

Investigations and Regulatory Inquiries

Getting incident investigations wrong will be a major problem for any health and care organisation. As the criminal and regulatory burden increases, putting patient safety first, proof of learning and auditing of action plans are essential to good governance. But, it's more than that. It's vital that reports are evidence based and produce meaningful and practical recommendations and solutions. This subject could not be more topical.

Recent developments mean a lot of changes for providers

- The Morecambe Bay Investigation report
- The House of Commons Public Administration Select Committee report on investigating clinical
- The publication of the report of the Independent Review of Children's Cardiac Services in Bristol
- NHS England's Serious Incident Framework
- Health Foundation's learning report on continuous improvement in patient safety
- The first prosecution of an NHS Trust for corporate manslaughter
- Mazars' report
- The creation of the Healthcare Safety Investigation Branch
- The statutory duty of candour and the criminal incidents in the NHS offences attached
- Proposals due to take effect in April 2017 that there is a single board level lead for deaths in care (Jeremy Hunt is thinking of the Medical Director and a NED).
- DH consultation on "Safe Space"
- CQC's report on Learning, Candour and Accountability

Mills & Reeve have the experience to help you perform better

We have been supporting health and care clients with inquiries and investigations in all settings for over 30 years.

Acute	Low/medium secure mental health	High secure mental health	Prison	Community services
-------	---------------------------------	---------------------------	--------	--------------------

Our experience allows us to develop novel approaches, to analyse multiple points of view, to challenge assumptions and to inject an appropriate level of challenge. In short we stand shoulder to shoulder with our clients as you look to deliver and create safety and best practice across the health and care system.

How can we help?

- Bespoke, practical advice
- Helping deliver on patient safety first
- Responding to an approach by regulators or the Police
- Proactive steps to prevent enforcement action
- Construct a thorough defence, if prosecuted, or to present the most effective mitigation, to minimise the penalties

Training

We run bespoke training for senior staff, managers and investigators to ensure you have the relevant tools to hand to produce meaningful, evidence based investigations reports, and conclusions with deliverable recommendations

Conducting the investigation

- Ensuring compliance with NHS England's Serious Incident Framework
- Advising investigators or conducting the investigation on your behalf
- Ascertaining your status, risk and the investigation's scope and terms of reference
- Liaising with patients and families – noting and investigating relevant concerns
- Identifying immediate issues
- Advising on duties of candour
- Ensuring all relevant documents are preserved
- Protect non-disclosable (e.g. privileged) documents
- Identifying relevant witnesses
- Collecting evidence and undertaking full 'forensic' analysis
- Evidence-based conclusions with meaningful recommendations and timescales
- Agreeing appropriate channels of communication and providing updates
- Drafting conclusions and recommendations in partnership with you
- Reviewing draft SI reports

- Production of final report suitable for publication and putting patient safety at its heart

Staff interviews

- Employees may be nervous about the prospect of attending an interview. We will:
- Agree approach for making contact
- Familiarise our team with your culture
- Keep our interview team to the minimum practical size
- Be clear about our role, the purpose of the interview and provide support
- Give time and support in reviewing and approving evidence

Additional services

- Review factual and legal analysis with respect to potential offences, defences and penalties
- Support inquests and coronial inquiry
- Manage communication and negotiations with CQC, commissioners, HSE, Coroners, police or prosecutors

Case studies

- Designing and implementing incident management processes and training for a mental health provider. This led to improved safety, lower risk and better accountability.
- Assisting with investigation and liaison with regulators and stakeholders in connection with historic allegations of "inappropriate conduct" by health and care staff against patients
- We were appointed adviser to the independent review into children's cardiac services in Bristol.
- Advising two key parties throughout the Mid Staffs Public Inquiry
- Inquiries into historic deaths of patients following 'medication issues' in the 1980s and 1990s
- Advising an independent healthcare provider on allegations of inadequate and dangerous services highlighted by the front pages of the national press.



Key contacts

- Advising on terms of reference and conduct of inquiry into the death of a prisoner with mental health problems following physical and chemical restraint.
- Helping a hospital with an international reputation following deaths of a patient and a consultant and concerns about controlled drugs. We uncovered the facts, revised processes and advised on personnel changes. We gave a full account to coroners and regulators, whilst avoiding press attention
- Assisting hospitals on responses to the Jimmy Savile inquiries.
- Investigations and enforcement actions in other sectors - for example financial services.
- Investigation of a patient death following a 'never event' including liaison with the police and regulatory bodies.



Jill Mason
Partner and Head of Health & Care
 T +44(0)121 456 8367
 jill.mason@mills-reeve.com

Jill leads our healthcare and mental health law practice nationally. With day to day director and Board level contact, Jill understands, first hand, the pressures you are under. She is a highly respected adviser.

- Led the team representing Professor Sir Ian Kennedy and Anna Walker at The Mid Staffs Inquiry.
- Key adviser for a Trust where our team recently conducted a full scale investigation.
- Delivers risk identification, ownership and management workshops
- Speaks at national events, e.g. for NHS Confederation Mental Health Network



Stuart Knowles
Consultant
 T +44(0)121 456 8461
 stuart.knowles@mills-reeve.com

A former coroner and BBC journalist, Stuart is one of most experienced healthcare lawyers, with a particular specialism in investigations and inquests.

- Lectures on the conduct of investigations including to the International Association of Medical Regulatory Authorities
- Conducts serious incident investigations producing evidence based conclusions and practical solutions.
- Advises on reputation and media implications



Katrina McCrory
Principal Associate
 T +44(0)121 456 8451
 katrina.mccrory@mills-reeve.com

- Represented the Chair and CEO of the Healthcare Commission in the Mid Staffordshire NHS Foundation Trust Public Inquiry.
- Appointed as solicitor to the independent review into children's cardiac services in Bristol



Eric France

Partner

T +44(0)20 7 648 9295

eric.france@mills-reeve.com

Eric brings commercial experience to the team. Eric has first-hand experience helping clients handle regulatory investigations and enforcement action brought by the Financial Conduct Authority and other regulators.

- Supported RBS in the FCA review into the failure of RBS' computer systems and in relation to subsequent enforcement and litigation.
- Helped conduct an internal investigation by the Conservative Party into allegations of bullying and harassment in the party's youth wing, Conservative Future.



Jo Newport

Senior Paralegal

T +44(0)121 456 8203

jo.newport@mills-reeve.com

Jo is a key part of our investigations team. Jo's work involves research, meeting and supporting witnesses, preparing statements and documents and managing liaison with clients.

