

# Implications of Regulation of Health Care Professionals from a “Governance” point of view

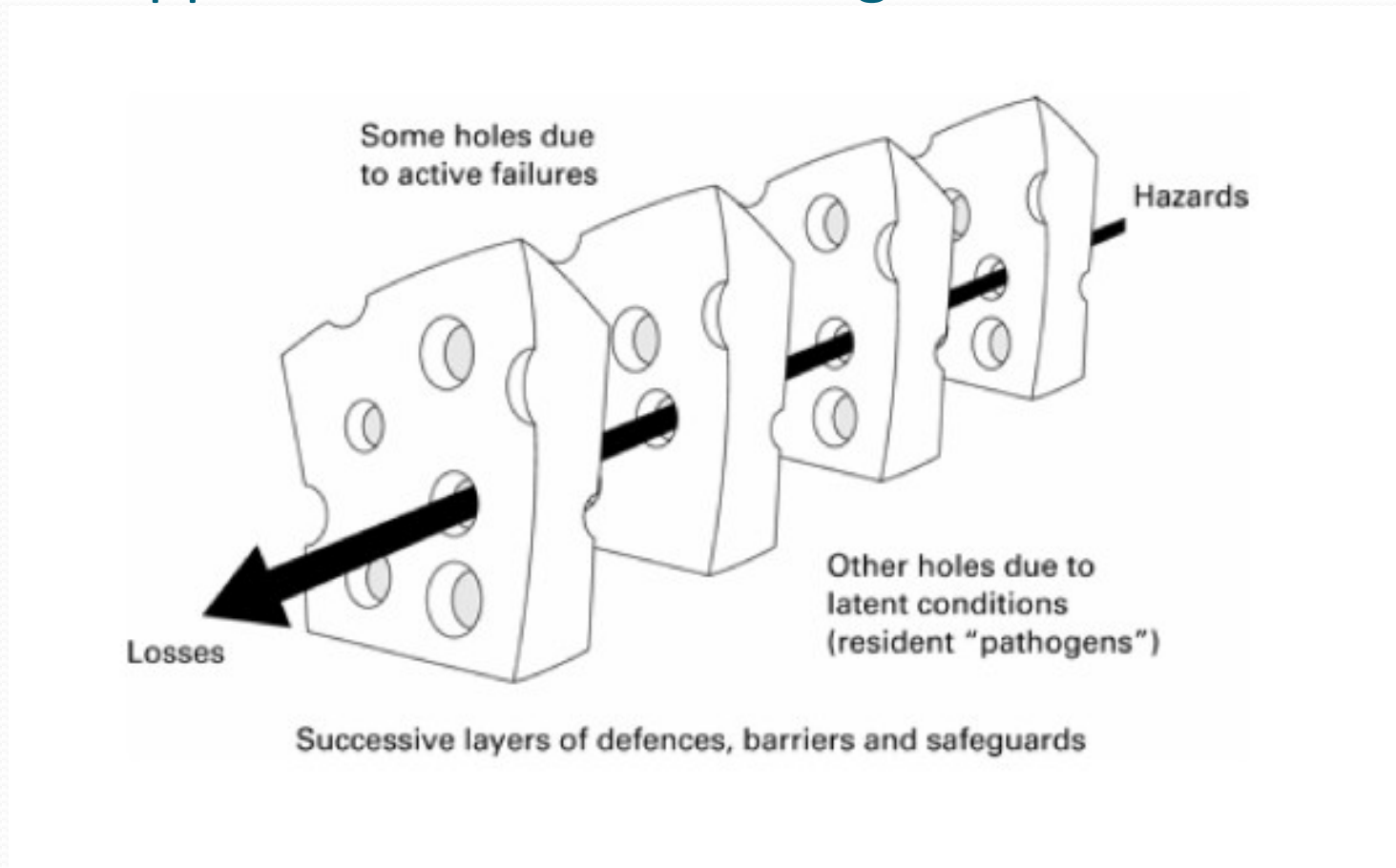
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# Risk Management:

James Reason's Swiss Cheese Model of critical incidents can be applied to current challenges



# Key Activities of Regulators

- Direction
  - Set out expectations and requirements
- Surveillance
  - Performance and compliance with rules
- Enforcement and Change
  - Legal and other powers including Investigation

*(“Building a Culture of Patient Safety”-Report of the Commission on Patient Safety and Quality Assurance, July 2008)*

# Principles of Effective Regulation

- Necessity/Risk Assessment
- Effectiveness/Targeted
- Proportionate
- Transparency and Accountability
- Consistency/Continuous Improvement

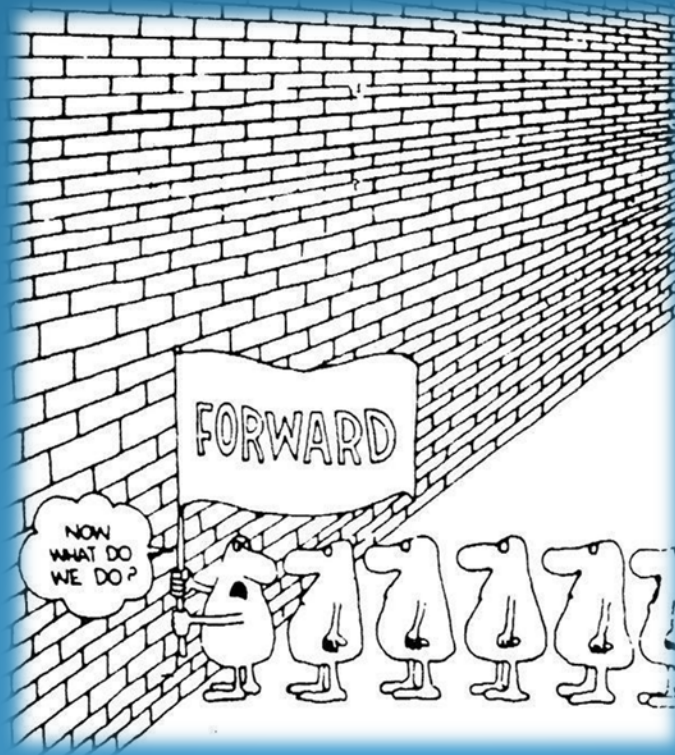
Not Light-Touch But Right-Touch Regulation

*(CHRE June 2010)*

# Standards

- Best practice/Best models/Protocol based
- Minimum output consistent with maintenance of expertise, quality and best outcome
- Performance measurement
  - Pre-defined standards
  - Review of organisational structures and processes
- Adoption of new systems and technologies
- Building a culture of patient safety

# The Challenges to Regulators



# Reports on Adverse Events in the EU

- The Kennedy Report from the Bristol Royal Infirmary Inquiry (UK)
- Dame Janet Smith's Reports on Dr. Harold Shipman (UK)
- Judge Maureen Harding Clark's Report on Our Lady of Lourdes Hospital Drogheda (Ireland)
- Report from HIQA on the provision of care to Ms. Rebecca O'Malley in relation to her treatment for symptomatic breast cancer (Ireland)

# Policy Response

- Patient safety and quality authorities and Institutes with involvement of professional bodies
- Prioritising clinical excellence and clinical risk management
- Public reporting on sentinel events and incident reporting systems
- Engaging with CEOs, service providers, senior managers, patients, their carers and advocates

- Mandatory licensing systems for pharmacies – the Pharmacy Act 2007
  - Hospitals/Hospital facilities
  - All other health care facilities to follow
  - Service specific licences
    - ❖ Intensive care
    - ❖ Cancer care
    - ❖ Pharmacy care and treatment
- Review every 3-5 years



- Intervention by Regulators

- To improve quality of care
- To set standards of clinical competence for practice
- Fostering CPD and practice excellence
- Assuring the competence of the individual practitioner and the clinical team or network
- Political/Public and patient reassurance

*(Sutherland and Leatherman 2006 and “Building a Culture of Patient Safety”-Report of the Commission on Patient Safety and Quality Assurance, July 2008)*

# Meeting the challenges

- Registration and Licensure
- Certification and Re-Certification
- Credentialing
- Privileging

*(Sutherland and Leatherman 2006 and “Building a Culture of Patient Safety”-Report of the Commission on Patient Safety and Quality Assurance, July 2008)*

# Registration and Credentialing

- EU based Directives on qualification recognition
- EU Commission and Parliament focussing on patient safety
- Systematic collection and verification of qualifications
- Use of patient and clinical data
- Practitioners of assessed quality

*(Calebrase et al 1997 and “Building a Culture of Patient Safety”-Report of the Commission on Patient Safety and Quality Assurance, July 2008)*

# Privileging and Extended Practice

- Allows certain high risk procedures
- Compliance with standards is essential
- Expert review of experience
- Specific categories of care and treatment
- Outcomes of care and treatment
- Conclusions from quality assurance activities

(“Building a Culture of Patient Safety”-Report of the Commission on Patient Safety and Quality Assurance, July 2008)

# Regulators Sharing and Working Together with Policy Makers and Service Providers in the Public Interest



# All Regulators

- Patient and public interest first
- Promoting best clinical practice
- Supporting Evidence-Based Policy Making
- Working together with all stakeholders
- Supporting high quality IT solutions
- Patient held E-records/company e-records

# Effective Risk Management

- Credentialing
- Review track record/reporting a risk
- Registration and specialisation
- Liability/disciplinary record
- EU and international collaboration

*(Calabrese et al 1997)*

# Irish Policy Responses – Health Sector

- New robust regulatory regimes for pharmacists, doctors, nurses and health and social care professionals and others to follow
- Health Information, Quality and Standards Authority → Patient Safety Authority (new government)
- New regulatory forum to facilitate and support health regulators working together

# Opportunities

- Supporting and expanding homecare and self-care
- Improving accessibility and high quality interventions
- Pharmacist led services
  - Chronic Disease Management
  - Mental Health interventions
  - Paediatric Care interventions
  - Immunisation and vaccination programmes
  - Medication reviews

# Governance - CEOs

- Clarity Essential

“The CEO has the primary responsibility for ensuring effective Risk Management Structures, systems and processes are in place”.

# Governance - CEOs

- CEO's authority and accountability
- CEO's delegation with Board approval to clinical directors and lead clinicians
- Authority and accountability of clinical leads
- Risk management is for everybody
- CEO and clinical leads and management teams will be held accountable in future
- Maintenance of collective competence

# Governance and Boards

## Clear lines

- Explicit comprehensive governing values
- Policy making that is evidence based
- Risk Management – holding to account the CEO and Senior Clinical Managers/Leads
- CEO's Responsibility is to whole Board to preserve the integrity of governance
- Board has a primacy in respect of Patient Safety and Public Protection.

# Effective Regulation = Patient Safety + Public Protection = Protection for all in society

Safe Pilot

Safe Crew

Safe Aircraft

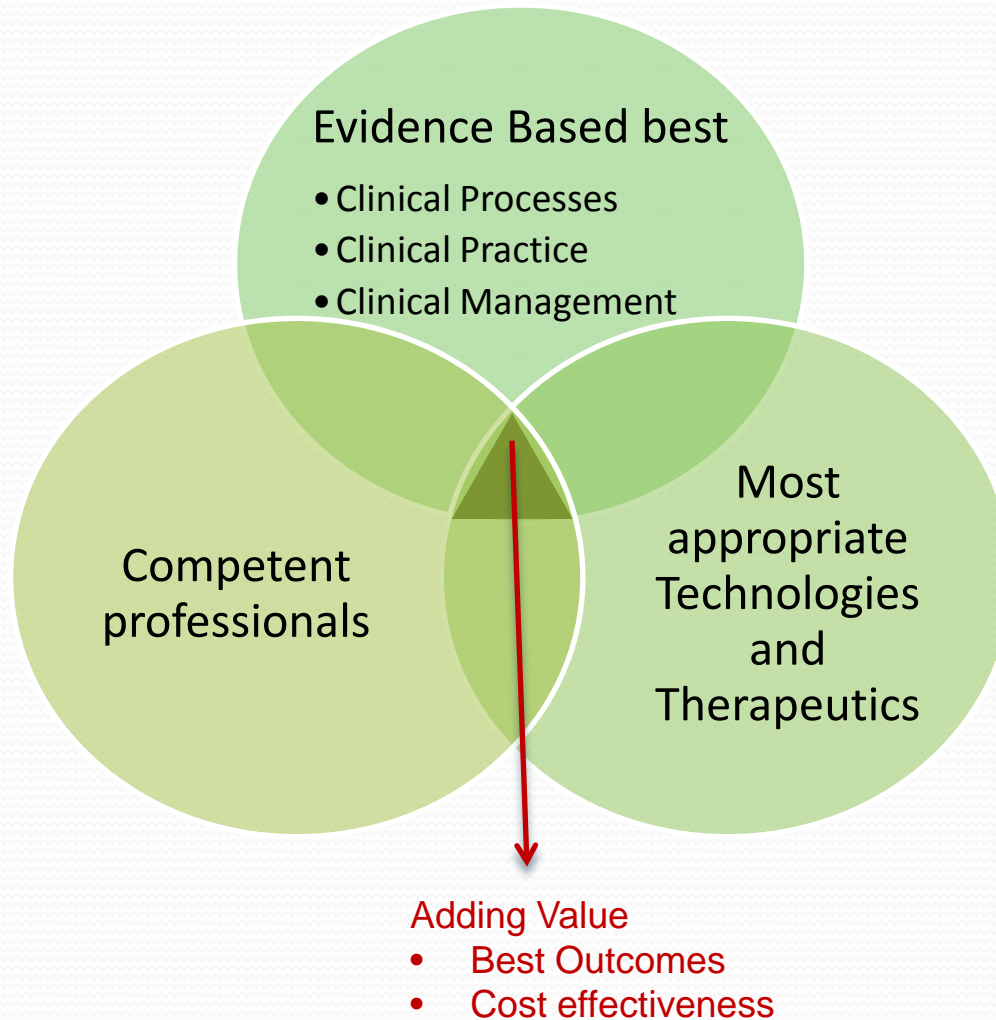
Safe Air Space

Safe Cargo

Safe Ground Space



# Clinical Governance



# Thank You for Your Attention!

## Questions?

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