

 EURADOS<sup>®</sup> SENTINEL WORKSHOP  
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## REFERENCE LEVELS AT EUROPEAN LEVEL FOR CARDIAC INTERVENTIONAL PROCEDURES

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## EC Guideline 109: Guidance on Diagnostic Reference Levels

- According to Article 4 of the MED, Member States shall promote the establishment and the use of diagnostic reference levels (DRLs) ...
- DRLs .... are particularly useful in those areas where a considerable reduction ... in absorbed dose means a relatively high reduction in risk:
  - high-dose examinations: CT, procedures requiring long fluoroscopy times, such as for interventional radiology;
  - examinations with more radiosensitive patients, such as children.
- However, it should be recognised that it is rather more difficult to establish DRLs for CT, interventional radiology ...

## RL in interventional procedures

- In interventional procedure there are some experiences to assess RL for the more common procedures.
- When procedures become more complicated there is a greater individual variation in the patient doses due to pathology severity or procedure complexity (e.g. catheters and guidewires).
- Uncertainties in the mean or median values on small samples of patients will be high and comparisons with national/international RLs will be more difficult.
- However, as stated by ICRP 73, RLs have to give an indication of situations where an optimisation of protection of the patient is required.



“... interventional procedures are viewed as too dependent on individual patient situations to be managed by reference levels ...” (October 2006)

## Objectives

This SENTINEL study on interventional cardiology had the purpose:

- to evaluate the level of the practice in European countries
- to assess the performance of angiography equipment in a sample of hospitals in the country partners
- to collect patient doses, in diagnostic and therapeutic x-ray image guided procedures, to assess an updated set of reference levels
- to update the set of quality criteria for cardiac images considering the use of angiographic systems with digital flat panel imaging detectors
- to evaluate the methodologies applied for staff dosimetry and to collect staff exposure in a sample of installations to assess dose constraints for staff exposure.

## Objectives

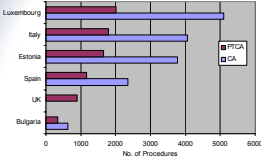
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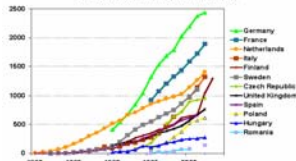


## Frequency of cardiac interventional procedures in Europe

Number of diagnostic and interventional haemodynamic procedures per million inhabitants in 6 countries participating to SENTINEL project (2005). Increasing frequency of PTCA in European countries



Time trends in the annual use of PCI numbers per 1 million inhabitants



- Very different level of interventional cardiology practice
- Frequencies are rapidly increasing
- Increasing use of MSCT for diagnostic in cardiology will be another factor to consider in the future



## Equipment performance assessment

- A protocol to assess equipment performances has been developed:

- Clinical setup:
  - Fluoroscopy and cine image acquisition modes used in the practice
  - PMMA of 20 cm positioned at the isocenter to simulate standard patient and AP projection
  - FOV  $\approx$  18 cm
- Dose rates measured at the entrance of the phantom
- Images of a standard test phantom, positioned in the phantom at the isocenter have been collected

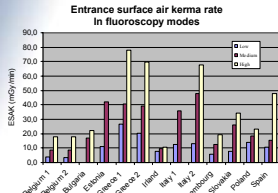


- A survey on 13 interventional cardiac systems has been conducted

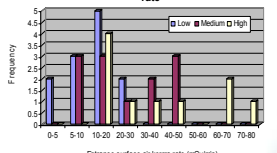


## Equipment performance assessment

### Fluoroscopy modes



Frequency distribution of entrance surface air kerma rate



Large variability in equipment set-up and performances:

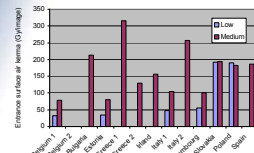
- Dose rates:
  - fluoro low: up to 25 mGy/min (ratio max/min 7)
  - fluoro medium: up to 50 mGy/min (max/min 5)
  - fluoro high: up to 80 mGy/min (max/min 7)
- Equipment setup:
  - on some systems modes not separated in term of doserate



## Equipment performance assessment

### Image acquisition modes:

Entrance surface air kerma rate in image acquisition (cine) modes



Large variability in equipment set-up and performances:

- Dose rates:
  - cine low: up to 0.2 mGy/frame (ratio max/min 4)
  - cine normal: up to 0.32 mGy/frame (max/min 4)
- Equipment setup:
  - on some systems modes not separated in term of doserate



## Equipment performance assessment

- Image quality in fluoroscopy modes:
  - identified poor image quality on some old systems

Image quality: high contrast resolution

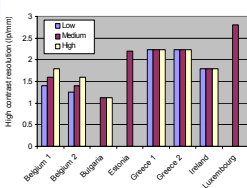
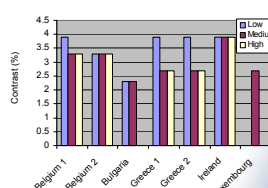


Image quality: low contrast resolution



## RL for equipment performance

- Variability in doserates assessed in standard conditions, is one of the factor explaining the patient dose variability seen in angiographic cardiac procedures
- Preliminary reference levels for doserates measured in standardised conditions are proposed:

Entrance surface air kerma rate (20 cm PMMA; FOV $\approx$ 18 cm)	Fluoroscopy low: 13 (mGy/min)
	Image acquisition: 100 ( $\mu$ Gy/fr)



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## Survey on patient doses

- A European survey inside the SENTINEL group to investigate doses in selected interventional cardiac procedures and to assess reference levels has been performed in 2005-2006.
- Sample of cardiac interventional procedures collected in 9 centres:

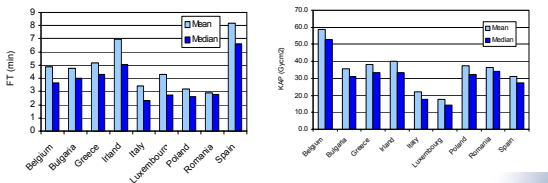
Procedure	No. of patients
Coronary angiography (CA)	672
Percutaneous transluminal coronary angioplasty (PTCA)	662
Electrophysiology diagnostic procedure	112
Pacemaker implantation (PM)	51
Radiofrequency cardiac ablation (RFCA)	337

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## Patient dose: coronary angiography procedures

- CA:
  - FT: median values in a range from 2.3 to 6.6 (factor 3)
  - KAP: median values in a range from 15 to 53 (factor 3.5)

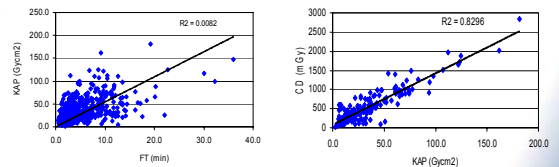


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## Patient dose: coronary angiography procedures

- For CA:
  - Poor correlation between KAP and FT
  - Good correlation between CD and KAP

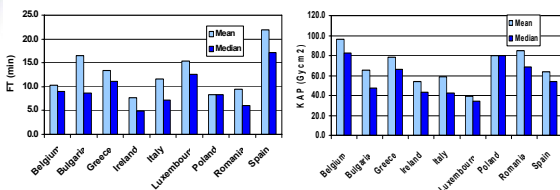


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## Patient dose: PTCA procedures

- PTCA:
  - FT: median values in a range from 5 to 13 (factor 2.5)
  - KAP: median values in a range from 35 to 85 (factor 2.5)

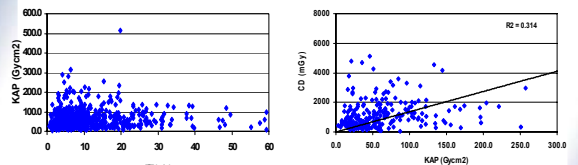


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## Patient dose: PTCA procedures

- For PTCA:
  - Poor correlation between KAP and FT
  - Poor correlation between CD and KAP



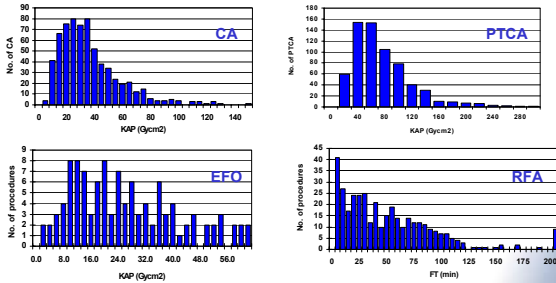
- FT, KAP and CD quantities are not always correlated

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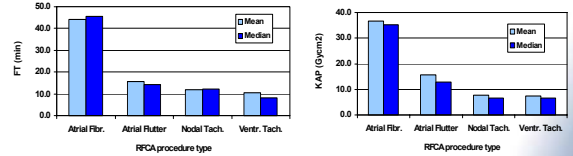
## KAP: pooled data

- Frequency distribution for CA, PTCA, EFO and RFA



## RF cardiac ablation sample

- For RFA it was necessary to share the sample in different types of interventions (only Udine data):
  - atrial fibrillation,
  - atrial flutter,
  - nodal tachycardia,
  - ventricular tachycardia and WPW



## Reference levels (I)

- From the pooled data, reference levels have been derived as the rounded values of the 3rd quartile of the frequency distributions

Dose or dose analogue	Procedures		
	CA	PTCA	EFO
KAP (Gycm <sup>2</sup> )	45	85	35
Effective dose (mSv)	8	15	6
CD at IRP (mGy)	650	1500	-
Fluoroscopy time (min)	6.5	15.5	21
No. of cine images	700	1000	-
Entrance surface air kerma rate	Fluoroscopy low: 13 (mGy/min) Image acquisition: 100 (µGy/frame)		



## Reference levels (II)

- The Cumulative Dose at IRP, today available on new equipment, is added to the list of RLs to help practitioners in preventing skin injuries;
- Relationship between CD and peak skin dose should be derived in each installation and for each high dose procedure; a proper “trigger level” in term of CD should be adopted in each installation

Dose or dose analogue	Procedures		
	CA	PTCA	EFO
KAP (Gycm <sup>2</sup> )	45	85	35
Effective dose (mSv)	8	15	6
<b>CD at IRP (mGy)</b>	<b>650</b>	<b>1500</b>	-
Fluoroscopy time (min)	6.5	15.5	21
No. of cine images	700	1000	-
Entrance surface air kerma rate	Fluoroscopy low: 13 (mGy/min) Image acquisition: 100 (µGy/frame)		



## Reference levels (III)

- RL for Effective dose, evaluated from KAP value, is introduced to help in risk comparison with procedures performed with other technologies (CardiacMSCT, PET/CT, SPECT/CT, etc)

Dose or dose analogue	Procedures		
	CA	PTCA	EFO
KAP (Gycm <sup>2</sup> )	45	85	35
<b>Effective dose (mSv)</b>	<b>8</b>	<b>15</b>	<b>6</b>
CD at IRP (mGy)	650	1500	-
Fluoroscopy time (min)	6.5	15.5	21
No. of cine images	700	1000	-
Entrance surface air kerma rate	Fluoroscopy low: 13 (mGy/min) Image acquisition: 100 (µGy/frame)		



## Reference levels (IV)

- Equipment performance: because of the large variability of doserates in clinical conditions, RLs for entrance surface air kerma rate, measured in standardised conditions, are also proposed to help optimisation of equipment set-up.

Dose or dose analogue	Procedures		
	CA	PTCA	EFO
KAP (Gycm <sup>2</sup> )	45	85	35
Effective dose (mSv)	8	15	6
CD at IRP (mGy)	650	1500	-
Fluoroscopy time (min)	6.5	15.5	21
No. of cine images	700	1000	-
<b>Entrance surface air kerma rate</b>	<b>Fluoroscopy low: 13 (mGy/min) Image acquisition: 100 (µGy/frame)</b>		



## RLs comparison (I)

- **DIMOND 2003:** The proposed set of reference level are lower (-12%) compared to those introduced in 2003 by the DIMOND group  
CA: KAP = 57; PTCA: KAP=94 Gy $\text{cm}^2$   
The main difference derives from the lower number of cine images today generally used (12-15 instead of 25-30 frames/s).

V. Neofotistou, E. Vano, R. Padovani, J. Kotze, A. Bowling, M. Tolonen, S. Kotbui, V. Tsapaki, S. Willis, G. Bernardi, K. Faulkner. **Preliminary reference levels in interventional cardiology.** Eur Radiol (2003) 13:2259-2263

- **IAEA CRP 2006:** The reference level proposed are derived from a sample of thousand of procedures collected in 6 centres (to be published).
  - KAP value for PTCA is higher than our (+ 50%) probably reflecting different level of optimisation in centres outside Europe.
  - Evaluation of complexity of procedures performed on a sub-sample of PTCA, accounts for a factor of 2 on median KAP for simple and complex PTCAs.

Procedure	KAP (Gy $\text{cm}^2$ )	Fluoroscopy Time (minutes)	Number of Images
Coronary Angiography (CA)	50	9	1000
Percutaneous Cardiovascular Intervention (PCI)	125	22	1700

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## RLs comparison (II)

### HPA (NPRB): Doses to Patients from Medical X-ray Examinations in the UK – 2000 Review

- 2000 survey: 7 hospitals in UK; CA: mean fluoroscopy time: 4.3 min; 3rd quartile: 36.3 Gy $\text{cm}^2$
- KAP comparable to our RL for CA (-30%)

### Swiss study:

- A nationwide survey to investigate the use of fluoroscopy and establish national reference levels (RL) for dose-intensive procedures
- A wide variation in dose and image quality in fixed geometry was observed.
- DAP RLs of ... 80, ..., 110 Gy $\text{cm}^2$  were established for ..coronary angiography, ..., PTCA, respectively.
- RL values higher than ours for CA (+ 75% for CA)

Arua A, Verdun FR et al, University Institute of Applied Radiation Physics, Lausanne, Switzerland. Euro Radiology, Oct 2006

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## Conclusions

- The survey results confirm a large variability in the entrance dose rates and patient doses.
- **Equipment performance:** reference levels are proposed to be used in the process of optimisation of equipment set-up.
- **Patient doses and dose analogues:** reference levels comprise also the effective dose and the cumulative dose to IRP.
- **A larger set of quantities can help practitioners to better understand reasons of poor practice.**
- Proposed RLs are comparable to those proposed by DIMOND group and, with some exceptions, to those derived from other smaller studies.
- Also if the sample is not very large, the agreement with other studies assures on the accuracy of RLs proposed for the optimisation of the interventional cardiology practice at European level.

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## SENTINEL partners

Many thanks for your attention



Dogan Bor  
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Kelle Kepler  
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Constantin Miltu  
Silvia Papiers  
Dusan Salat  
Pavle Torbica  
Virginia Tsapaki  
Annalisa Trianni  
Eliseo Vano  
Jenia Vassileva

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