

Regulatory Control - Clinical Audit and the BSSD(key outcomes from WP 3)

A.Karoussou-Schreiner
Medical Physics Expert
Radiation Protection Dpt.
Ministry of Health
Luxembourg



QuADRANT Survey on Clinical Audit

Section 2 relates to the requirement for clinical audit as defined within the European Basic Safety Standards Directive and its enforcement through regulatory inspection



Introduction

- Questions
- Answers/Results
- Analysis of the results
- Conclusions

Section	Question
2	1

Is there awareness in your country of the requirement to undertake clinical audit of medical radiological practice mandated within the European Basic Safety Standards Directive?

- ☐ At individual/healthcare professional level
- ☐ At hospital level
- ☐ At regional/state official level
- ☐ At national professional society/professional body level
- ☐ At senior governmental/ministerial level

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Section	Question
2	1

Results

- Only 4 countries reported broad awareness at all the levels contained within the question
- 1 country reported no awareness at any level
- Broad awareness was indicated, although levels were variable and awareness was most common at national professional society (n=17 countries) and senior governmental (n=16) levels
- State, hospital and individual awareness was lower



Section	Question
2	1

Conclusions

- Actions are required in order to increase awareness at State, hospital and individual level
- Good cooperation between regulators and professional associations is important
- National healthcare professional education/training programs need to include training in clinical audits taking into account the multidisciplinary composition of clinical audit teams

Section	Question
2	2

Is there an established process of hospital/departmental inspection by the relevant national competent authority in your country?

- ☐ It was well established before the Basic Safety Standards Directive
- ☐ It has been established since the Basic Safety Standards Directive
- ☐ No - it is in development
- ☐ No - not in development
- ☐ Don't know

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Section	Question
2	2

Results

- 22 countries reported this process to be in place and that this pre-dated the BSSD (2013/59/Euratom)
- In 3 countries the process was established after the BSSD
- In 3 countries the inspection process was said to be in development
- No national inspection process in existence/planned was reported in 1 country
- 2 countries did not respond

Section	Question
2	3

Does the inspection process include assessment of clinical audit?

- ☐ Yes, limited to audit practice/process
- ☐ Yes, including audit outcomes
- ☐ No
- ☐ Don't know
- ☐ Not applicable

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Section	Question
2	3

Results

- 11 countries indicated that the inspection process included the assessment of clinical audit but that this was limited to audit practice/process
- In 7 countries the process was also reported to include audit outcomes
- In 10 countries clinical audit assessment is not part of inspection



Section	Question
2	3

Conclusions

- In a number of countries clinical audit assessment is not part of inspection
- It is recommended that clinical audit assessment be part of the inspection process
- Clinical audit results should be part of the inspection assessment
- This will help to increase awareness at the hospital and individual level as well as the implementation of clinical audit

Section	Question
2	4

What effects (if any) has the Basic Safety Standards Directive (Council Directive 2013/59/Euratom) had on related clinical audit activity in your country?

- A system of clinical audit practice and process was established as a result of the Directive
- Process of inspection by radiation protection/enforcement authority introduced to include assessment of clinical audit processes
- Clinical audit guidelines/directives developed/in development

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Section	Question
2	4

What effects (if any) has the Basic Safety Standards Directive (Council Directive 2013/59/Euratom) had on related clinical audit activity in your country?

- ☐ Clinical audit activity incorporated into national hospital accreditation programmes
- ☐ Individual healthcare professional engagement in clinical audit mandated
- ☐ Clinical audit findings/recommendations published in peer-reviewed journals/national guidance

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Section	Question
2	4

What effects (if any) has the Basic Safety Standards Directive (Council Directive 2013/59/Euratom) had on related clinical audit activity in your country?

- ☐ No change, a well-established system of clinical audit was already in place
- ☐ There has been introduction of new processes/technologies or changes in practice to improve audit outcomes (for example - the introduction of decision support software to improve justification and supporting audit processes)
- ☐ Don't know - Other (Please specify)

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Section	Question
2	4

Results

- A well established system of clinical audit was considered already to be in place (n=9 countries)
- Clinical audit guidance development (n=13 countries)
- The inspection process to include assessment of clinical audit (n=12 countries)
- A system of clinical audit practice and process developed as a result of the Directive was described (n= 8 countries)
- Mandating of healthcare professional involvement (n=3 countries)
- Incorporation of clinical audit into hospital accreditation (n=2 countries)
- Introduction of new processes/technologies (n=3 countries)

Section	Question
2	4

Results

- It is also of relevance and important to note that mandated involvement in clinical audit within departments utilizing ionising radiation procedures outside of radiology, radiotherapy and nuclear medicine only occurs in 16 countries and in private radiology/radiotherapy/nuclear medicine providers in 17 countries



Section	Question
2	4

Conclusions

- A number of practice changes concerning clinical audit have been observed with the implementation of the BSSD
- There is no harmonised approach for the implementation of clinical audit at an European level
- The sharing of best practices and guidance and the participation in European and international clinical audit related initiatives could help a harmonised implementation of clinical audit



Main Conclusions

- The BSSD provides the legal framework mandating participation in clinical audit “in accordance with national procedures”
- The inspection process should include clinical audit assessment as well as assessment of clinical audit outcomes
- Participation of the private sector and all departments undertaking ionizing imaging procedures outside of radiology/radiotherapy/nuclear medicine (orthopedic/urology/theatres...) must be provided



Main Conclusions

- For the implementation of clinical audit there is a need to increase awareness
- Education and training for all the professionals concerned should be put into place
- The implementation of clinical audit has improved with the publication of the BSDD



Main Conclusions

- However there is no European harmonised approach
- It is clear that a common reference document is needed - guidelines to help countries organize and implement clinical audits



Thank you for your attention