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Design and Professional Practice 2

Risk Analysis

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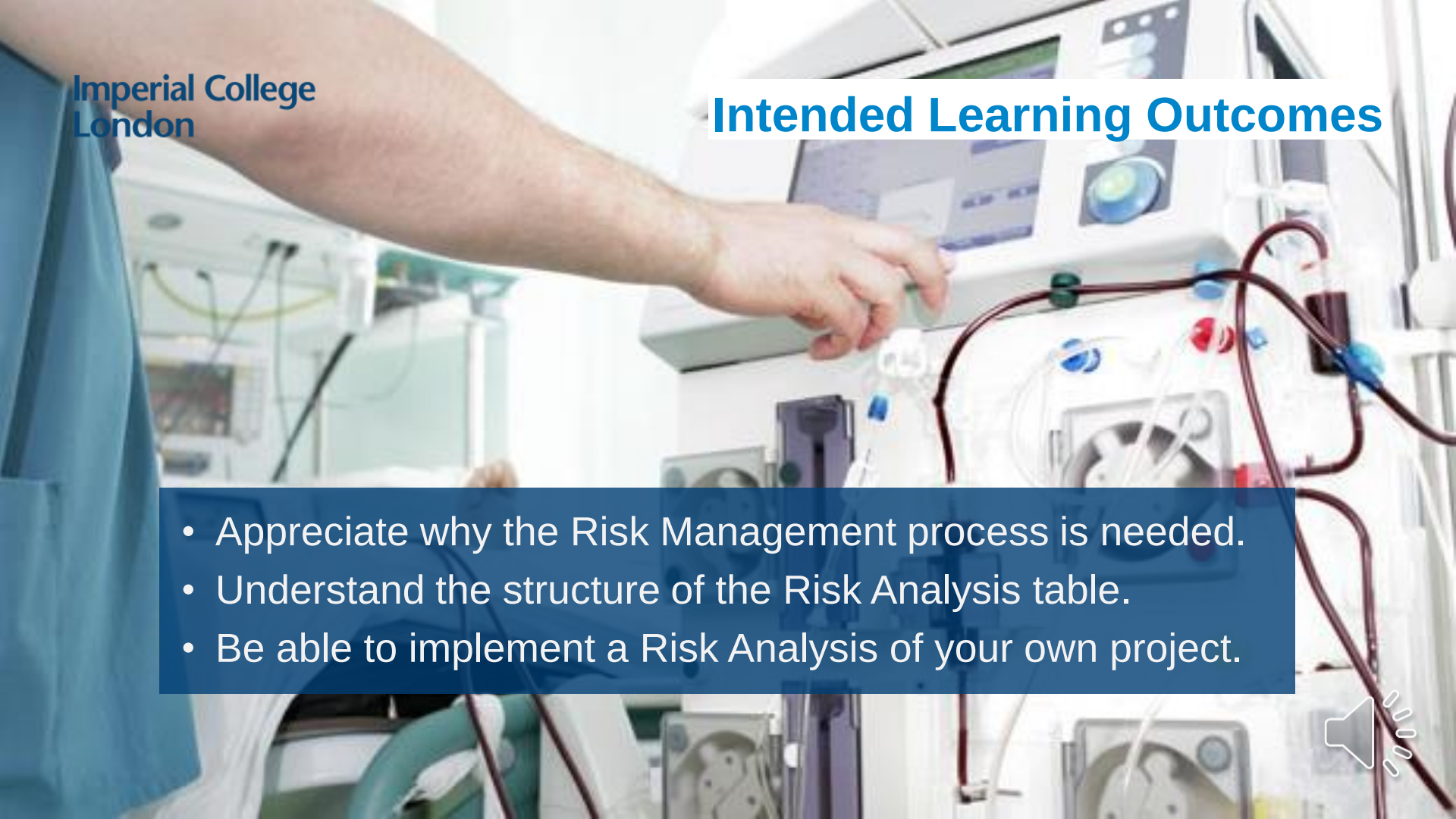
Aims and Objectives

The aim of this session is to provide you with an appreciation of the basic risk management procedures that need to be considered when designing devices.



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Intended Learning Outcomes

- Appreciate why the Risk Management process is needed.
- Understand the structure of the Risk Analysis table.
- Be able to implement a Risk Analysis of your own project.

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Risk and Benefit

- Medical devices include risks/hazards;
  - Uncertainties in design and production ,
  - Can cause harm,
- The benefit should outweigh the risk;
  - Never know until patients experience device,
- In the meantime the risk should be minimised.

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Risk and Hazard

- **Hazard -** any source of potential damage, harm or adverse health effects on something or someone.
- **Risk** - the chance or probability that a person will be harmed or experience an adverse health effect if exposed to a hazard.

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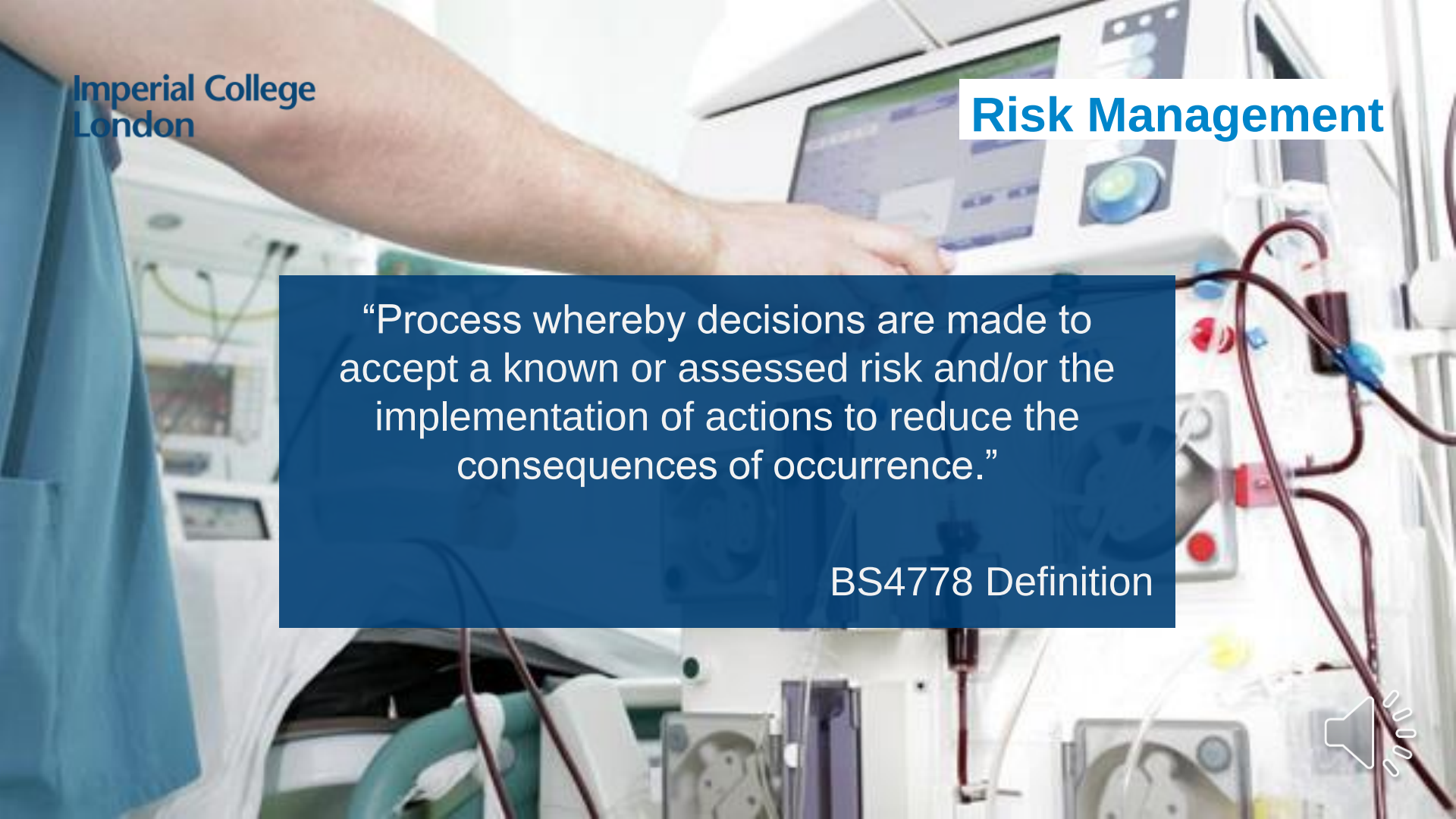
Risk Management

"Process whereby decisions are made to accept a known or assessed risk and/or the implementation of actions to reduce the consequences of occurrence."

BS4778 Definition



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Risk Management

Three main activities:

- Risk Identification,
- Risk Assessment,
- Risk Control / Mitigation.

- Identify hazards,
- Evaluate and classify hazards,
- Risk reduction programme,
- Re-evaluate hazards,
- Assess risk vs benefit.

ISO14971 (Medical devices. Application of risk management to medical devices)


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Areas of Risk
Risks to Health & Safety
Risks to the Environment
Cost
Risks to the Activity / Function / Performance
Project Management Risks

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Risk Identification

- Common sense,
- What ifs,
- Brainstorming,
- Structured interviewing,
- Benchmarks (check lists, prompt lists),
- Experience (experts),
- Historic Data.

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Risk Evaluation

"Risk is the combination of the probability or frequency of occurrence of a defined hazard and the magnitude of the consequences of the occurrence."

Engineering Council Definition

- Severity – consequence or what is the impact on the user,
- Occurrence – likelihood of hazard happening,
- Detection – speed of detecting a potential risk.

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Risk Evaluation

S – Severity

Rating S	Criteria: Severity of effect	Consequence	Treatment
10	Death	-	-
9	Quadriplegia	Life-long medical care necessary / coma / permanent damage	Hospital stay
8	Amputations, paraplegia, blindness, deafness, traumatic brain injury (severe), fourth-degree burns	Life-long medical care necessary / coma / permanent damage	Hospital stay
7	Complex fractures, open fracture, inner injuries, traumatic brain injury (severe), third-degree burns	Permanent damage possible	Hospital stay
6	Gash, fractures, torn muscles, articular cartilage injury, traumatic brain injury (moderate), second-degree burns	Permanent damage possible	Hospital stay
5	Gash, fractures, torn muscles, articular cartilage injury, traumatic brain injury (mild), second-degree burns	Reversible injury	Hospital stay or ambulant treatment
4	Severe cuts, severe scratches, severe contusions, strains, first-degree burns	Reversible injury	Ambulant treatment or self-treatment
3	Minor cuts, minor scratches, minor contusions, stiff muscles, tension, blisters, excoriations, sickness, first-degree burns	Discomfort during application up to three days after application	Self-treatment
2	Slight sickness, pressure marks	Discomfort	-
1	No harm	-	-

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Risk Evaluation

O – Occurrence

Rating O	Criteria: Probability of occurrence
10	Occurs or may occur very likely during every use of the session
9	Occurs or may occur likely during every use of the session
8	Occurs in 1 of 5 sessions (less than once a day)
7	Occurs in 1 of 10 sessions (less than once a day)
6	Occurs in 1 of 50 sessions (less than once half a month)
5	Occurs in 1 of 100 sessions (less than once a month)
4	Occurs in 1 of 500 sessions (less than once half a year)
3	Occurs in 1 of 1000 sessions (less than once per year)
2	Occurrence very unlikely
1	Occurrence nearly impossible

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Risk Evaluation

D – Detection

Rating D	Criteria: Likelihood of detection by design control
10	No chance of detection
9	Very remote chance of detection
8	Remote chance of detection
7	Very low chance of detection by indirect methods (hardware or software)
6	Low chance of detection by indirect methods (hardware or software)
5	Moderate chance of detection by indirect methods (hardware or software)
4	High chance of detection by indirect methods (hardware or software)
3	High chance of detection by direct or indirect methods (hardware/software)
2	Direct and indirect detection: Hardware or software
1	Direct detection: Hardware or safe software (category 4, performance level e)

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Risk Evaluation

Risk Priority Number (RPN) = S x O x D

Threshold when RPN > X mitigation is needed

X = 75 is a good starting point

- Severity – consequence or what is the impact on the user,
- Occurrence – likelihood of hazard happening,
- Detection – speed of detecting a potential risk.

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Risk Mitigation

Objective:

- Reduce unfavourable impacts,
- Reduce likelihood of occurrence of causes,
- Improve chance of detection.

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Risk Management

Risks	Effects / Consequences	S1	O1	D1	RPN before	Preventing measures	S2	O2	D2	RPN after
Operational hazards										
Wrong placement of connections between the device and the oxygen supply	Lack of gas delivered to the baby and hence possible asphyxia and death.	10	3	3	**90**	Introduce labels at the connections to ensure complete clarity and distinction between input and output.	10	2	2	**40**
Incorrect placement of oxygen mask or nasal cannulae from the controller to the neonate	Lack of gas delivered to the baby and hence possible asphyxia and death. Also, possible physical damage of the neonate.	10	3	3	**90**	Add an extra section in the user manual to explain how to place the nasal cannulae or oxygen mask to the baby.	10	2	2	**40**
Ambient light interference	Incorrect measurements from pulse oximeter.	10	6	8	**480**	Include machine learning in the code used with the pulse oximeter to detect unusual behaviour of the sensor. Include a warning in the user manual advising staff to cover the pulse oximeter from ambient light.	10	6	1	**60**
Movement of pulse oximeter	Generates incorrect measurements and could potentially block the valve's code.	10	9	4	**360**	Improve the design of the strap connecting the pulse oximeter to the neonate. Include machine learning in the code used with the pulse oximeter to detect unusual behavior of the sensor.	10	6	1	**60**

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Summary

- A hazard is a source of harm
- Risk is the probability of someone getting hurt
- To manage risk we look at three factors:
  - Severity of the risk
  - Likelihood of occurrence
  - Chance of detection
- Mitigation looks to improve the rating of these three factors