Figure 14: Guidelines Survey: Strategies for Guidelines reinforcement. Periodical reminders for implementation and use, educational messages, often in reports and clinical audit are among the strategies used. For this question there were 23 responses from 13 countries out of a total of 52 professional organisations



Only two national societies have reported that they have incorporated their Guidelines into clinical decision support systems (CDSS) (Finland, Italy).

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

3.3.2 European preferences for Guidelines

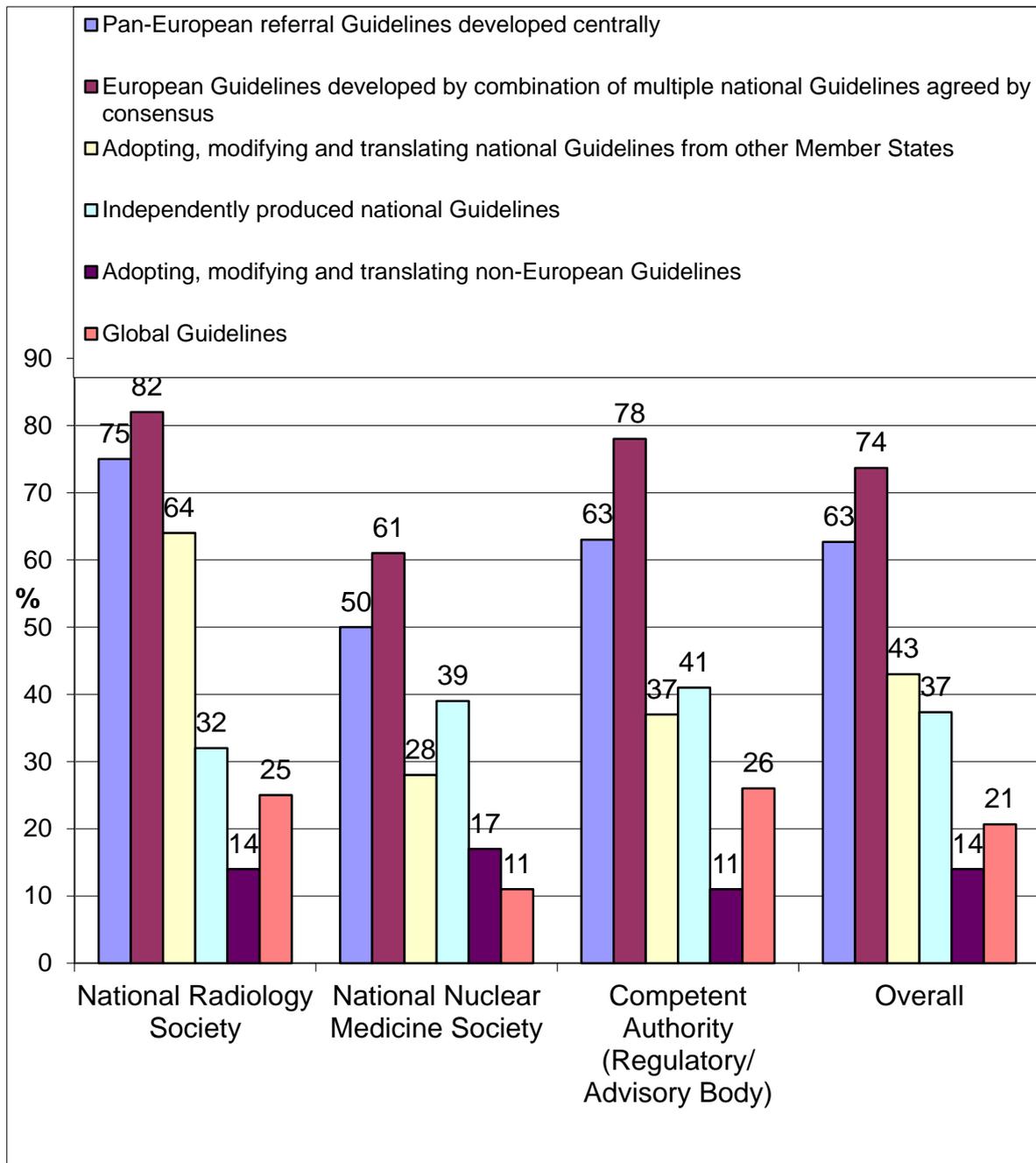
For the remaining items in the survey, respondents were asked to rate agreement on a 7-point balanced Likert scale regarding preferences for European Guideline development, format, media, barriers and their solutions, and methods for monitoring. There were 28 responses from radiology societies, 18 from NM societies and 27 from competent authorities. All responses were taken into account. Positive responses rated 5-7 were taken as agreement and consensus considered strong where there was agreement by at least 75% of respondents.

3.3.2.1 Source of Guidelines

Eighty-two percent 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%).

Seventy-five percent of radiology societies support Pan-European Guidelines developed centrally. (See Fig. 15.)

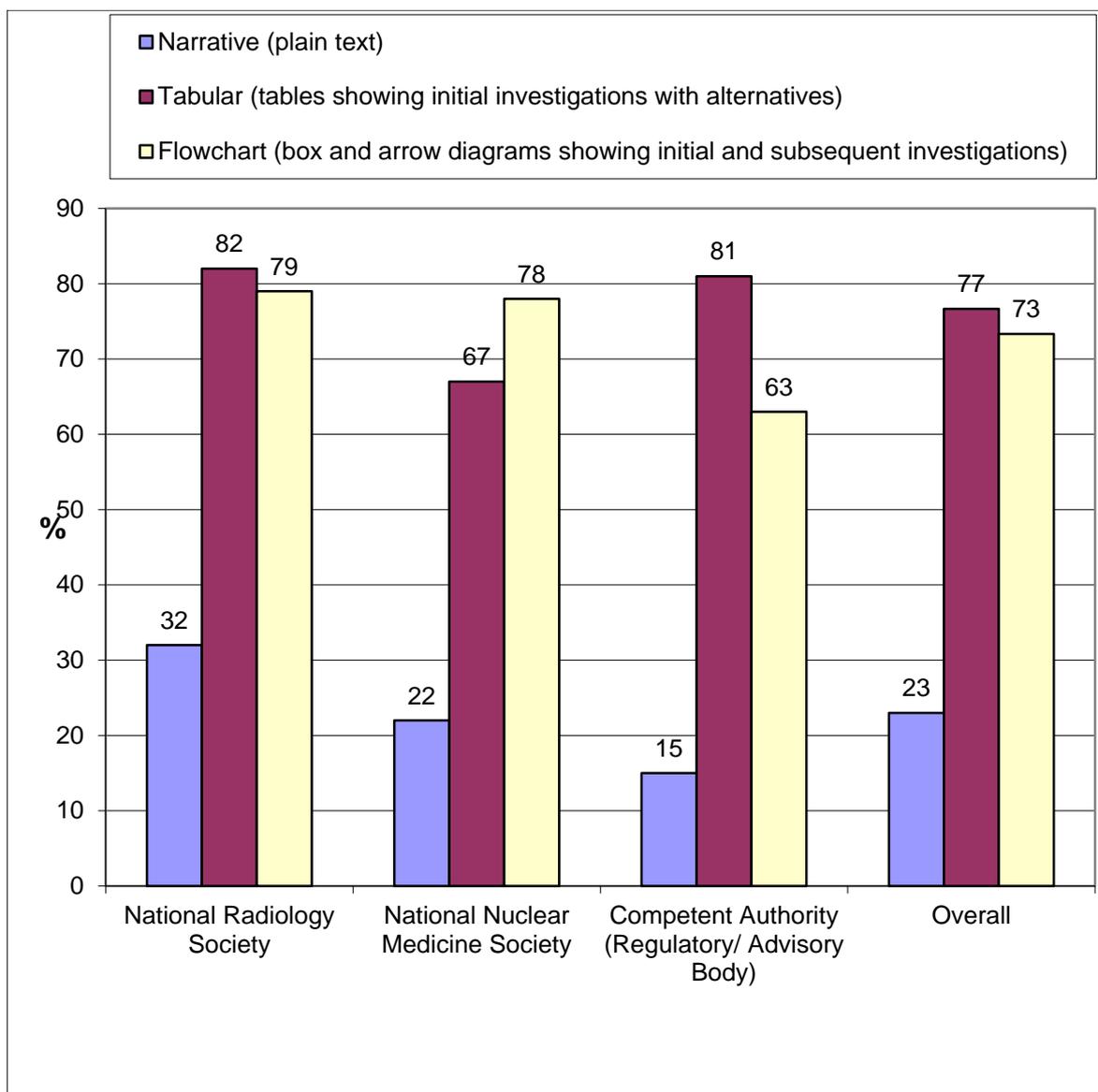
Figure 15: Guidelines Survey: Preferences for the future of imaging referral guidelines in Europe. European Guidelines preferably developed by combination of National Guidelines were favoured with high level agreement (Likert scores 5-7/7) among Radiology Societies and Competent Authorities



3.3.2.2 Guideline format

Most societies and competent authorities support tabular and flowchart format for the Guidelines. (See Fig. 16.)

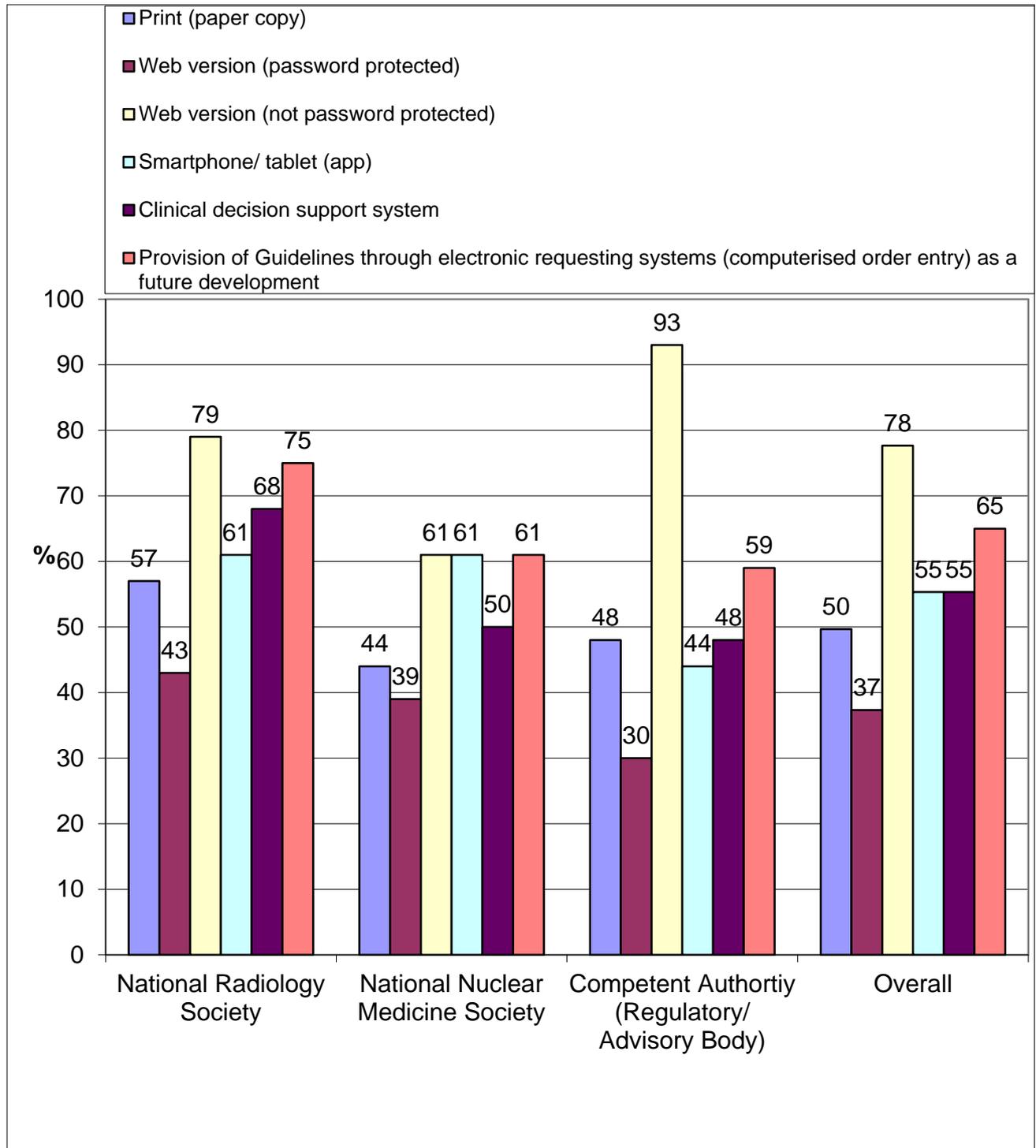
Figure 16: Guidelines Survey: Format. Tabular and flow chart formats are preferred, both reaching a high level of consensus at Likert 5-7/7 scores



3.3.2.3 Media and mode for distribution

Most societies and competent authorities support web version (not password protected) for distribution mode. Seventy five per cent of radiology societies support provision of Guidelines through electronic requesting systems as a future development. (See Fig. 17.)

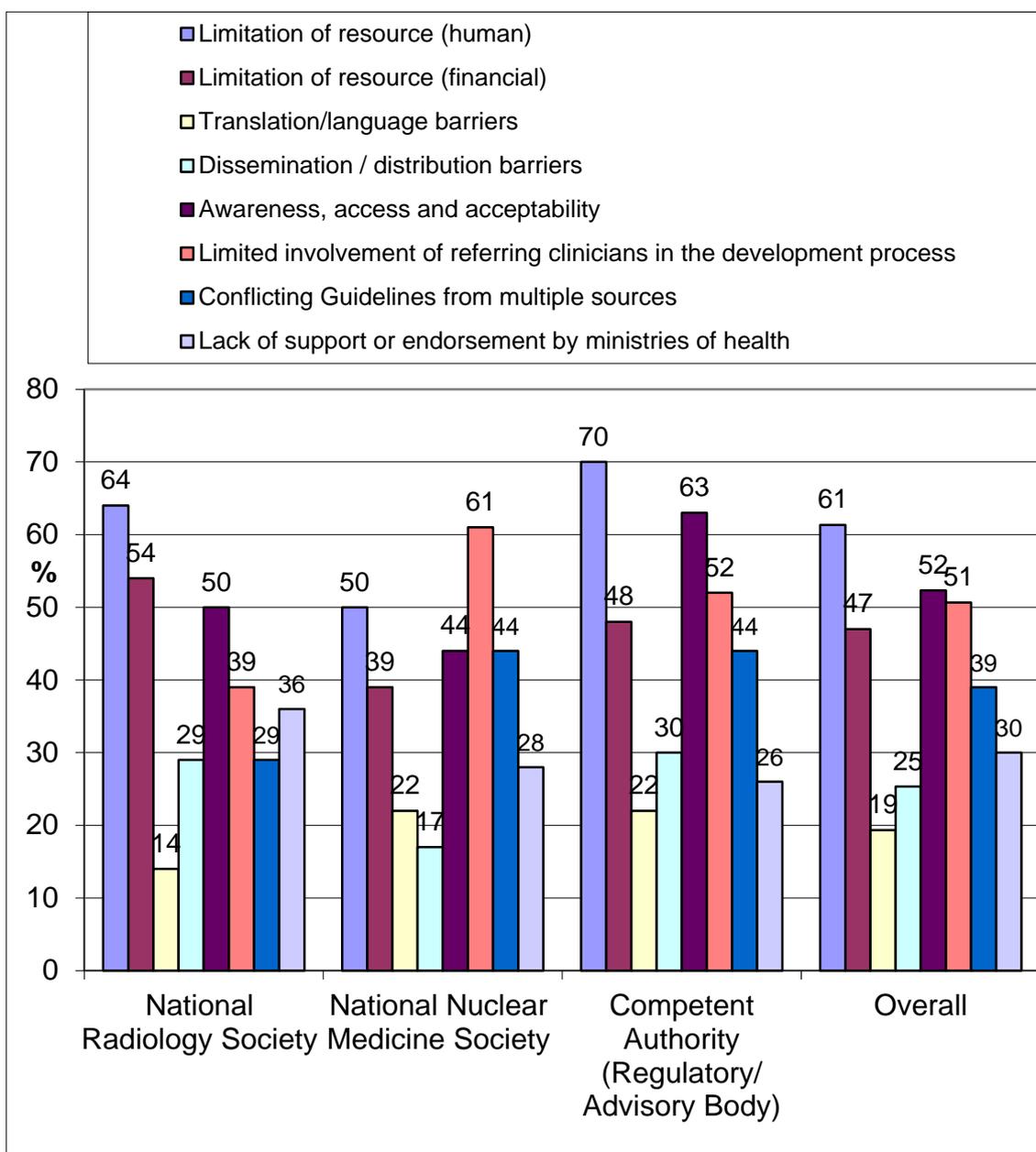
Figure 17: Guidelines Survey: Distribution. Although multiple media are favoured, a web version is the preferred basic medium. Provision of guidance through electronic requesting systems (such as an open architecture decision support system) has good support reaching strong consensus among radiological societies



3.3.2.4 Potential barriers/ challenges to the effective distribution of Guidelines

Resource limitation, limited awareness and limited clinician involvement are common barriers but none reach strong consensus. (See Fig. 18.)

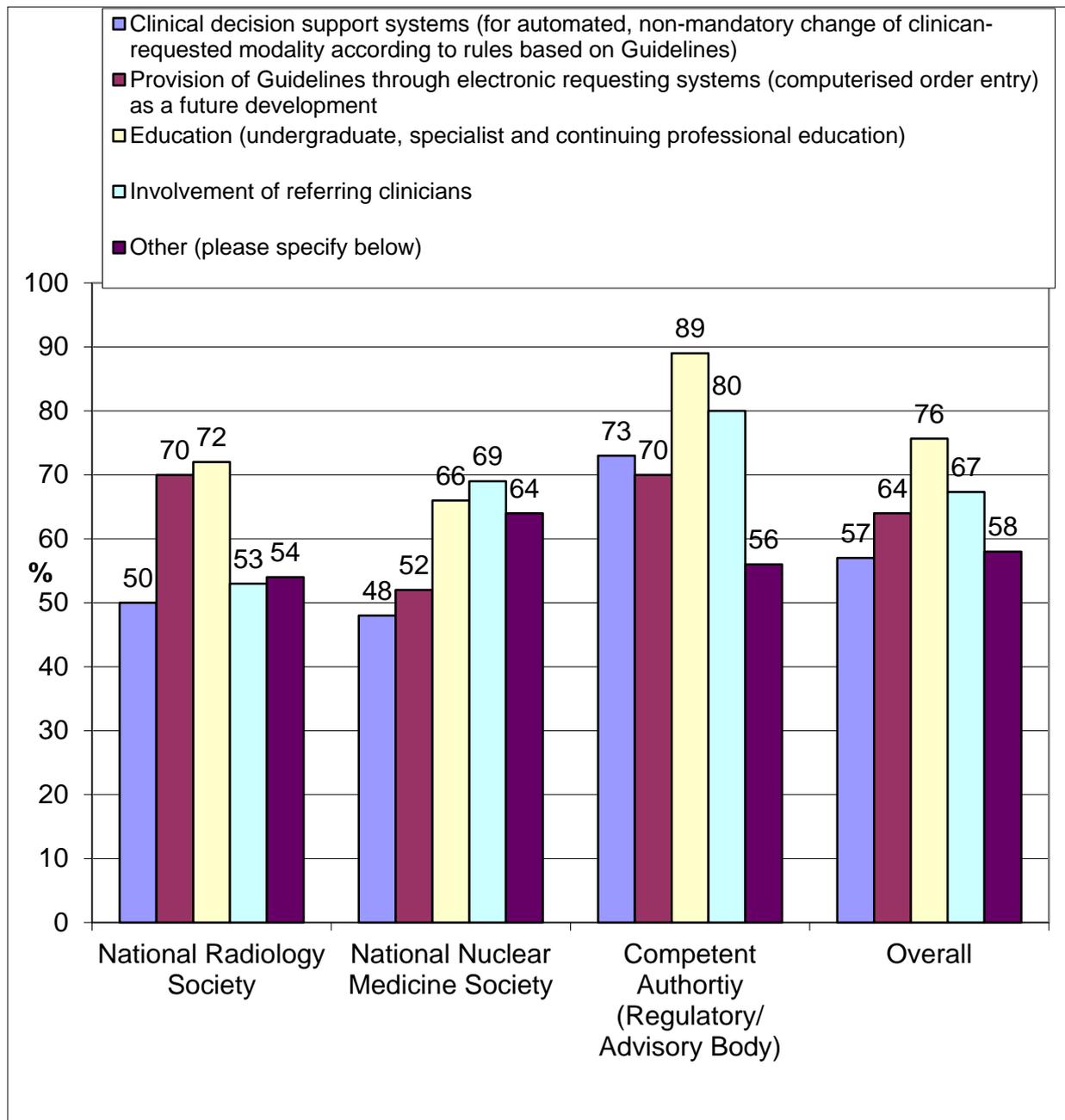
Figure 18: Guidelines Survey: Potential barriers to distribution. Agreement at Likert 5-7/7 for resource limitation, limited awareness and limited clinician involvement are common barriers. Translation and language issues are not perceived by many to be a barrier



3.3.2.5 Suggestions of solutions to barriers limiting the availability of Guideline use

Education and involvement of referring clinicians are mostly proposed by competent authorities to solve barriers limiting the availability of Guidelines. (See Fig. 19.)

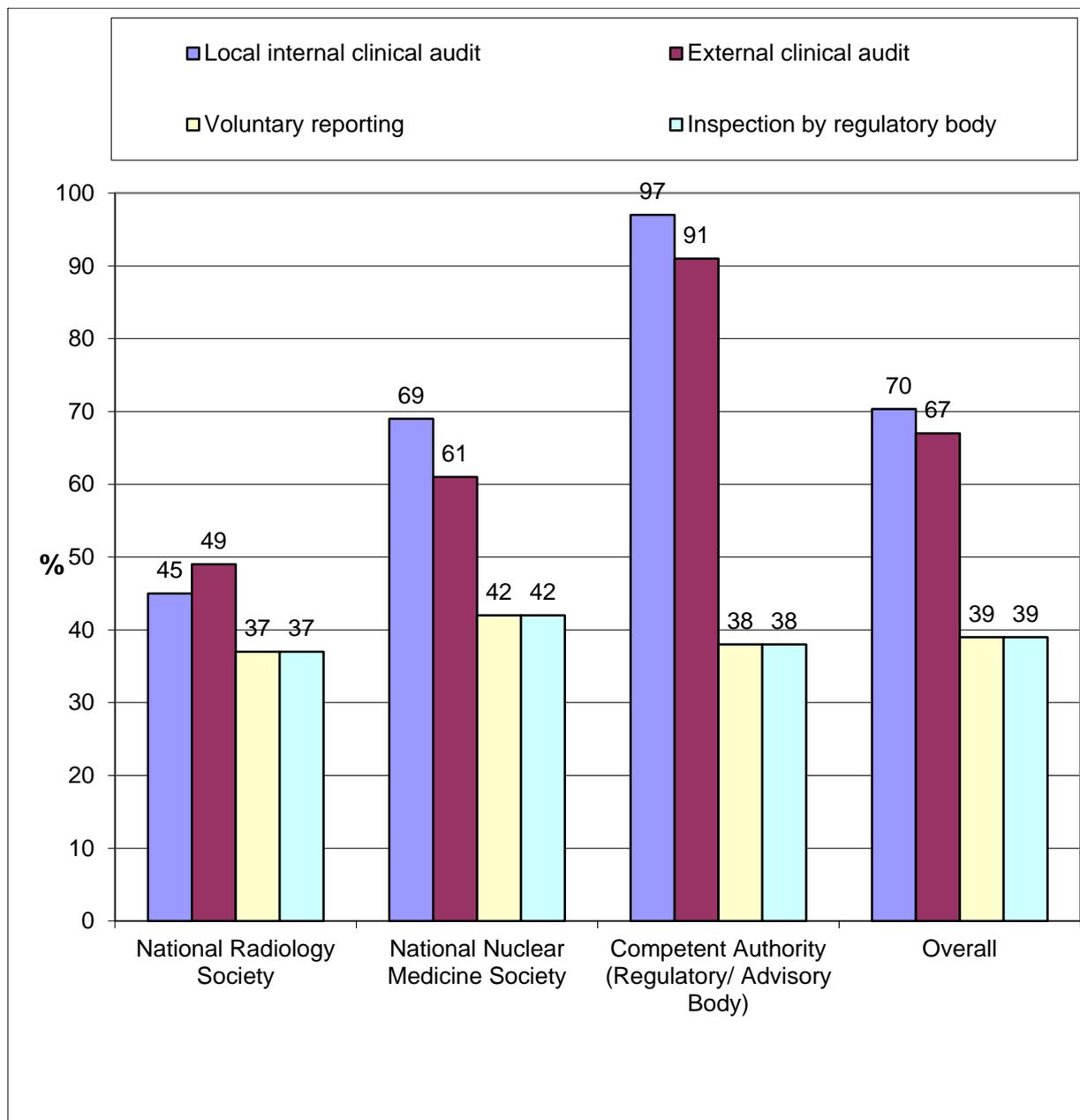
Figure 19: Guidelines Survey: Suggested solutions to barriers. Education is favoured followed by encouragement of clinician involvement and provision of guidelines through electronic requesting systems



3.3.2.6 Preferred methods for monitoring Guideline use

All respondents and particularly competent authorities strongly support local internal and external clinical audits to monitor Guideline use. (See Fig. 20.)

Figure 20: Guidelines Survey: Preferred methods for monitoring. Clinical audit, both internal and external, are favoured, particularly by competent authorities



3.4 Survey conclusions

The following conclusions were made from the Guidelines survey based on responses from radiological societies, nuclear medicine societies and radiological competent authorities:

3.4.1 Availability of Guidelines

- Survey respondents in 21/30 countries were aware of legal requirements for Guidelines, i.e. sixty per cent of respondents indicated that they have a legal requirement for imaging referral guidelines including radiation doses (see Table 2).
- Survey respondents in 18/30 countries were aware of the availability of Guidelines in their country. Twenty-three national radiology societies (77%), twelve national nuclear medicine societies (66%) and fourteen competent authorities (52%) indicated that there are nationally recognised imaging referral guidelines including radiation doses available (see Table 2).
- From responses, 2/3 of countries with a legal requirement for Guidelines have Guidelines available whereas only 1/3 of countries without a legal requirement have Guidelines available.

3.4.2 Guidelines development methodology

- Responses to survey questions concerning Guideline methodology may not be fully representative of the whole EU as only 23 respondents (out of 80 in total) from 17/30 countries replied to this section. The low response rate is in part due to the popular principle of adoption.
- The majority of responders support the development of European Guidelines. These may either be from a combination of multiple national Guidelines with consensus or Pan-European Guidelines developed centrally.
- Not all national Guidelines available are based on clinical presentations. Some nuclear medicine Guidelines are based on indications.
- Good practices were demonstrated in several countries which included some of the important methodological features shown below. Guidelines developed in 2 countries included all of these features:
 - radiation dose information
 - specific advice for imaging children
 - specific advice for the pregnant woman/ unborn child
 - an evidence-based process
 - formal consensus for recommendations.

3.4.3 Suggestions for initiatives for improving the use of Guidelines

- There was an agreement that additional measures were needed to reinforce the use of Guidelines.
- Educational initiatives are highly favoured to improve implementation, followed by involvement of referring clinicians in guidelines development.
- There is strong support for the concept of integrating Guidelines into clinical decision support systems and, as a future development, provision of guidance through existing electronic requesting systems.
- Clinical audit should be used for monitoring of Guidelines' availability, their use and implementation.

4 ORGANISATION OF A EUROPEAN WORKSHOP ON THE DEVELOPMENT OF REFERRAL GUIDELINES FOR RADIOLOGICAL IMAGING IN THE EU MEMBER STATES

4.1 Methods, approach and structure

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. (See Appendix 3 “Workshop Programme”)

Good practices regarding appropriateness and use of referral guidelines from Europe and globally were presented at the workshop. Results were presented from the survey of guidelines in Europe (see section 3). These included ideas, innovations and wishes for future Community action. Over 60 participants followed the call to Vienna with registration of representatives from national radiology societies and regulatory bodies of 30 European countries. Speakers were from Europe, USA, Canada and Australia. In addition, there were presentations by expert advisors from the WHO, IAEA, EANM as well as key stakeholders: representatives from patient groups, radiographer societies and general practitioners.

The programme included 35 talks organised in five sessions: scene setting; stakeholders' specific issues; presentation of the imaging guidelines survey: innovations for improving Guideline use; and a final session where a summary, conclusions and recommendations were agreed. Each session allowed ample time for discussions with enthusiastic participation from the floor.

4.2 Programme

The workshop programme was organised in 5 sessions, each of them addressing 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. International Organisations such as WHO and IAEA presented their expert's perspective as well as invited speakers from Europe, USA, Canada and Australia shared their views on Referral Guidelines from their national perspective.

Session 2 focussed on **Specific Issues** within the field of Imaging Referral Guidelines and stakeholders such as Paediatrics, Interventional Radiology and Nuclear Medicine as well as representatives from Radiographer societies and Patient Groups shared their views with workshop participants.

Session 3 **Survey Feedback** was subject to discuss the most important findings from the survey, conducted under work package 1 of the EC Tender Project Referral Guidelines. A time-slot within this session was scheduled for workshop participants to present their good practices from a national perspective.

Session 4 dealt with **Innovations** and the question on the improvement of Guideline use. Clinical decision support systems, radiology benefit management and the quality and outcomes framework were only few of discussed items.

Session 5 was used to summarise the main findings of the workshop and to present **Conclusions** of the workshop with the support of nominated Rapporteurs.

For further details of the workshop programme, please refer to Appendix 3.

4.3 Summary of findings – key points

The major conclusions and recommendations from the workshop can be summarised as follows:

1. Broad agreement that European imaging referral guidelines are essential and should include specific advice for imaging children. The recommendation is for amalgamation of existing, rigorously-developed national referral guidelines rather than duplicating efforts through developing Guidelines de novo.
2. The results of the survey carried out by the project consortium indicate that imaging referral guidelines are available in two thirds of the EU Member States with legal requirement for Guidelines and that in only one third of those countries who do not have a legal requirement for Guidelines. As the situation in many European countries is rapidly changing, participants agreed that a re-audit should be performed by the project organisers prior to making recommendations for Community action.
3. Agreement that reinforcement for use of imaging referral guidelines is essential. Recommendations are to use educational initiatives and to consider clinical decision support systems.
4. Agreement and recommendation for monitoring through clinical audit, preferably external but also local internal audit.

For further information on the workshop and the workshop conclusions please refer to the full workshop proceedings in Appendix 5.

5 DEVELOPMENT OF CONCLUSIONS OF THE WORKSHOP REGARDING THE NEED FOR NATIONAL AND/OR COMMUNITY ACTION

5.1 Methods, approach, and structure

The Draft Conclusion Document was sent for consultation to 138 organisations.

The final conclusion document is based on:

1. Findings from the survey Europe (see section 3.3).
2. Conclusions from the workshop (see section 4.3 and Appendix 5 “Workshop Proceedings”).
3. Re-audit of the availability of national Guidelines in those countries initially reporting that national Guidelines were not available.
4. Further information from partner organisations and expert advisors.
5. Feedback from consultation.

5.2 Re-audit of the availability of Imaging Referral Guidelines in Europe

Following the workshop where good practices were exchanged, the decision was made to re-audit the availability of Guidelines in those countries previously reporting that Guidelines were not available. It was felt that the encouragement from the workshop and survey together with facilitation of processes for adopting, adapting and translating Guidelines may have had a positive influence on the dynamic situation of Guideline availability with some national projects and initiatives underway. This may have been a reason behind some variance in responses during the initial survey. In order to update the situation, those countries previously reporting no Guideline availability were re-audited with surveys sent out to national professional societies and competent authorities enquiring as to the availability of national legislation and to the availability of Guidelines including work in progress.

This re-audit showed that since the survey in the spring of 2012, a further 7 countries had either begun measures to make Guidelines available or identified existing National Guidelines bringing the number of countries with such Guidelines available, to 25/30. (See Table 3)

Table 3: Combined survey and follow-up responses to the questions of a legal requirement for, and the availability of Guidelines in 30 European Countries. In the follow-up survey only those countries whose representatives who had initially indicated that Guidelines were known to be available were re-audited following the workshop. Some national representatives were then able to identify Guidelines

Country	European Survey Spring 2012 (majority response)	Follow-up survey of countries initially responding "No", (majority response)		Combined survey and follow-up data
	Guidelines Available	Guidelines available OR in preparation	Guidelines in preparation	Guidelines available
Austria	Yes	-	-	Yes
Belgium	Yes	-	-	Yes
Bulgaria	Yes	-	-	Yes
Croatia	No	Yes	Yes	Yes
Cyprus	No	No		No
Czech Repub.	No	Yes		Yes
Denmark	Yes	-	-	Yes
Estonia	No	Yes	Yes	Yes
Finland	Yes	-	-	Yes
France	Yes	-	-	Yes
Germany	Yes	-	-	Yes
Greece	Yes	-	-	Yes
Hungary	Yes	-	-	Yes
Ireland	No	Yes		Yes
Italy	Yes	-	-	Yes
Latvia	Yes	-	-	Yes
Lithuania	No	No		No
Luxembourg	Yes	-	-	Yes
Malta	No	No		No
Netherlands	Yes	-	-	Yes
Norway	No	Yes	Yes	Yes
Poland	Yes	-	-	Yes
Portugal	No	No		No
Romania	Yes	-	-	Yes
Slovakia	Yes	-	-	Yes
Slovenia	No	Yes	Yes	Yes
Spain	Yes	-	-	Yes
Sweden	No	Yes		Yes
Switzerland	No	No		No
UK	Yes	-	-	Yes
Total 30	18 yes	7 yes	4 yes	25 yes

5.3 Stakeholder Consultation

5.3.1 Organisation and process

A contact-list with selected relevant organisations and professional groups was compiled, comprising the most important radiology organisations, competent authorities, patient groups and external stakeholders in Europe. A contact list of all contacted organisations can be found in Appendix 7.

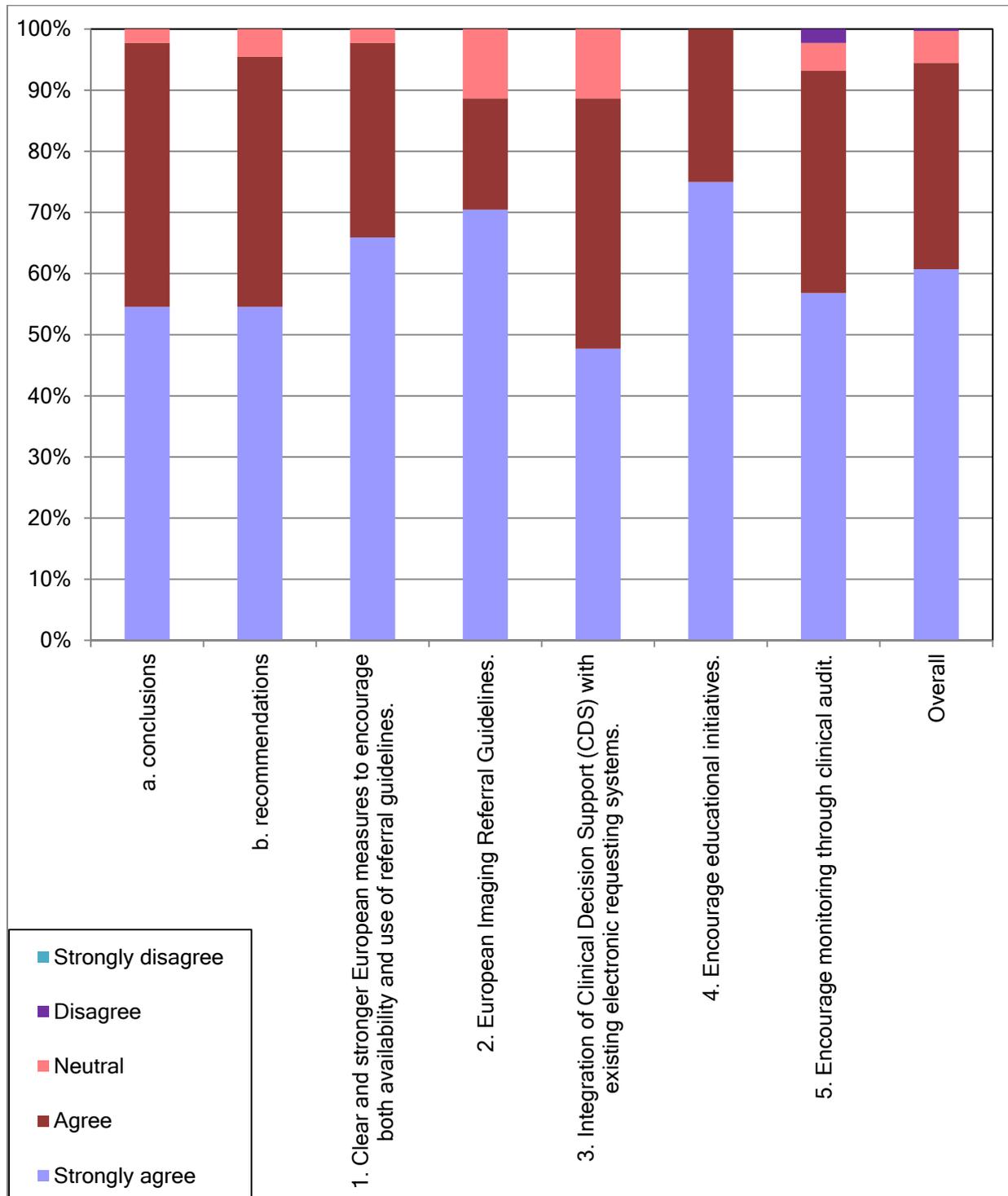
In order to facilitate the collection and analysis of responses and comments on the draft conclusions and recommendations, a web questionnaire was compiled consisting of just 9 questions. A balanced 5-point Likert scale was used to assess consensus of stakeholder organisations with draft conclusions and recommendations (see Appendix 6).

5.3.2 Consultation findings

Draft conclusions and recommendations were made available to 138 organisations and professional bodies (Appendix 7). Representatives of these groups were asked to give structured comments and to indicate their level of agreement with conclusions and recommendations. Responses were collated and analysed giving particular attention to referenced or comments with common themes made by multiple organisations. Comments relevant to the conclusions and recommendations were used to inform amendments following approval by the Steering Committee.

Forty-four of 138 organisations (32%) responded (see Appendix 7). There were 37 comments in general or specific areas, most of which were already addressed in the body of the report (Table 3). A few minor amendments were made but none altering the spirit of the conclusions or recommendations. Regarding levels of agreement, there was virtually unanimous agreement with only 1/301 items in disagreement. The median Likert score for conclusions and all recommendations was 4 or 5/5 (Agree to strongly agree) with strong consensus for all points (see Fig 21). Bodies responding to consultation show the same strong support as stakeholders at the European Workshop, for European imaging referral guidelines and initiatives for their implementation, including clinical decision support.

Figure 21: Stakeholder consultation: Agreement to draft conclusions and recommendations by organisations responding to consultation. Individual recommendations are numbered 1 to 5. Conclusions and recommendations, individually and collectively received high level consensus from respondents



6 CONCLUSIONS AND RECOMMENDATIONS

Conclusions and recommendations for the EC Guidelines Project are based on the Workshop conclusions together with those from the survey of 30 European countries carried out in the spring of 2012, with refinement through the Steering Committee, taking into account information from expert advisors, feedback from stakeholder organisations and further correspondence with national organisations participating in the survey.

6.1 Availability of Guidelines

1. Survey respondents in 21/30 countries were aware of legal requirements for Guidelines. Subsequent to the survey the legal requirement has been confirmed in all EU countries.
2. Survey respondents in 18/30 countries were aware of the availability of Guidelines nationally. In the later stages of the project, respondents in a further 7 European countries have reported availability of referral guidelines mostly through work in progress to make such Guidelines available. This takes the total number countries with Guidelines available or in preparation to 25/30.
3. Respondents from 17 countries gave reference to 24 sets of national Guidelines, several countries having separate guidance for diagnostic radiology and nuclear medicine. Of the 24 sets of Guidelines, 10 were reported to be “nationally developed”, 8 adopted and modified, and 6 adopted without modification.

6.2 Guidelines development methodology

1. In both the Survey and Workshop there was agreement that European imaging referral guidelines (Guidelines) are essential.
2. A single set of European Guidelines is preferred. This was made clear at the European Workshop in Vienna (the Workshop).
3. National Guidelines, either developed de novo through accepted methodology or adopted, adapted and translated are alternatives.
4. Good practices were demonstrated in several countries which included some of the important methodological features shown below. Guidelines developed in 2 countries included all of these features:
 - radiation dose information
 - specific advice for imaging children
 - specific advice for the pregnant woman/ unborn child
 - an evidence-based process
 - formal consensus for recommendations
5. Stakeholders should include patients and their carers in addition to referrers, radiological practitioners, radiographers, regulators and other professionals involved in the process.
6. Responses to survey questions concerning Guideline methodology may not be fully representative of the whole EU as only 23 respondents (out of 80 in total) from 17/30 countries replied to this section.

6.3 Use of Guidelines

1. In both the Survey and Workshop there was agreement that additional measures were needed to reinforce the use of Guidelines.
2. Educational initiatives are in place but further measures would be helpful. Such measures include: radiation protection awareness in undergraduate and post-graduate training curricula; lifelong learning (continuing professional development) for referrers; and also through educational messages in reports with radiation dose.
3. Clinical Decision Support (CDS) systems to facilitate access, use and compliance were highly favoured both in the Survey and at the Workshop. An “add-on” system interfacing with existing radiology information systems and electronic requesting systems was preferred. A CDS system should not replace the role and responsibility of the radiological practitioner with respect to justification.
4. Clinical audit should be used for monitoring of Guidelines’ availability, their use and implementation. Although recommendations from such audits are not binding, they enable considerable quality improvement. Both external audit and local internal audit are needed.

6.4 Recommendations

1. Clearer and stronger European measures to encourage both availability and use of referral guidelines. Such measures should be made centrally or through European competent authorities.
2. European Guidelines. These may be produced initially by a combination of existing national Guidelines, developed using accepted methodology, under the auspices of a European professional organisation. European Guidelines must contain dose information and must include separate advice for children, and the pregnant woman/ unborn child.
3. Development and integration of Clinical Decision Support (CDS). This should interface with existing electronic requesting systems (computerised physician order entry systems) and radiology information systems.
4. Encourage educational initiatives. Such initiatives should complement European Medical ALARA Network (EMAN) [2] and Medical Radiation Protection in Education and Training (MEDRAPET) [3]. Referrers, radiologists and radiographers will benefit. Initiatives such as life-long-learning should be encouraged.
5. Both external audit and local internal audit are needed for monitoring. External audit has been addressed in EC guidelines on clinical audit [4], but further measures to promote local internal audit are needed.

7 REFERENCES AND ACKNOWLEDGEMENTS

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8 APPENDICES (only available on the website)

APPENDICES (AVAILABLE ONLY IN ELECTRONIC FORMAT FROM http://ec.europa.eu/energy/nuclear/radiation_protection/radiation_protection_en.htm)

APPENDIX 1	SURVEY QUESTIONNAIRE AND FAQ
APPENDIX 2	NATIONAL GUIDELINES
APPENDIX 3	WORKSHOP PROGRAMME
APPENDIX 4	WORKSHOP REGISTRANTS
APPENDIX 5	WORKSHOP PROCEEDINGS
APPENDIX 6	CONSULTATION: QUESTIONNAIRE
APPENDIX 7	CONSULTATION: INVITED ORGANISATIONS
APPENDIX 8	CONSULTATION: COMMENTS & ACTION POINTS
APPENDIX 9	ABBREVIATIONS

