Managing the Regulators – The Medical Director's Dilemma

Ian C Martin

THE FACE OF SURGERY

British Association of Oral and Maxillofacial Surgeons

Overview

The Changing Regulatory Enforcement Picture

- The law
- CQC
- HSE
- NHSI
- NHSE
- GMC/GDC
- Commissioners
- Coroner (Rule 28)

Medical Director Roles

- Executive Board Director
- Trustee
- Consultant
- GMC Responsible Officer
- DIPC
- Responsible for Education
- Responsible for Research
- Responsible for Clinical Governance
- Collective Responsibility for Performance & Finance
- Professionally responsible for medical staff (discipline)

The Law

Organisations	Individuals
Corporate Manslaughter	Gross Negligence Manslaughter
s.2 & 3 Health and Safety at Work Act 1974 (HSWA)	s.7 and 37 HSWA
Ill-treatment and wilful neglect	Ill-treatment and wilful neglect
Health and Social Care Act 2008 (Regulated Activities) Regulations 2014	

Corporate Manslaughter

- The way in which an organisation's activities are managed or organised:

- Causes a person's death
- Amounts to a gross breach of a relevant duty of care

- An organisation is guilty of an offence if the way in which its activities are **managed or organised** by **its senior management** is a **substantial** element in the breach.

Who falls within "senior management"?

- "Senior management" means the persons who play a significant role in:

- The **making of decisions** about how the **whole or a substantial part** of its activities are to be **managed or organised**; or
- The **actual managing or organising** of the **whole or a substantial part** of those activities.

CEO

Other Executive Directors

Group Directors

Directorate Managers

Service Managers

Gross Negligence Manslaughter

Gross breach

- Matter for a Jury to consider
- Must be proved beyond all reasonable doubt
- Jury considerations include:
  - How serious was the failure?
  - How much of a risk of death was posed?
  - Were there attitudes, policies, systems or accepted practices that encouraged the failure?
  - Is there any relevant health and safety guidance?

Ill Treatment and Wilful Neglect

- Criminal Justice and Courts Act 2015
- In force since 13 April 2015
- “small but significant gap” in existing legislation
- Individual and organisational offences
- Mirrors structure of Corporate Manslaughter legislation

Care worker offence

- Section 20

- "It is an offence for an *individual who has the care of another individual* by virtue of being a *care worker* to *ill-treat or wilfully neglect* that individual" (s20(1))

Care provider offence

- Section 21(1) - a care provider commits an offence if:
  - An individual who has the care of another individual by virtue of being part of the care provider's arrangements, ill-treats or wilfully neglects that individual
  - The way in which care provider's activities are managed or organised amounts to a gross breach; &
  - In the absence of that gross breach by the care provider, the ill treatment or neglect to the individual would not or would have been less likely to occur

Penalties

Offence	Penalty
Corporate Manslaughter	Unlimited fine Publicity Order / Remedial Order
Gross Negligence Manslaughter	Unlimited fine Life imprisonment
Breach of HSWA (and regulations)	Unlimited fine 2 years imprisonment
Ill treatment/Wilful neglect	Unlimited fine Publicity Order / Remedial Order 5 years imprisonment

The changing role of the CQC

Role of CQC

- “we monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety”
- "In future, if we find that a care provider has put people in its care at risk of harm, we will always consider using those powers to the full to prosecute those who are responsible".

CQC as Enforcement Body

- A service user falling from a window
- Scalding
- Improper treatment not in line with care plan resulting in serious harm or death
- Service user receiving inappropriate food and suffering harm
- Injury caused after being physically restrained
- The ill treatment or wilful neglect of a service user

Potential offences

Regulation	Requirement
11	Need for consent
16(3)	Providing details of complaints to the CQC
17(3)	Providing governance information to the CQC
20(2)(a)	Duty of candour
20(3)	Duty of candour
20A	Display of performance ratings
12	Safe care and treatment
13	Safeguarding service users from abuse and improper treatment
14	Meeting nutritional and hydration needs

Safe care and treatment

In order to comply with regulation 12 the RP must:

- Assess risks to the health and safety of service users
- Do all that is reasonably practicable to mitigate risks
- Ensure persons providing care and treatment have the qualifications, competence, skills and experience
- Ensure premises are safe for the intended purpose
- Ensure equipment used is safe
- Proper and safe management of medicines
- Assess risk of and prevent and detect spread of infection.

Regulation 12 - Defence

- Regulation 22(4)
- Registered Person took all reasonable steps and exercised all due diligence to prevent the breach.
- Burden of proof on RP to demonstrate the defence.

Penalties

- Organisation – unlimited fine
- Individuals – unlimited fine

CQC Case Law

Southern Health NHS Foundation Trust

- The first NHS Trust to be prosecuted by CQC
- Incident in December 2015
- MH patient injured after falling from a roof he had climbed onto in the courtyard of a psychiatric unit in Winchester.
- Several other patients had climbed onto the same roof in an attempt to abscond, both before and after the fall incident
- CQC issued warning notice relating to governance arrangements and response to safety concerns raised by patients and staff.
- Further CQC inspection in September 2016.

Southern Health NHS Foundation Trust

- Very obvious risk that existed for some time.
- Building works were not carried out because money was not available.
- Full credit for early guilty plea
- Evidence of a "real sea change" in governance
- Public status of defendant taken into account

- £125,000 fine plus £36,000 costs

Joseph Rowntree Housing Trust

- Convicted for failure to provide safe care and treatment
- Resident suffered fatal injuries after falling from his bed in August 2015
- Previous safety incidents and concerns raised by CQC
- Registered Provider pleaded guilty in April 2017
- Fined £150,000 plus prosecution costs of £13,000.

St Anne's Community Services

- Convicted for failure to provide safe care and treatment
- Disabled service user suffered fatal injuries after tipping from a shower commode.
- Incident in April 2015
- Provider pleaded guilty in June 2016
- Fined £190,000 plus £16,000 prosecution costs

Responding to the new enforcement regime

External Guidance

- HSE
  - HSG 65 “Managing for health and safety”
- Institute of Directors
  - “Leading health and safety at work”
- CQC
  - “Driving improvement – case studies from eight NHS Trusts”
  - “Learning, candour and accountability – a review of the way NHS Trusts review and investigate deaths of patients in England”

Well – Led Inspections

- Annual inspection of leadership and organisational culture of providers
- Specific “well led” report and rating applied
- Focus on quality and effectiveness of:
  - Leadership
  - Management
  - Governance

  at every level of the organisation

Key Inspection Themes

- Quality of leadership
- Managing cultural change
- Engagement with staff at all levels
- Authenticity of vision and values
- Effectiveness of governance processes
- Focus on safety and quality of experience
- Patient and public involvement
- Level of CQC engagement

Questions to consider

- Have we got a strategy?
- What are our priorities?
- How are we approaching quality and safety?
- Are we building relationships with staff?
- What partnerships have we got to support what we do?
- How is our performance?
- What is our public perception?

The Way Forward

Investigations and Enforcement

- Increased Police and CPS involvement
- Wilful neglect?
- Focus on leadership and governance issues
- Investigations becoming more rigorous
- CQC enforcement activity on the increase
- Increase in number of prosecutions
- Penalties have increased significantly
- More complex relationship between Trust and CQC

HSE

Shropshire hospital trust fined £300,000 for patient death falls

By Lisa O'Brien | Health | Published: Nov 29, 2017

> The trust that runs Shropshire's two main hospitals has been fined more than £300,000 for failing to ensure the safety of five elderly patients who suffered falls and later died.

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lford's Princess Royal Hospital

Shrewsbury and Telford Hospital NHS Trust admitted failing to ensure the safety of the five elderly people following a prosecution brought by the Health and Safety Executive.

NHSI

Single Oversight Framework (SOF)

- **Quality (safe, effective, caring, responsive)**
- **Finance and use of resources**
- **Operational performance**
- **Strategic change**
- **Leadership and improvement capability (well-led)**

Single Oversight Framework (SOF)

- help more providers achieve CQC ‘good’ or ‘outstanding’ ratings
- reduce the number of providers in special measures for quality
- help the sector achieve aggregate financial balance
- help providers meet NHS Constitution standards, with a particular focus on the aggregate accident and emergency (A&E) standard.

NHSI

Monitoring → Identifying support needs → Support decision and segmentation → Support activity

Monitoring	Identifying support needs	Support decision and segmentation	Support activity
Focus is on actual performance and, where possible, early warning	Focus is on identifying whether a provider has any support needs, and if so what type, level and intensity of support is required	Focus is on confirming the proposed level of support and assigning the provider to a segment accordingly	Focus is on coordinating a tailored support package relevant and proportionate to a provider's circumstances

NHSI Monitoring

	In-year	Annual/ less frequently	By exception[1]
Quality of care	In-year quality information to identify any areas for improvement (see Appendix 1)	Annual quality information	Results of CQC inspections CQC warning notices, fines, civil or criminal actions and information on other relevant matters
Finance and Use of Resources	Monthly returns	Annual operational plans Information relating to Use of Resources (UoR) assessments	One-off financial events (eg sudden drops in income/ increases in costs) Transactions/mergers
Operational performance	Quarterly/monthly/weekly operational performance information (see Appendix 3)		Any sudden and unforeseen factors driving a significant failure to deliver
Strategic change	Delivery of Sustainability and Transformation Plans (STPs) Progress of any new care models, devolution plans	Sustainability and Transformation Plans	Any sudden and unforeseen factors driving a significant failure to deliver
Leadership and improvement capability	Third-party information with governance implications[2] Organisational health indicators - staff absenteeism - staff churn - board vacancies	Staff and patient surveys Third-party information with governance implications[2]	Findings of well-led reviews and developmental well-led reviews Third-party information with governance implications[2]

Responsible Officer

Protecting patients, supporting professionalism, improving quality: addressing concerns about medical practice

A practical guide for the responsible officer

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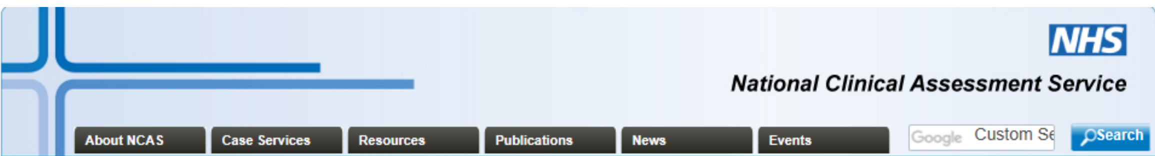
NCAS

IRM

GMC ELA

MHPS and NHSE Guidance



Bringing expertise to the resolution of concerns about professional practice

Who we are

The National Clinical Assessment Service (NCAS) has been an operating division of NHS Resolution (the operating name of NHS Litigation Authority, [NHS LA]) since 2013.

We are in the process of replacing the current NCAS and NHS LA websites with a new user-orientated website going live on resolution.nhs.uk in early 2018.

NCAS contributes to patient safety by helping to resolve concerns about the professional practice of doctors, dentists and pharmacists. We provide expert advice and support, clinical assessment and training to the NHS and other healthcare partners.

NCAS is changing many of its ways of working and this will affect the services we provide. The information on this website is a guide but please contact us about accessing specific services and discuss your needs with our advisory team. Most of our services are currently free of charge to the NHS.

- Contact us
- Our partners

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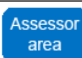

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RCS Invited Reviews

Support rather than replace local Trust management systems for surgeons/surgical services through:

- Case note reviews
- Individual reviews
- Service reviews

How we undertake our reviews

Request
- CEO or MD
- Approval by College/ specialty
- Terms of reference and indemnity
- Review planning

Review
- 2 Clinical Reviewers
- 1 Lay reviewer
- 1 RCS Review Manager
- 2-3 days
- Interviews and documentation

College support for reviewers
- Recruitment and training
- Planning/Visits/Reports
- Quality assurance
- Dedicated staff support

Report
- Team produces report
- Recommendations
- Quality control via IRM committee input
- Handed to Trust – Trust property

Monitoring
- 1 - 6 month follow up
- Take action if recommendations are not acted on

General Medical Council

Working with doctors Working for patients

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- **Information for employers**

You are here: Home > Registration and licensing > Information for employers > **Employing a doctor**

Employing a doctor

This page is to help employers to understand their obligations relating to employing and contracting with doctors.

Registration and licensing

Pre-employment checks

What to check

GMC reference numbers

Checking a doctor's identity

Employing a doctor with restrictions on their practice

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GMC ELA

- **Employer Liaison Service**
- The ELS creates closer working relationships between the GMC and employers.
- Establish good links with ROs and their teams to support two way exchange of information about under performing doctors
- Share our data about under performing doctors, including regional trends
- Help ROs understand GMC thresholds and procedures
- Support ROs and employers in relation to revalidation

MAINTAINING HIGH PROFESSIONAL STANDARDS IN THE MODERN NHS

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MHPS

- Part I: Action when a concern arises; and
- Part II: Restriction of practice and exclusion
- Part III: Conduct hearings and disciplinary matters;
- Part IV: Procedures for dealing with issues of capability;
- Part V: Handling concerns about a practitioner’s health.

Summary

- Complex and overlapping regulatory structures
- Medical Directors have multiple roles
- There is a degree of conflict between some roles
- Over-riding priority must be clinical quality and safety

Questions