

“Patient Safety in the Cathlab.”



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The Netherlands 2008-2009: 22 PCI-centers

1989: 7000
1996: 15.000
2003: 25.000
2008: 36.367 PCI 's



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1650 PCI 's
750 diagnostic cag
250 hart-biopsies
30 Aortic Valve-implant.
2-4 Pulmonary Valve-impl.
15 PFO/ASD closures

Patient Safety:

“Patient safety comprises the prevention of unintended harm to the patient.”

(report for the Dutch minister of Health by the Inspection for Healthcare in October 2008)

1. To avoid procedural complications and adverse outcomes.
2. To optimize the care process in order to minimize the risk of avoidable harm.

Similar to surgical procedures, patient safety (in the Interventional Cardiology Department) starts when the patient enters the department just prior to the test or treatment, and ends when the patient leaves the department and returns to a nursing ward.



The Inspection of Healthcare has identified (in 22 OR's in the Netherlands) the following factors that increase patient risk:

(report for the Dutch minister of Health by the Inspection for Healthcare in October 2008)

- Incomplete data.
- Poor quality of the transfer of that information.
- Lack of clarity of arrangements.
- Lack of structural safety-check procedures of maintenance.
- Poor quality of infection prevention.





Findings and conclusions:

(report for the Dutch minister of Health by the Inspection for Healthcare in October 2008)

1. Communication and transfer:

- Frequent lack of structure and inadequate coordination.
- No adequate use of formal checklist and not used at all appropriate transfer moments.
- No structured controls of high-risk interventions (double-check during preparation of medication and used materials).
- Double checking (TOP-procedures) are not standard practice.
- Unclear who is responsible for the organization and individual tasks.

2. More attention must be devoted to the safe use of materials and equipment:

- Information about maintenance is not uniformly structured.
- Proper storage and monitoring of materials and medication is essential.

3. Behavior regarding infection prevention and air-control lacks discipline:

- Staff behavior and culture have to counter the risk of infection.
- Air circulation has to be controlled.

Some of these safe practices may be built in to new interventional cardiology departments so, that the conditions are the same conditions as in OR departments.

This may lead to *lower risks* and *increase patient safety and quality* in future! Important because of expected increasing complexity of Percutaneous Coronary Interventions and Percutaneous Valve Implantations.

Six distinct elements can be identified which strongly increase patient risks:



1. Transfer of the patient: *a uniform approach.*
2. Control and check lists: *substantive support for a patient transfer.*
3. Cooperation and teamwork: *it should be clear that the first operator is responsible for the process of the patient's care (while maintaining the professional responsibility of other team members).*
4. Structural control moments: *double-check prepare and administer of medication.*
5. Technical reliability: *uniform presentation of information on maintenance (and security) of equipment.*
6. Behavior and dedication: *behavior around infection prevention and control air needs discipline.*

Important questions have been identified that provide clarity on measures to improve quality and patient safety:

- What information is important for the team?
- Use of checklists and standardized procedures?
- How is the staff trained on the safety and suitability of the required devices and equipment?
- Who is directly responsible concerning the patient care on the operating table?
- What is the policy on infection control, (*infection prevention measures including air control*) and how is it used and safeguarded?



Communication and data transfer are the most important subjects:

- Formalization and standardization of communication is essential:
 - Transfer patient from the nursing or holding ward to the cathlab.
 - Contact between operator and patient before the procedure.
 - How is the availability and accessibility of patient and procedural information safeguarded?



The use of checklists and clear procedures (such as a Time Out Procedure-TOP) will ensure this.

Time Out Procedure:

Time-out is defined as:

“A verification process performed by two people just before the start of the intervention or treatment as a last check for” :

- Patient identity.
- Operation type.
- Indications, required treatments or tests.
- (pre) Medication data.
- Availability and functionality of sterile and unsterile equipment and resources.



Perform a time-out (1):

The procedure is not started until all questions or concerns are resolved:

- Conduct a time-out immediately before starting the invasive procedure or making the incision.
- A designated member of the team starts the time-out.
- The time-out is standardized.
- The time-out involves the immediate members of the procedure team: the individual performing of the procedure, anesthesia providers, scrub nurse, technician, and other active participants who will be participating in the procedure from the beginning.



Perform a time-out (2):

- All relevant members of the procedure team actively communicate during the time-out.
- During the time-out, the team members agree on the following:
 - correct patient identity**
 - correct site**
 - procedure to be done**
- When the same patient has two or more procedures: If the person performing the procedure changes, another time-out needs to be performed before starting each procedure.
- Document the completion of the time-out. The organization determines the amount and type of documentation.



Checklist:

The most senior member of the team in the theatre leads the completion of the following checklist:

Place this checklist in the patient's medical record!



Time Time Out Checklist (for Surgical Procedures)	
The most senior proceduralist in theatre leads the completion of the following checklist. Time Out should be completed immediately before the surgery or procedure starts.	
Correct patient?	<input type="checkbox"/>
Correct procedure?	<input type="checkbox"/>
Correct Site / Side / Level?	<input type="checkbox"/>
	<input type="checkbox"/> yes <input type="checkbox"/> no
Imaging data confirmed?	<input type="checkbox"/>
Correct implants / prosthesis (Type / Size / Side) are available?	<input type="checkbox"/>
Any special equipment needed is available?	<input type="checkbox"/>
Does the patient need antibiotic prophylaxis?	<input type="checkbox"/> yes <input type="checkbox"/> no
<i>If yes, has it been given?</i>	<input type="checkbox"/> yes
	<input type="checkbox"/>
	<input type="checkbox"/>
Is the patient receiving treatment for Venous Thromboembolism prophylaxis?	<input type="checkbox"/> yes <input type="checkbox"/> no
<i>If yes, are graduated stockings on?</i>	<input type="checkbox"/> yes <input type="checkbox"/> no
<i>Are compression device(s) attached and on?</i>	<input type="checkbox"/> yes <input type="checkbox"/> no
<i>Has preoperative Subcutaneous LDU / LMW* Heparin been given?</i>	<input type="checkbox"/> yes <input type="checkbox"/> no
Does the patient need any special pre-operative medications?	<input type="checkbox"/> yes <input type="checkbox"/> no
<i>If yes, have they been given?</i>	<input type="checkbox"/> yes
* Low Dose Unfractionated / Low Molecular Weight	<input type="checkbox"/>
Date:	/ /
Time(24hr):	
Time Out led by:	
Form completed by:	
	Record the results of Time Out in the patient's Operating Suite Nursing Record.
	Place this checklist in the patient's medical record.

Medical materials, medicines and equipment:

- Regular check of expiry date and used equipment.
- Proper storage of sterile materials “first-in first out-procedure”:
 - *Expiry date input equipment: has to be clear and when preventive maintenance should be done (use sticker)*
- Infection Prevention:
 - Hand Wash-protocol has to be followed
 - Behavior of the staff is important
 - Prevention Hepatitis-B transmission and MRSA in host operators and temporary employees
- Technical maintenance has to be ensured.
- Staff following the infection prevention rules.
- Presence of an Air Handling System.



Air handling system: 3 classification zones

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	Operation room class 1	Operation room class 2	Operation room class 3
Zones:	3 zones (A-B-C)	2 zones (A-B)	0 zone
Building structure of the department:	Isolated from hospital	Isolated from hospital	Not isolated from hospital
Locks	4 types of locks	Lock for the staff	No locks
Holding:	Belongs to zone C	To be nearby	No holding
Ventilation:	Not mixing	No special air-conditioning	No special air-conditioning
Ventilation frequency:	20 x p/hr	6 x p/hr	6 x p/hr
Air filtration:	Hepa-filter	Hepa-filter	No hepa-filter
Air pressure:	Pressure zone A vs. B vs. C	Pressure zone A vs. B	No pressure

Measures to take after findings and conclusions (1):

- Produce an action Plan for the implementation of necessary improvements. This plan shall comprise a step-by-step approach with priorities allocated on the basis of a risk evaluation.
- Produce formal protocols for the transfer of responsibilities to include set procedures for checks and 'time-outs' at the critical moments.
- Implement protocols based on existing guidelines.
- Professional norms, including those for double-checks on medications.
- Responsible aftercare demands adequate registration of relevant clinical information.

Measures to take after findings and conclusions (2):

- Every person present in the cathlab. is to observe all infection prevention guidelines and procedures.
- Hospitals are to ensure that all equipment requiring preventive maintenance bears a clearly visible sticker stating the date before which the next inspection or service must be conducted.
- There must be written agreements and instructions for the safe use of medical equipment.
- Regular reports to the Board of Management regarding the quality and safety of the department (*overall quality and safety of patient care*).

Other safety issues concerning patient care in cathlabs. in the Netherlands are:



- Requirements set out in a special act on cardiac interventions by the Health Council and the Minister of Health in 2008 concerning Dutch national guidelines.
- Cooperation with the anesthetic department (*amount of procedures where anesthesia support is needed is still increasing*).
- Presence of a holding area in the Interventional Cardiology Department.
- Presence of an evacuation plan for emergencies.
- Presence and involvement of a qualified Radiation Safety Officer and radiation safety-rules.



Radiation safety rules (1):



Necessary Radiation:

A patient in a cathlab. is exposed to X-rays. This exposure to radiation is necessary because the treating physicians want to see where they have their tools, catheters and other materials.

Regulations:

There are many laws and rules for the use of radiation, where X-rays are part of. Studying these laws and regulations will show that they are for almost all members of the public.

For patients, there is nothing to be found. Maybe this is logical, because you never can predict in advance how much radiation a patient will receive during an examination or treatment.

Radiation safety rules (2):



ALARA principle:

The only way patients are legally protected against radiation is that the ALARA principle (*As Low As Reasonably Achievable*) has to be applied. Only by applying this principle the patient is legally protected against an overdose of radiation.

Incompetence:

Another possible interpretation is that when the patient receives too much unnecessary radiation and consequently is injured, the patient can sue the person (*physician*) who has administered the radiation for incompetence (*malpractice*).

This interpretation of ALARA also applies to treatment where the patient was given too much radiation.

Radiation safety rules (3):



Training:

The legal obligation of the staff working in a cathlab. to follow radiation courses, indirectly protects the patient.

The training is primarily designed to convey how to deal with radiation and how to protect yourself. When staff protect themselves against radiation, the patient is automatically protected.

The physicians who treat patients must follow additional courses on how to safely administer radiation to a patient and how to use minimize radiation dose.

Technology:

In addition the equipment may produce high levels of radiation and have to be adjusted in such a way that the patient receives only the minimum dose required to his treatment. Unnecessary radiation is filtered out. This may often apply when image quality is poor.



Conclusions (1):

- All these findings can be a valuable addition for interventional cardiology departments to work under similar conditions as an OR-department.
- Standardization of the basic processes within the cathlab.(*room*) including good transfer practices which incorporate the use of checklists and “*stop and confirm moments*” will do much to reduce the risk to patient safety.
- It should be clear that the (*senior*) interventional cardiologist in the cathlab.(*room*) has the primary responsibility for the entire procedural process involving the patient while other team members have their own professional responsibilities.

Conclusions (2):



- The management of the department is responsible for the organization and assessment of the procedures and protocols to ensure that this part of the overall process is conducted responsibly and safely.
- The hospital's Board of Management is accountable for ensuring that the staff are fully competent, and for implementing all measures required to ensure that the process can be conducted responsibly and safely.

Interventional Cardiology Department Erasmus MC 2010:



“Thank you for your attention.”

