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Abstract. The purpose of this work was to assess the: (a) impact of regulations on radiation safety and development of radiation safety culture, (b) perceived safety level in the participating facilities, (c) future needs regarding strengthening of regulations, patient dose consideration, and exposure tracking, in different countries around the world. Appropriate questionnaires probing the above-mentioned themes were sent to radiologic professionals working in healthcare facilities. A total of 257 responses from 25 countries were received and analyzed. Average scores for the three different sections/themes of the questionnaire ranged from 64.6% to 74.9%. Higher scores indicated stronger agreement of the survey participants with the theme in question. Statistical comparisons among different professional groups revealed that professionals in developing countries perceived regulations to be significantly more important for improving safety than their counterparts in developed countries did. Radiologic professionals believe that regulation enhances radiation safety and the development of safety culture. However, there is still room for improvement regarding the implementation of regulatory tools. Safety levels were perceived to be satisfactory, and future needs point toward strengthening of regulations regarding patient dose control, patient dose consideration, and patient exposure tracking. The results of this study should be interpreted keeping possible selection bias in view. © 2017 Society of Photo-Optical Instrumentation Engineers (SPIE) [DOI: 10.1117/1.JMI.4.3.031204]

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1 Introduction

Healthcare is a sector that strives for the improvement of human health and life in a broader sense. However, healthcare-related efforts are not necessarily risk-free. In fact, they often involve decision-making based on cost/risk-benefit analysis. In this view, ionizing radiation used in diagnostic and therapeutic procedures bears the risk of cancer induction to exposed patients and, to a small extent, to involved staff if radiation protection measures are not implemented and observed. Traditionally, maximizing the benefit to the patient while keeping radiation risks reasonably low has been achieved through the promotion of a system of radiation protection based on the pillars of justification, optimization, and application of dose reference levels. Recently, the importance of establishing radiation protection culture in radiology departments is being recognized.¹ The International Atomic Energy Agency (IAEA) has dedicated a lot of effort toward controlling radiation risks by launching multinational projects covering many countries of the world. Projects include, among others, training, assessment of the radiation safety situation in each country or region as well as dissemination of information and provision of support to improve the existing situations.^{2–10} Another method that has been utilized is providing support through publication of guidance and safety reports. One would suppose that, since regulations and guidance documents have been published for so long, their contribution to

enhancing radiation safety would be undisputed and by now it would have been quantitatively known how much radiation protection has benefited due to regulations. The National Academies Press published its report entitled “To Err is Human: Building a Safer Health System” in 2000.¹¹ This report discusses the fact that the complexity of contemporary healthcare systems increases the “opportunities” for human errors and in order to mitigate this situation, efforts should be made to “design safety in the processes of care”. However, it is still unexplored whether regulations have enhanced the development of a radiation safety culture in the clinical environment.

The purpose of this study was to: (a) probe the opinion of the professionals directly involved on whether regulation has brought about any changes to the radiation safety level and development of safety culture, (b) assess the level of radiation safety itself by asking about the facts in facilities indicating the level of safety, and (c) assess the future needs on further regulatory actions for patient dose control, increased consideration for patient dose, and the need to track patient exposures.

2 Materials and Methods

2.1 Survey Participants and Administration of Survey

A questionnaire was distributed to available contact points in 37 countries in Africa, Asia, and Europe. Contact points were mainly IAEA counterparts in developing countries while personal

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contacts were mobilized in the case of developed countries where counterparts did not exist. There is a reason that the IAEA has mainly contacts in developing countries. The IAEA supports the United Nations sustainable development goals. In view of this, IAEA activities aim to build capacity, primarily in developing member states where capacity is limited or nonexistent. As a result, most of IAEA's projects and activities are conducted in developing countries, using expertise derived from developed countries. For this reason, the IAEA has collaborators and contact points for its projects in developing countries. All contacts were asked to distribute the questionnaire to radiologic professionals in their countries. The radiologic professionals who participated in the study were mainly physicians, radiation technologists, and medical physicists working in diagnostic radiology, nuclear medicine, and radiotherapy departments. A few of the professionals were specialized in other areas related to the previously mentioned main specialties. Those professionals were mainly radiologic nurses and clinical scientists/researchers and were all pooled in the "other" category of professionals.

2.2 Survey Contents

The questionnaire included 19 multiple choice questions offering 3 to 5 possible answers. Some of the questions allowed the participants to select more than one answer. The questions were pooled into three groups designed so as to evaluate: (a) the opinion of radiologic professionals about the impact of regulations on safety and on the development of safety culture, (b) the safety level in the facilities, and (c) the future needs, including further regulatory actions for patient dose control and enhancement of patient dose consideration and dose monitoring. The question groups (a), (b), and (c) included 8, 7, and 4 questions, respectively. The questions along with the possible answers are shown in Table 1. Demographic data regarding the participants' country of residence, their profession (physician, radiographer, medical physicist, other), and area of work (diagnostic radiology, radiotherapy, nuclear medicine) were also collected. Optional information regarding the institution and name of the participants were also provided.

2.3 Analysis of Questionnaires

The received responses were analyzed using spreadsheets. A grading system was used to evaluate the answers received. The third column of Table 1 shows the points corresponding to each answer. The grading of possible answers was set according to the agreement of responses with the theme where they belonged. The individual possible answers were given scores ranging from 0 to 1. Higher total scores in each section of the questionnaire indicated that the participant returned answers that: (a) agreed more with the notions that the impact of regulations was positive with regard to enhancing radiation safety in medicine and the development of safety culture, (b) indicated higher safety levels, and (c) pointed to future needs commensurate with the strengthening of regulations regarding patient dose control and also strengthening patient dose consideration and exposure tracking in clinical settings. The maximum achievable score per question was 1 while for the groups of questions was 8, 7, and 4 for groups (a), (b), and (c), respectively. The minimum achievable score was zero for individual questions as well as for groups of questions.

2.4 Statistical Analysis

The statistical package GraphPad Prism (GraphPad Software, San Diego California) was used for the statistical calculations to estimate possible differences in the answers received by the various groups of respondents by specialty, development status of country of residence, and area of expertise, i.e., diagnostic radiology, nuclear medicine, and radiotherapy. In order for the statistical analysis to be meaningful, comparisons of mean scores per question group (section/theme of the questionnaire) for the different professional groups were performed. Two tailed Student *t*-test or two tailed Mann–Whitney nonparametric test was used depending on whether the distribution of data was normal (Gaussian) or not. The normality of data was assessed utilizing the D'Agostino and Pearson omnibus normality test. Statistical analysis was performed for all cases where the number of responses was more than 20 to ensure the power of the normality and nonparametric tests is adequate to yield meaningful *P* values.

3 Results

A total of 257 responses was received from the following 25 countries arranged alphabetically. Numbers in parentheses show the number of responses received from each country: Afghanistan (1), Albania (1), Algeria (6), Armenia (1), Bosnia and Herzegovina (5), Peoples Republic of China (PRC) (2), Cote D'Ivoire (1), Croatia (7), Cyprus (9), Czech Republic (14), Estonia (1), Gabon (2), Jordan (3), Kyrgyz Republic (1), The Former Yugoslav Republic of Macedonia (3), Malaysia (10), Malta (10), Niger (1), Philippines (2), Poland (46), Romania (80), Slovakia (1), Slovenia (9), United Arab Emirates (40), and Zimbabwe (1). A total of 44 responses (17.1%) was received from developed countries, namely Cyprus, Czech Republic, Estonia, Malta, Slovakia, and Slovenia, and the remaining 213 (82.9%) were received from developing countries. The classification of developed and developing countries at the time of the survey agreed with the classification followed by the International Monetary Fund.¹² Out of the 257 respondents, 57 (22.2%) were physicians, 91 (35.4%) were radiologic technologists, 89 (34.6%) were medical physicists, and 20 (7.8%) were professions of other related specialties. Regarding the participants' area of work in medicine, 190 (73.9%) worked in diagnostic radiology, 39 (15.2%) worked in radiotherapy, and 28 (10.9%) worked in nuclear medicine. The last column of Table 1 presents the answers of participants to each question. The number of respondents who selected each answer as well as respective percentages is shown. Note that in case of questions allowing multiple answers, the sum of single answers selected for a question could be larger than the number of participants answering that question. In the questions requiring only single answers, the number could be less than the total number of participants because some participants did not answer all the questions. The number of participants who provided no answers to each question is also given in Table 1 in angle brackets after each question. The percentages were calculated as a fraction of the total number of responses to each question.

3.1 Impact of Regulations

The vast majority of responses (>90%) to the first two questions of this section stated that the methodology of certification and licensing of facilities as well as the qualification and experience requirements for staff have contributed to enhancing safety or

Table 1 Questions addressed to radiologic professionals to probe their opinion about the impact of regulations on radiation safety in medicine, the assessed level of safety and future needs regarding strengthening of regulations, and enhancement of patient dose consideration and patient exposure tracking. Values in parentheses represent the percentage of each answer as a fraction of the total answers for each question. The numbers in angle brackets equal the number of participants who provided no answer to each question.

(a) Impact of regulations				
	Question	Possible answers	Score	Answers received
1	Do you think the methodology of certifying or licensing a radiation facility in medical practice (multiple answers allowed) (1)	(a) Has contributed to enhancing safety	(a) 0.5	(a) 210 (53.6)
		(b) Has contributed to development of safety culture	(b) 0.5	(b) 158 (40.3)
		(c) Is unimportant from the stand point of radiation safety	(c) 0	(c) 20 (5.1)
		(d) I do not know	(d) 0	(d) 4 (1.0)
2	The requirements that the staff working in radiological facilities should meet necessary qualifications and experience is important because (multiple answers allowed) (0)	(a) It assures safety	(a) 0.5	(a) 212 (52.2)
		(b) It helps develop manpower with safety skills	(b) 0.5	(b) 192 (47.3)
		(c) Is not really important	(c) 0	(c) 1 (0.2)
		(d) I do not know	(d) 0	(d) 1 (0.2)
3	Assigning responsibility for radiation safety in regulations on the head of the organization (multiple answers allowed) (0)	(a) Helps in implementing radiation safety in hospital	(a) 0.5	(a) 178 (42.8)
		(b) Contributes to safety consciousness at management level	(b) 0.5	(b) 175 (42.1)
		(c) Exists on paper without the person knowing his/her responsibilities	(c) 0	(c) 50 (12.0)
		(d) Does not contribute to safety culture at operator level	(d) 0	(d) 10 (2.4)
		(e) I do not know	(e) 0	(e) 3 (0.7)
4	Requirements that the facility should appoint or have access to medical physicist/radiation safety expert (multiple answers allowed) (1)	(a) Are useful and have contributed to improved levels of radiation safety	(a) 0.75	(a) 217 (77.8)
		(b) Are implemented on paper but the expert is not really involved in practice	(b) 0.25	(b) 37 (13.2)
		(c) Are not implemented	(c) 0	(c) 12 (4.3)
		(d) Do not really contribute to radiation safety	(d) 0	(d) 5 (1.8)
		(e) I do not know	(e) 0	(e) 8 (2.9)
5	Did regulation motivate you or your department to estimate patient doses and compare them with reference/guidance levels? (0)	(a) Yes, otherwise it would not have received the attention that it did	(a) 1	(a) 104 (40.5)
		(b) Yes, but it did not change our practice	(b) 0.5	(b) 56 (21.8)
		(c) We would do it regardless of regulations	(c) 0	(c) 71 (27.6)
		(d) No	(d) 0	(d) 17 (6.6)
		(e) I do not know	(e) 0	(e) 9 (3.5)
6	How do requirements to perform regular QC tests on radiological equipment affect your practice? (1)	(a) Yes, otherwise it would not have received the attention that it did	(a) 1	(a) 126 (49.2)
		(b) Yes, but it did not change our practice	(b) 0.5	(b) 48 (18.8)
		(c) We would do it regardless of regulations	(c) 0	(c) 65 (25.4)
		(d) No	(d) 0	(d) 7 (2.7)
		(e) I do not know	(e) 0	(e) 10 (3.9)

Table 1 (Continued).

7	Regulatory requirement to optimize patient doses (4)	(a) Helps in obtaining resources from the management	(a) 1	(a) 134 (53.0)
		(b) Has no influence on our practice as we will do it regardless of regulations	(b) 0	(b) 107 (42.3)
		(c) Increases the unnecessary work	(c) 0	(c) 6 (2.4)
		(d) I am not aware of such requirement	(d) 0	(d) 6 (2.4)
8	Requirement to keep records of patient doses or exposure parameters (0)	(a) Is very useful to improve patient protection	(a) 1	(a) 169 (65.8)
		(b) Is good but not yet implemented in our facility	(b) 0.25	(b) 35 (13.6)
		(c) Has no influence on our practice as we will do it regardless of regulations	(c) 0	(c) 32 (12.5)
		(d) Increases the amount of record-keeping with no clear benefit	(d) 0	(d) 17 (6.6)
		(e) I am not aware of such a requirement	(e) 0	(e) 4 (1.6)
(b) Assessment of safety level				
	Question	Possible answers	Score	
1	How often QC checks are performed? (2)	(a) Regularly	(a) 1	(a) 197 (77.3)
		(b) Occasionally	(b) 0.5	(b) 30 (11.8)
		(c) When there are problems	(c) 0.25	(c) 11 (4.3)
		(d) We do not	(d) 0	(d) 5 (2.0)
		(e) I do not know	(e) 0	(e) 12 (4.7)
2	Is patient exposure in your institution compared with diagnostic reference levels or with exposure in other institutions? (5)	(a) Yes, we evaluate them regularly	(a) 1	(a) 86 (34.1)
		(b) Yes, irregularly	(b) 0.5	(b) 76 (30.2)
		(c) No	(c) 0	(c) 60 (23.8)
		(d) I do not know	(d) 0	(d) 30 (11.9)
3	How justification of a radiological procedure is performed? (multiple answers allowed) (11)	(a) By the radiologist getting back to the clinician and discussing the case	(a) 0.5	(a) 131 (38.9)
		(b) By the radiologist deciding on which examination is more appropriate than the examination requested by clinician	(b) 0.5	(b) 99 (29.4)
		(c) By always following clinician's request	(c) 0	(c) 97 (28.8)
		(d) I do not know	(d) 0	(d) 10 (3.0)
4	How often reject analysis and bad quality images are assessed? (12)	(a) One week every month	(a) 1	(a) 80 (32.7)
		(b) One week in 6 months/in a year (choose)	(b) 0.5	(b) 46 (18.8)
		(c) No record of assessment is kept	(c) 0	(c) 79 (32.2)
		(d) I do not know	(d) 0	(d) 40 (16.3)
5	Is information on the number of radiological procedures a patient has undergone readily available in your facility? (6)	(a) Yes, it is very easy to dig out from records	(a) 1	(a) 144 (57.4)
		(b) It is not easily possible	(b) 0.5	(b) 82 (32.7)
		(c) It is not possible	(c) 0	(c) 10 (4.0)
		(d) I do not know	(d) 0	(d) 15 (6.0)

Table 1 (Continued).

6	Is a medical physicist/radiation protection expert involved in your practice? (2)	(a) Yes, is involved on regular basis	(a) 1	(a) 158 (62.0)
		(b) Yes, is available on request	(b) 0.5	(b) 69 (27.1)
		(c) On paper but not in practice	(c) 0.25	(c) 13 (5.1)
		(d) No	(d) 0	(d) 14 (5.5)
		(e) I do not know	(e) 0	(e) 1 (0.4)
7	Do you use personal dosimeter? If yes, do you keep track of your personal doses? (0)	(a) I am checking my doses regularly	(a) 1	(a) 210 (81.7)
		(b) I check my doses occasionally	(b) 0.75	(b) 21 (8.2)
		(c) I use the dosimeter but do not know where to check the report of the badge	(c) 0.5	(c) 13 (5.1)
		(d) I do regularly get a dosimeter but do not use it regularly	(d) 0.1	(d) 3 (1.2)
		(e) I am not issued a personal dosimeter	(e) 0	(e) 10 (3.9)
(c) Future needs				
	Question	Possible answers	Score	
1	Do you think that regulatory requirements for evaluation of patient doses in diagnostic and interventional procedures should be more strictly enforced? (2)	(a) Yes	(a) 1	(a) 126 (49.4)
		(b) Yes, particularly in CT, interventional procedures and pediatric and pregnant patients	(b) 0.5	(b) 94 (36.9)
		(c) No, the current level of enforcement is adequate	(c) 0	(c) 35 (13.7)
2	Do you think that more consideration should be given to patient doses when purchasing new equipment? (3)	(a) Yes	(a) 1	(a) 163 (64.2)
		(b) Yes, particularly in CT, interventional procedures and pediatric and pregnant patients	(b) 0.5	(b) 72 (28.3)
		(c) No, the current level of enforcement is adequate	(c) 0	(c) 19 (7.5)
3	Do you think that regulatory requirements to have written protocols for radiological procedures should be more strictly enforced? (8)	(a) Yes	(a) 1	(a) 158 (63.5)
		(b) Yes, particularly in CT, interventional procedures and pediatric and pregnant patients	(b) 0.5	(b) 60 (24.1)
		(c) No, it would just increase unnecessary paperwork with no clear benefit	(c) 0	(c) 31 (12.4)
4	Do you think a system for quickly obtaining information about the number of radiological procedures a patient has undergone should be established? (7)	(a) Yes	(a) 1	(a) 187 (74.8)
		(b) Yes, particularly for CT, interventional procedures and pediatric patients	(b) 0.5	(b) 46 (18.4)
		(c) No, it would just increase the amount of recordkeeping with no clear benefit	(c) 0	(c) 17 (6.8)

contributed to the development of safety culture. Over 80% of the respondents stated that assigning responsibility for radiation safety to the heads of organizations helps in implementing radiation safety or contributes to safety consciousness at the management level. However, 12.0% stated that such regulations exist only on paper but people do not really know their responsibilities. Meanwhile, 77.8% of respondents agreed with the notion that regulations requiring appointment of, or access to, medical physicists/radiation safety experts have been useful

and have contributed to improved levels of radiation safety in clinical environments. A combined 17.5% stated that the above requirements exist and are not implemented or just are not implemented. Additionally, 40.5% thought that regulations motivated them or their department to estimate patient doses and compare them with reference levels otherwise such actions might not have received such attention. A considerable 21.8% said that they were motivated by regulations but their practices did not change. A total of 27.6% stated that they

compare their dose with reference levels regardless of regulations. Similar responses were received for the next question as well (question no. 6). It was found that 49.2% believed that regulation requirements to perform quality control (QC) tests regularly affected their practice, while 18.8% and 25.4% stated that regulations did not change their practices and that they would do it either way, respectively. More than half (53.0%) of the total respondents stated that the regulatory requirements for optimization of patient dose help them obtain resources from management. For the same question, 42.3% answered that regulatory requirements had no influence on

Table 2 Average scores achieved on the three sections of the questionnaire for the groups of participants in this study. The numbers in brackets represent the score as a percentage of the maximum achievable score for the corresponding section of the questionnaire.

Group of respondents	(a) Impact of regulations	(b) Assessment of safety level	(c) Future needs
All respondents	5.170 (64.6)	4.553 (65.0)	2.994 (74.9)
Diagnostic radiology workers	5.078 (63.5)	4.492 (64.2)	3.018 (75.5)
Nuclear medicine workers	5.259 (65.7)	4.968 (71.0)	3.107 (77.7)
Radiotherapy workers	5.558 (69.5)	4.551 (65.0)	2.795 (69.9)
Developed countries	4.636 (58.0)	4.713 (67.3)	2.841 (71.0)
Developing countries	5.281 (66.0)	4.517 (64.5)	3.026 (75.7)
Physicians	5.026 (62.8)	4.543 (64.9)	2.939 (73.5)
Technologists	4.956 (62.0)	4.490 (64.1)	3.082 (77.1)
Medical physicists	5.455 (68.2)	4.691 (67.0)	2.949 (73.7)
Other	5.288 (66.1)	4.225 (60.4)	2.950 (73.8)

their practice as they would do it themselves either way. Another 2.4% answered that the requirement to optimize patient doses increased unnecessary work. The requirement to keep records on patient dose or exposure parameters was deemed very useful by 65.8% of respondents to improve patient protection, while 13.6% answered that it is good but not yet implemented in their facility. An additional 12.5% answered that they record patient doses regardless of regulations. A combined 8.2% found this requirement not clearly beneficial or were not aware of such a requirement. The average score for this section of the questionnaire amounted to 5.170 (64.6% of the maximum score of 8 points in this section). Scores for the different groups of respondents ranged from 58.0% to 69.5% of the maximum score for this section of the questionnaire. Table 2 shows the average scores in each section for each group of participants. The score achieved by professionals in developing countries was significantly higher than the score achieved by their counterparts in developed countries ($P = 0.0266$). Table 3 shows the probability values for the comparisons of various average scores among groups of respondents.

3.2 Assessment of Safety Level

According to the responses to the first question of this section, 77.3% stated that QC checks were performed regularly while 11.8% stated that they were carried out only occasionally. For the second question, a combined 64.3% stated that patient exposure in their institution is compared with diagnostic reference levels (DRLs) or with exposure in other institutions and that it is evaluated regularly (34.1%) or at least irregularly (30.2%). Regarding justification of radiological procedures, 28.8% of respondents stated that the clinician's request is always followed. About the same percentage (29.4%) stated that the radiologist decides which examination is appropriate. A considerable 38.9% stated that the radiologist discusses the case with the clinician in the decision-making process. A total of 51.5% answered that reject analysis is performed and bad images are assessed with some regularity (one week in a month/6 months/one year), whereas the rest answered that no

Table 3 Probability values (P) for comparison of the average scores achieved by different groups of participants. $P < 0.05$ (bold fonts) implies that the compared average scores are significantly different.

Categories under comparison			Impact of regulations	Assessment of safety level	Future needs
Diagnostic radiology workers	versus	Nuclear medicine workers	0.7332	0.0596	0.6231
Nuclear medicine workers	versus	Radiotherapy workers	0.5357	0.1579	0.2511
Radiotherapy workers	versus	Diagnostic radiology workers	0.1618	0.8093	0.2762
Developed countries	versus	Developing countries	0.0266	0.3985	0.1046
Physicians	versus	Technologists	0.6554	0.8267	0.2877
Physicians	versus	Medical physicists	0.1352	0.5781	0.9331
Physicians	versus	Other	0.5643	0.4092	0.9663
Technologists	versus	Medical physicists	0.0524	0.1912	0.2436
Technologists	versus	Other	0.4603	0.4040	0.6523
Medical physicists	versus	Other	0.6674	0.0609	0.8417

such record was kept or that they did not know. A little more than half (57.4%) of the respondents stated that information on the number of previous radiological procedures for patients was readily available, whereas 32.4% stated that it is not easily possible to retrieve such data. It was encouraging that a combined 89.1% of respondents stated that they have regular (62.0%) or on-request (27.1%) access to medical physics/radiation protection experts, and that a majority of them used a personal dosimeter and checked their personal dose regularly (81.7%) or at least occasionally (8.2%). The data give a feel of the safety level in the different areas of work (diagnostic radiology, nuclear medicine, radiation therapy), and in developed and developing countries. The average score for this section of the questionnaire was 4.553, which is 65.0% of the maximum score of 7 points for the section. Scores for various groups ranged from 4.492 to 4.968 (64.2% to 71.0% of maximum). The differences in achieved average scores among groups of respondents were not significant ($P > 0.05$) at the predefined significance level, as shown in Table 3.

3.3 Future Needs

The combined percentage of respondents agreeing that the regulatory requirements should be more strictly enforced were 86.3% and 87.6% for questions 1, addressing evaluation of patient doses in diagnostic and interventional procedures, and 3, addressing regulatory requirements for the existence of written protocols for radiological procedures, respectively. 49.4% and 63.5% for questions 1 and 3, respectively, were of opinion that they should be more strictly enforced in general, whereas 36.9% and 24.1%, respectively, thought that the above requirements should be more strictly enforced particularly for high-dose procedures such as CT or high-dose interventional procedures and for pediatric and pregnant patients. A combined 92.5% of participants thought that patient dose should be a consideration when purchasing new equipment, with 64.2% agreeing in general and 28.3% particularly for equipment used in CT and interventional procedures as well as on pregnant and pediatric patients. The establishment of a system providing information about the number of previous procedures a patient has undergone (exposure tracking) was considered useful by a combined 93.2% of respondents including those who stated that it would be needed especially for CT, interventional procedures, and pediatric and pregnant patients (18.4%). The average score for all respondents in this section was 2.994 (74.9% of maximum score of 4 for this section). Scores for groups of respondents ranged from 2.841 to 3.107 (71.0% to 77.7% of maximum). No significant differences were observed among the average scores achieved by different groups of respondents.

4 Discussion

The management system in accordance with IAEA has to also ensure the promotion of safety culture. In the revised Basic Safety Standards, the principal parties (registrants and licensees, employers, radiological and medical practitioners, persons or organizations designated to deal with emergency or existing exposure situations) are encouraged to promote and maintain a safety culture through various actions. Such actions include, among others, promotion of collective commitment to protection and safety at all levels, ensuring accountability of organizations and individuals for protection and safety, and encouraging participation of workers and their representatives in the development and implementation of policies.¹³

This multinational study in 25 countries in Africa, Asia, and Europe explored the impact of regulations on safety and the development of safety culture in the clinical environment. It also explored the future needs from a regulatory point of view, as well as whether more consideration should be given to patient dose and exposure tracking through an appropriate system. Participants in this study were professionals of every major specialty working in all main clinical areas where radiological procedures are performed. This study was mostly directed at estimating the situation in developing countries for two main reasons. First was the expectation that regulatory infrastructure could possibly be less developed in developing countries and the second was to evaluate the impact of IAEA's actions in developing countries on the improvement of radiological safety. Also, most IAEA projects are with recipient developing countries. The authors are familiar with some aspects of radiation safety in some of the studied countries, but data are spurious and the exact situation is not known. Developed countries were also included in this study, in order to compare the situations in the developing countries to the situation in the developed ones. This study was designed so as to provide comprehensive information from radiologic professionals working in the clinical environment of each country.

4.1 Impact of Regulations

The average scores being higher than 50% of the maximum achievable score imply that participants in general selected possible answers that agree with the notion that impact of regulations was positive in enhancing safety and helping in the development of safety culture. It is important to point out that the average scores of the various specialties in different areas were not significantly different. This implies that professionals of all the various specialties included in this study generally perceived regulatory actions as positive in improving safety culture and safety and not only the ones mostly working on radiation protection such as medical physicists/radiation protection experts. Requirements such as using DRLs, appointing radiation protection experts, performing regular QC, optimizing patient dose, and patient exposure record keeping were generally perceived as positive (majority of respondents provided the highest score responses to the respective questions) indicating maturity and familiarity with radiation protection issues. Regarding the requirement for comparison of patient doses with existing DRLs, responses revealed that only 27.6% answered that it is a standard practice, while 40.5% of participants said that only regulation directed proper attention to it. Similar findings were observed regarding the performance of QC checks. About the requirement for patient dose optimization, up to 42.3% of respondents stated that they had already been doing it regardless of regulation. This is encouraging. A significant percentage, 13.2%, of responses to question no. 4: "Requirements that the facility should appoint or have access to medical physicist/radiation safety expert are implemented on paper but the expert is not really involved in practice." indicates that there is still enough room for improvement in the involvement and availability of medical physicists/radiation safety experts in clinical practice. Finally, a significant 65.8% of respondents believed that having a regulatory requirement for tracking patient exposure would improve radiation protection while only 6.6% provided a totally negative response. This means that exposure tracking is perceived as a good idea by radiologic professionals.

The significantly higher score in responses from developing countries indicates that the perceived impact of regulations in developing countries is higher, probably in part as a result of IAEA actions. This result complements the impact of other IAEA actions toward achieving better radiation protection, through projects in developing countries around the world.⁴ The significantly higher score in developing countries also points out the importance of regulation as perceived by the people in countries lacking regulation in contrast to the developed countries where regulation has a longer tradition. In such countries, the state is usually well established and organized. It consists of many different sectors providing a multitude of services spanning from food and water safety to education and research regulation. It is customary for regulatory authorities to control the rules of conduct in many aspects of social life and thus regulation is almost taken for granted by the citizens of developed countries.

4.2 Assessment of Safety Level

Responses from all categories of respondents to the questions of this section pointed out that the level of safety was satisfying (by convention: a satisfying safety level is considered to be present when average scores exceed 50%). Implementation of QC testing of radiological equipment and comparison of doses with DRLs (regularly or at least irregularly) were found to be fairly widespread although regular evaluation against DRLs was not as widespread as desired. Regarding justification practices, it was found that a considerable percentage, 28.8%, of respondents claimed that the clinicians' request was always followed. The revised International Basic Safety Standards require that the responsibility be shared between the clinician and the radiologist.¹³ The encouragement of consultation between the referring clinician and the radiologist could reduce the number of unnecessary examinations which, according to estimations, may constitute a large fraction of all examinations.¹⁴ The survey identifies the need to strengthen regulations for promoting the systematic use of reject analysis and bad quality images assessment, as only 51.5% of respondents claimed that such procedures are regularly performed. Also regulating actions are needed for enhancing record-keeping and tracking of previous radiological procedures and possibly dose received by the patient. More than 40% of respondents claimed that it is not easy or that it is impossible to access information on previous procedures. Responses to questions 6 and 7 reveal that regular availability of medical physics/radiation protection experts is more widespread than one would think (62.0%) and the same holds true about the regular use of dosimeters (81.7%).

4.3 Future Needs

Participants were found to believe that in the future stricter regulatory requirements for evaluation of patient doses in diagnostic/interventional procedures and existence of written protocols should be enforced. This indicates that such stricter regulation will, in their eyes, improve radiation safety. Patient dose seemed to be prominent in the mind-set of respondents as they considered that it is an important parameter to be taken into account in selection of new equipment. This hints that future regulations would probably need to be more centered on patient dose. The same patient-dose-sensitive mind-set appears to be generating the positive responses given for question 3 about written protocols and 4 about the need for future establishment of a

system that will be able to quickly provide information about the number of previous patient exposures. The IAEA has already initiated the Smart Card/SmartRadTrack project with the aim of tracking patient procedures and dose at a global scale taking into account mobility of modern patients.¹⁵

This study tried to involve as many radiologic professionals from as many countries as possible in order to produce results indicative of the real situation in a considerable part of the world. However, further research is needed to evaluate the situation in the rest of the world or even within each country. It is expected that for countries with diverse socioeconomic environments, radiologic professionals will have different levels of understanding regarding the contents of the survey. Response from the participants was voluntary and anonymous. It is reasonable to expect that there was a selection bias that could not be accurately accounted for under the circumstances in which this study was conducted. Individuals having a deeper sense of the role of regulations and the importance of safety culture were probably more likely to respond. They are also more likely to be already working in an environment that implements safety practices. In this light, the high availability of medical physics/radiation protection experts assessed in this study (62%) could actually be lower, as places without such experts may have not been sampled adequately. However, the authors believe that dissemination of the questionnaire by counterparts to the radiologic professionals without any intervention from the authors could be a factor contributing in reducing the effect of selection bias.

5 Conclusions

This survey in 25 countries has shown that the impact of regulations in enhancing patient safety and the creation of safety culture is perceived by respondents as positive, especially in developing countries. The results are encouraging in the sense that they indicate a relatively high level of use of regulatory tools. However, it seems that there is still room for improvement regarding the implementation of regulations. Responses received led to an impression that in the participating facilities safety levels are satisfactory. Future needs seem to be directed toward strengthening the regulatory framework especially regarding evaluation and consideration of patient doses and use of written protocols for radiological procedures. The results of this study could be suggesting that an exposure tracking system and regulatory actions supporting it may be useful and important in the ongoing task of improving radiation safety of patients in medicine.

Disclosures

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