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Health Service Executive

Quality & Patient Safety (QPS)

The Link between Self-Assessment and QPS

Marie Kehoe, RGN, MSN,
CPHQ

Agenda

- **Setting the Stage for Quality and Patient Safety (QPS)**
  - European Directives, Irish Law, PPPGs
  - Accreditation – ISO 13485 and 9001:2000
- **Quality Improvement**
  - Obtaining a baseline
  - Developing Quality Improvement Plans
- **Patient Safety**
  - Proactive Risk Management ISO 14971
  - Reactive Risk Management

Setting the Stage

Definition of Medical Device

Any instruments, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of **disease**; or compensation for an **injury** or **handicap**
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological means, but which may be assisted in its function by such means.

Council Directive 93/42/EEC

Background and Context

External

- 1993- European Directive 93/42/EEC (general)
- 2010 – amended by Directive 2007/47/EC

Internal

- Transposed in Irish Law by EC (Medical Devices) Regulations Statutory Instrument 1994 No. 252 and EC (Medical Devices) (Amendment) Regulations 2001 No. 444 and 2002 No. 576 and the EC (Medical Devices) (Amendment) Regulations 2009 No. 10
- Safety Health and Welfare at Work Act 2005

Internal Cont'd

HIQA, MHC, JCI -

- Licensing Standards for ALL healthcare services

HSE Internal PPPGs -

- HSE Code of Practice for Decontamination of RIMD V1.0 2007 (V. 2 2011)
- HSE Medical Device and Equipment Management Policy and Procedure (2009)

Role of the Irish Medicines Board (IMB) – Competent Authority

Accreditation

ISO 13485 –

- published 2003 – first step in achieving **compliance** with European regulatory requirements
- requirements for a comprehensive management system for the design and manufacture of medical devices (based on ISO 9001:2000 model) BUT requires only demonstration that quality system in **implemented and maintained.**

Accreditation cont’d

ISO 9002:2000 –

- Requires organisation to demonstrate **continual improvement**

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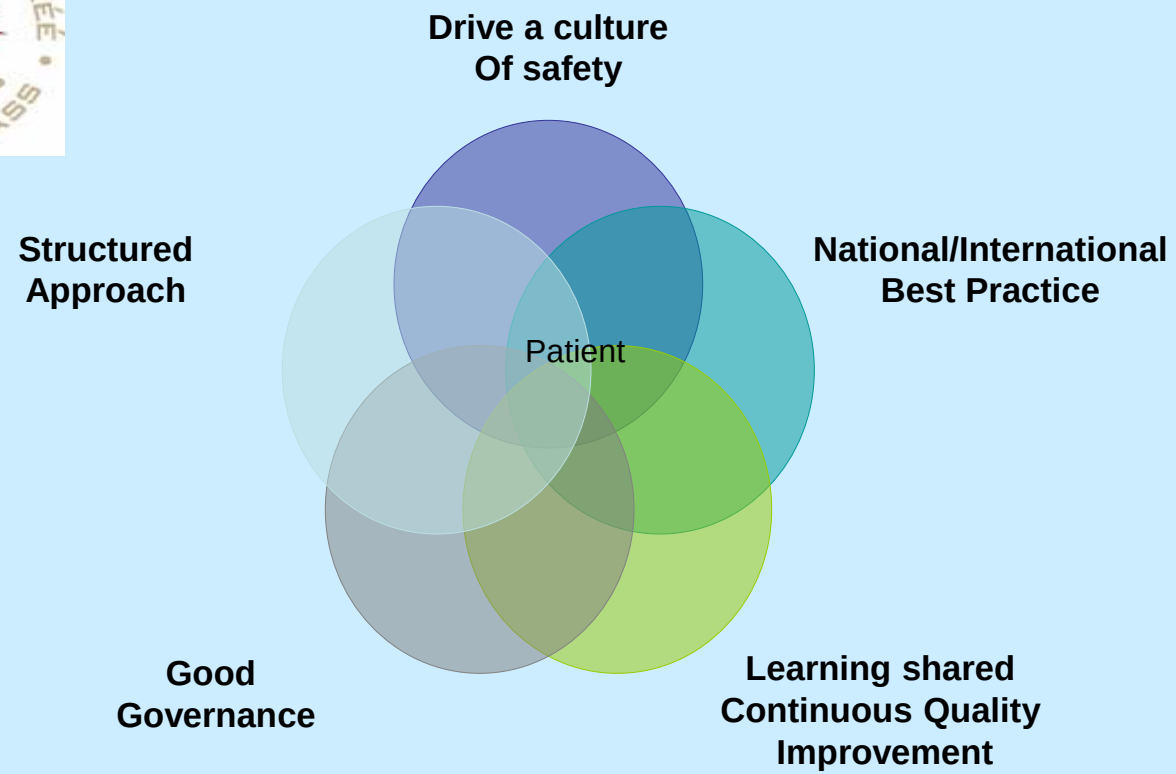
Why standards?



Policies, Procedures, Protocols and Guidelines (PPPGs)

- National template
- National Procedure
- National ICT system for storage and document control
- 2 PPPGs – National Procedure, National Medical Devices and Equipment Management Procedure

Key Performance Indicators (KPIs)

- Development of regional and national suite of healthcare quality indicators

Quality Improvement

Doing the right thing consistently to ensure the best possible outcomes for patients, satisfaction for all customers, retention of talented staff and a good financial performance

(Leahy 1998)

Quality is excellence
Quality is value
Quality is conformance to specifications
Quality is meeting and exceeding customers expectations

'Even though quality cannot be defined, you know what quality is'

Robert M. Pirsig US Author (1928)

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Quality Dimensions

- Appropriateness
- Availability
- Competency
- Continuity
- Effectiveness
- Efficiency
- Safety
- Timeliness

JCAHO 2000

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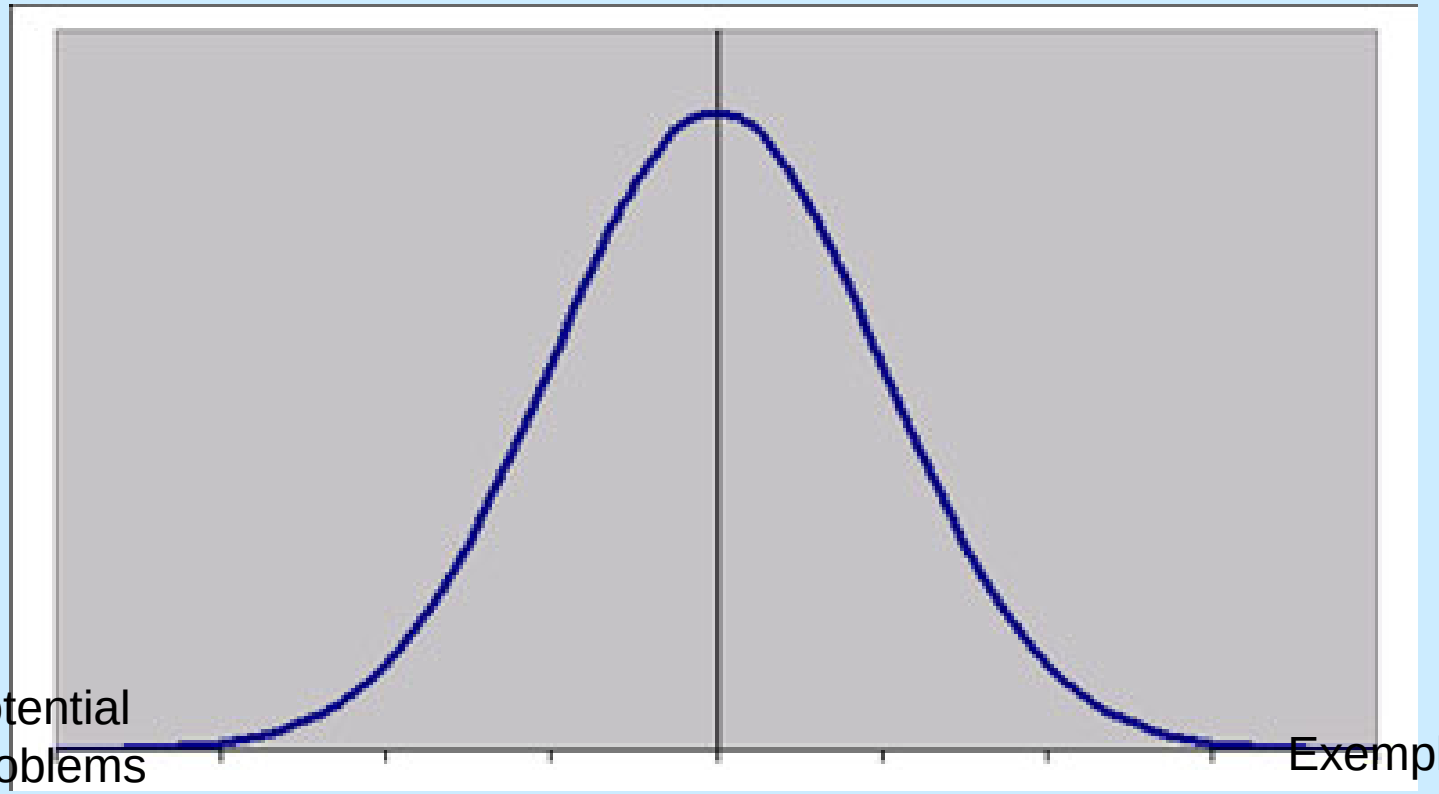
Change the Quality Curve

Average



Potential Problems

Exemplars

Quality

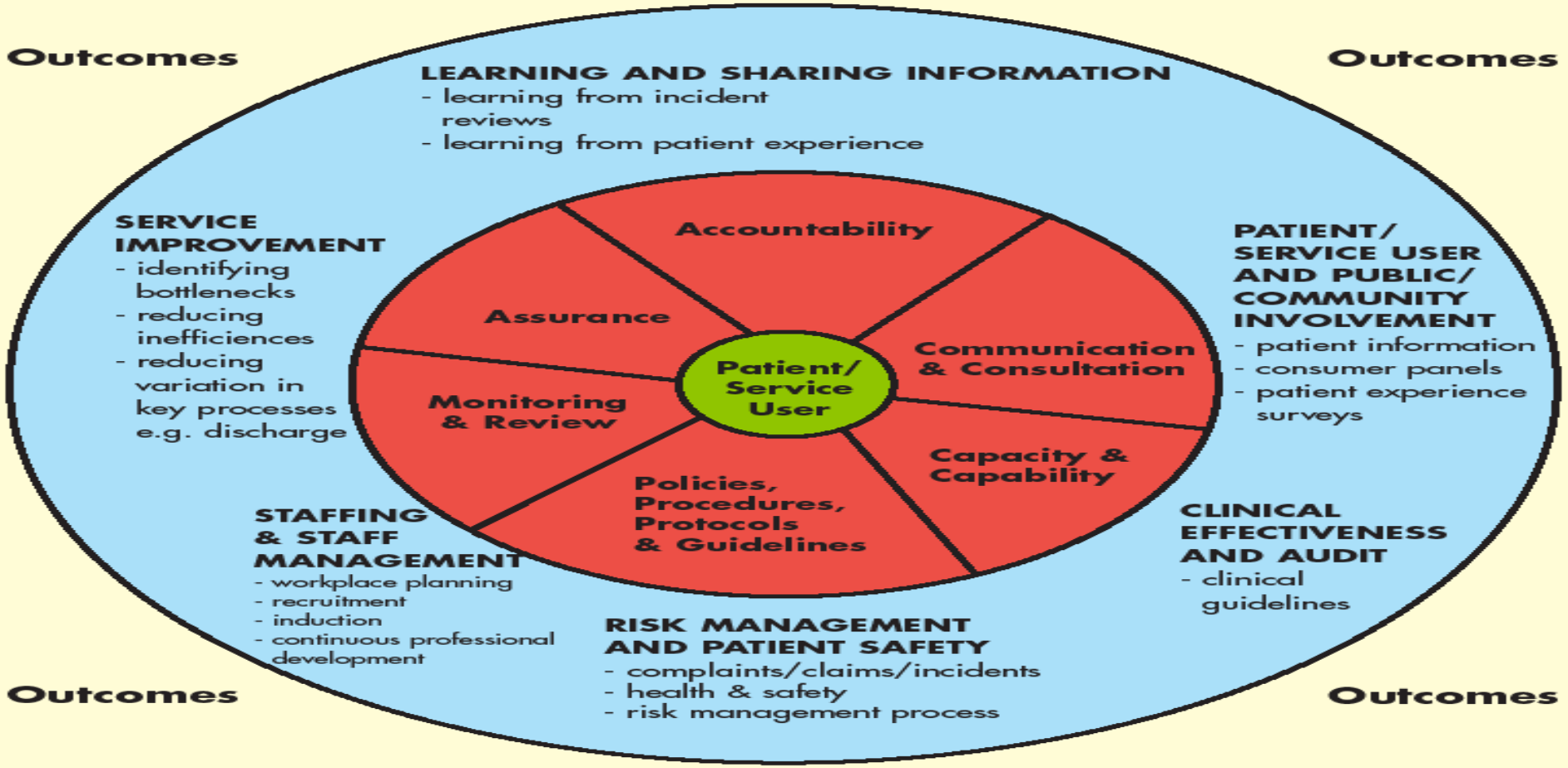
Quality

What is Continuous Quality Improvement (CQI)?

An integrated, corporately led programme of change, designed to engender and sustain a culture….based on customer oriented definitions of quality

Kogan et al 1994

Integrated Quality, Safety and Risk Framework



Essential Underpinning Requirements | Core Processes and Programmes | Outcomes

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Why Self Assess?

- Identifies what organisation is doing and how well they are doing it
- Allows team/organisation to consider their current situation and where they need to go
- Provides a framework for teams to ensure all aspects of care and service are included in their assessment
- Provides baseline from which to evaluate improvements
- Prepares organisation for Accreditation, Licensing etc.
- Provides assurance regarding adherence to National and International Law

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Historical View to Quality Improvement

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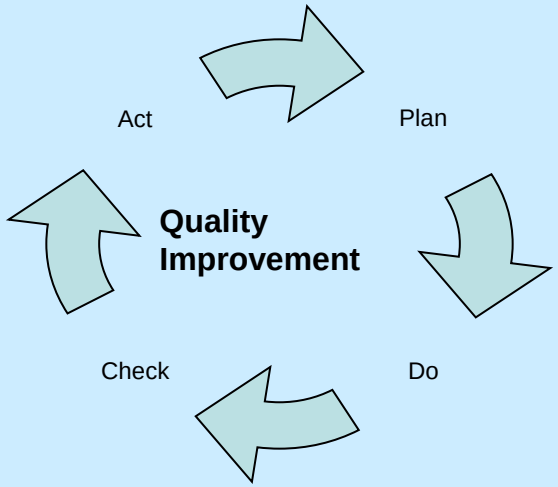
Quality Improvement Tools – systematic approach

PDCA



Plan: Plan the improvement and the data collection

Do: Do the improvement and the data collection

Check: Check the results of the implementation

Act: Act to hold the gain and continue the improvement

W. Edwards Deming

A quality improvement model based on four stages to ensure a structured approach to the improvement of quality

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Methodology for Quality Improvement Plan (QIP)

- Element 1 - Opportunity Statement (Plan)
- Element 11 - Action Plan (Plan)
- Element 111 - Timeframes for Implementation (Do)
- Element 1V - Monitoring (Check and Act)

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Key Performance Indicators (KPIs)

What is an Key Performance Indicator (KPI)?

Measurement used to help an organisation define and measure progress towards organisational goals

Parmenter, D, 2007

OECD Healthcare Quality Indicators (example)

Domain 1 – Hospital Acquired Infections

- No. of catheter-related bloodstream infections

Domain 2 – Operative and Post-operative complications

- No. of post-op pulmonary emboli and deep vein thrombosis
- **No. of post-op sepsis**
- No. of accidental punctures or lacerations

Domain 3 – Sentinel events (never events)

- No. of foreign bodies left in during procedure

Patient Safety

Risk Management

Proactive Risk Management – Risk Registers

Reactive Risk Management – Incident Management

What is **Proactive** Risk Management?

Work out what can go wrong and plan for the eventuality ….Spot a problem in the making and do something about it in advance

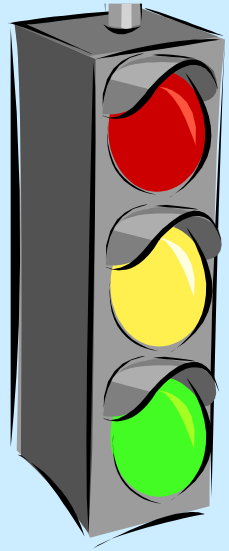
Proactive Risk Management

ISO 14971 –

- Published in 2007 (application standard)
- Represents the requirements for a risk management system for medical devices
- Establishes the requirements for risk management to determine the safety of a medical device during the product life cycle
- Required by MD regulation and the ISO 13485 standards.

What is a risk register?

A risk register is a database of risks that face an organisation its staff and service users at any time. Always changing to reflect the dynamic nature of risks and the organisation’s management of them.



Benefits of the risk register

- Systematic process
- Communication tool
- Assists with decision making
- Business/project planning

Making risk registers a useful tool

- Must be locally based and easy to use
- Must be multidisciplinary (development and management)
- Must be part of management arrangements and processes
- Must be reviewed and updated regularly

Describing the Risk

ICC approach

- Describe the primary area of Impact if the risk were to materialise.

- Describe the Causal Factors that could result in the risk materialising.

- Ensure that the Context of the risk is clear, e.g. is the risk ‘target’ well defined (e.g. staff, patient, department, hospital, etc.) and is the ‘nature’ of the risk clear (e.g. financial, safety, physical loss, perception, etc.)

Example of Risk

Threat to the integrity of the sterile reusable invasive medical devices (RIMD) leading to delays in the commencement of or cancelling of operative procedures from torn or damaged sterile set packaging due to compromised and restricted space in the sterile storage area.

Analysing the risk

- If this risk was to be managed effectively what controls would be required to be in place?
- What are the existing controls
- How effective are they
- Given the controls that are in place – how would you rate this risk?
- Are additional controls required? Y/N

Rating the Risk

Risk analysis can be a subjective process relying on the knowledge and experience of the person making the analysis.

Risk is analysed in terms of Likelihood (how likely is it to happen?) and

Impact (what is the likely harm that will occur if it does happen?)

In order to reduce subjective biases as far as possible and make the process more objective the HSE's Risk Assessment Tool should be used when analysing risk.

Rating the Impact

1. IMPACT TABLE	Negligible	Minor	Moderate	Major	Extreme
Injury	Adverse event leading to minor injury not requiring first aid.	Minor injury or illness, first aid treatment required <3 days absence < 3 days extended hospital stay Emotional Distress	Significant injury requiring medical treatment e.g. Fracture and/or counselling. Agency reportable, e.g. HSA, Gardaí (violent and aggressive acts). >3 Days absence 3-8 Days extended hospital Stay Emotional Trauma	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling Physical /emotional disability	Incident leading to death or major permanent incapacity. Event which impacts on large number of patients or member of the public (Emotional / Physical trauma)
Service User Experience	Reduced quality of service user experience related to inadequate provision of information	Unsatisfactory service user experience related to less than optimal treatment and/or inadequate information, not being to talked to & treated as an equal; or not being treated with honesty, dignity & respect - readily resolvable	Unsatisfactory service user experience related to less than optimal treatment resulting in short term effects (less than 1 week)	Unsatisfactory service user experience related to poor treatment resulting in long term effects	Totally unsatisfactory service user outcome resulting in long term effects, or extremely poor experience of care provision
Compliance with Standards (Statutory, Clinical, Professional & Management)	Minor non compliance with internal standards. Small number of minor issues requiring improvement	Single failure to meet internal standards or follow protocol. Minor recommendations which can be easily addressed by local management	Repeated failure to meet internal standards or follow protocols. Important recommendations that can be addressed with an appropriate management action plan.	Repeated failure to meet external standards. Failure to meet national norms and standards / Regulations (e.g. Mental Health, Child Care Act etc). Critical report or substantial number of significant findings and/or lack of adherence to regulations.	Gross failure to meet external standards Repeated failure to meet national norms and standards / regulations. Severely critical report with possible major reputational or financial implications.
Objectives/Projects	Barely noticeable reduction in scope, quality or schedule.	Minor reduction in scope, quality or schedule.	Reduction in scope or quality of project; project objectives or schedule.	Significant project over – run.	Inability to meet project objectives. Reputation of the organisation seriously damaged.
Business Continuity	Interruption in a service which does not impact on the delivery of service user care or the ability to continue to provide service.	Short term disruption to service with minor impact on service user care.	Some disruption in service with unacceptable impact on service user care. Temporary loss of ability to provide service	Sustained loss of service which has serious impact on delivery of service user care or service resulting in major contingency plans being involved	Permanent loss of core service or facility. Disruption to facility leading to significant 'knock on' effect
Adverse publicity/ Reputation	Rumours, no media coverage. No public concerns voiced. Little effect on staff morale. No review/investigation necessary.	Local media coverage – short term. Some public concern. Minor effect on staff morale / public attitudes. Internal review necessary.	Local media – adverse publicity. Significant effect on staff morale & public perception of the organisation. Public calls (at local level) for specific remedial actions. Comprehensive review/investigation necessary.	National media/ adverse publicity, less than 3 days. News stories & features in national papers. Local media – long term adverse publicity. Public confidence in the organisation undermined. HSE use of resources questioned. Minister may make comment. Possible questions in Daíl. Public calls (at national level) for specific remedial actions to be taken possible HSE review/investigation	National/International media/ adverse publicity, > than 3 days. Editorial follows days of news stories & features in National papers. Public confidence in the organisation undermined. HSE use of resources questioned. CEO's performance questioned. Calls for individual HSE officials to be sanctioned. Taoiseach/Minister forced to comment or intervene. Questions in the Daíl. Public calls (at national level) for specific remedial actions to be taken. Court action. Public (independent) Inquiry.
Financial Loss (per local Contact)	<€1k	€1k – €10k	€10 – €100k	€100k – €1m	>€1m
Environment	Nuisance Release.	On site release contained by organisation.	On site release contained by organisation.	Release affecting minimal off-site area requiring external assistance (fire brigade, radiation, protection service etc.)	Toxic release affecting off-site with detrimental effect requiring outside assistance.

Likelihood Scoring

2. LIKELIHOOD SCORING

Rare/Remote		Unlikely		Possible		Likely		Almost Certain	
Actual Frequency	Probability	Actual Frequency	Probability	Actual Frequency	Probability	Actual Frequency	Probability	Actual Frequency	Probability
May occur every 5 years or more	1%	May occur every 2-5 years	10%	May occur every 1-2 years	50%	Bimonthly	75%	At least monthly	99%

HSE Risk Matrix

3. RISK MATRIX	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
Almost Certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare/Remote (1)	1	2	3	4	5

Some more examples

- Infection control and potential damage to endoscopes during transportation
- Risk of harm to patients undergoing bronchoscopy in the endoscopy unit

Reactive Risk Management

Incident Management

- Identifying
- Reporting
- Investigating
- Implementing recommendations
- Sharing the learning

Procedure for managing incidents

HSE Incident Management Procedure (management)

- Regional Incident Report Form (in development)
- This form is to be completed **immediately** following an incident and is kept locally for local follow up and management

Serious Incident

Any incident which involved or is likely to cause extreme harm or is likely to become a matter of significant concern to service users, employees or the public.

Focus of work for reactive risk management

In response to customer complaints, undesired levels of internal non-conformity identified during internal/external audit, adverse incident, unstable trends.

Focus must be on:

- Decontamination risk assessment
- Systematic investigation of root cause of non-conformities

To prevent their recurrence (corrective action) or prevent occurrence (preventive action) – as discussed in Proactive Risk Management.

Area Quality and Patient Safety (QPS) Committees - membership

- Chaired by the Area Manager
- Membership from Hospital(s) – CEO, GM, CD or Chair of Hospital QPS committee
- Membership from Community – GM or Chair of Community QPS Committee
- Membership from ALL Care Groups – Managers from Child Care, Disability, Mental Health (CD), DON representative from Community Hospital (Older Person), also membership from Ambulance, Health & Safety (if not already sitting on Hospital or Community QPS committees)

Any Questions or Discussion?