

Memorandum of Understanding

The Care Quality Commission and Healthcare Safety Investigation Branch (HSIB)

Introduction

1. This Memorandum of Understanding (MoU) sets out the framework to support the working relationship between the Care Quality Commission (CQC) and HSIB, to promote the safety and wellbeing of the public receiving NHS funded health and social care in England. It is intended to inform members of staff about how the CQC and the HSIB will work together, and to ensure that effective channels of communication are maintained. The working relationship between CQC and the HSIB supports the maintenance of a regulatory and safety improvement system for health and adult social care in England that promotes patient safety and high-quality care.
2. CQC is the independent regulator of health and social care in England. Its purpose is to make sure health and care services provide people with safe, effective, compassionate, high-quality care and to encourage them to improve. CQC was established under the Health and Social Care Act 2008. CQC is independent but reports to Parliament through the Department of Health and Social Care. CQC works with other regulators, local authorities and commissioning groups, health and social care organisations, and organisations that represent people who use services, including the Healthwatch network.
3. HSIB is a safety investigation body established under the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 and the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018. The HSIB was set up to discharge the Secretary of State duties in relation to the promotion of a comprehensive health service and securing continuous improvement in the quality of services.
4. The responsibilities and functions of CQC and HSIB are set out in Annex 1. Both organisations seek to encourage and promote patient safety and quality within healthcare settings.
5. This MoU does not override the statutory responsibilities and functions of CQC and HSIB and is not enforceable in law. However, CQC and HSIB are committed to working in ways that are consistent with the principles of this MoU.

Principles of Co-operation

6. This MoU is a statement of principle which supports our focus on promoting patient and public safety and wellbeing. More detailed operational protocols and guidance can be developed as required.
7. CQC and HSIB intend that their working relationship be characterised by the following principles:
 - a. The need to make decisions which promote people's safety and encourage high-quality health and social care.
 - b. Respect for each organisation's independent status.
 - c. The need to maintain public and professional confidence in the two organisations and the regulatory process.
 - d. Openness and transparency between the two organisations as to when co-operation is and is not considered necessary and/or appropriate.
 - e. Addressing gaps in the regulatory framework via safety recommendations.

Areas of Co-operation

8. The working relationship between CQC and HSIB involves co-operation in the following areas:
 - a. To act in the public interest by sharing data and information of concern relating to patient safety and any other information it considers relevant (having regard to the list below) relating to the safety and quality of services to inform the regulatory functions of CQC through its inspection, registration and monitoring of providers of independent healthcare and the remit of HSIB relating to systemic safety investigations.
 - b. Where the CQC or HSIB encounters concerns which, it believes may fall into the remit of the other, they will raise these concerns at the earliest opportunity. This must not go against requirements set out for each organisation in either legislation or Secretary of State Directions.
 - c. Each party will be responsible for its own negligent acts or omissions.
9. Consideration of information should include but is not exclusive to:
 - a. Sharing information on how each organisation works to promote better cooperation.
 - b. Sharing information by the CQC on the safety performance of healthcare providers that are relevant to HSIB investigations.
 - c. Sharing information regarding serious, continuing risk to patient safety whilst respecting the safe space principle.
 - d. Sharing evidence of emerging themes which may be indicative of a wider safety issues across specific sectors of NHS funded care.
 - e. Co-operation between HSIB and CQC on national, thematic and other reviews that relate to safety.

- f. Sharing pre-published HSIB investigation reports and recommendations. To be open and transparent when in receipt of information regarding the safety of services that are registered with CQC and funded by the NHS in England. The information is shared with the CQC in a timely way through the named CQC contact or by a representative delegated by them.
- g. To share data that has been agreed on a regular, timely and ongoing basis.

10. CQC and HSIB recognises their responsibilities under the Freedom of Information Act 2000. Where CQC or HSIB receives a request under the Act for information received from the other organisation CQC and HSIB agrees to take reasonable steps to consult on the proposed disclosure and the application of exemptions but recognise that the responsibility for disclosure lies with the organisation that received the request.

Resolution of Disagreement

11. Where there is disagreement between CQC and HSIB, this should be resolved in the first instance at working level. If this is not possible, it may be referred through those responsible for the management of this MoU, up to and including Chief Executive of the CQC and Chief Investigator of HSIB who will then be jointly responsible for ensuring a mutually satisfactory resolution.

Duration and Review

12. This MoU commences on the date of the signatures below. The MoU will be reviewed every two years or when changes to either party's legislation or Directions. It will also be reviewed if the principles described above need to be altered and/or cease to be relevant for any other reason. Any alterations to the MoU will require both parties to agree.

13. Both organisations have identified a person responsible for the management of this MoU (known as 'Relationship Leads') and their contact details are set out in Annex 2. Relationship Leads will liaise as required to ensure that:

- a. This MoU is kept up to date;
- b. They identify any emerging issues in the working relationship between the organisations;
- c. They resolve any questions that arise regarding the interpretation of this MoU.

Signatures



Ian Trenholm
Chief Executive
Care Quality Commission
Date:



Keith Conradi
Chief Investigator
HSIB
Date: 10.03.19

Annex 1: Responsibilities and functions

Care Quality Commission

CQC is the independent regulator of health and adult social care in England. Its purpose is to make sure health and care services provide people with safe, effective, compassionate, high quality care and to encourage them to improve.

CQC does this by registering, monitoring, inspecting and regulating hospitals, adult social care services, dental and general practices and other care services in England, to make sure they meet fundamental standards of quality and safety. CQC sets out what good and outstanding care looks like and make sure services meet these standards which care must never fall below. CQC reports publicly on what it finds locally, including performance ratings for care providers, to help people choose care and encourage providers to improve. It also reports annually to Parliament on the overall state of health and adult social care in England.

Where appropriate CQC will pursue civil and/or criminal enforcement action against registered persons who provide health and social care services for breaches of health and social care law under HSCA 2008 and RAR 2014, in the way set out in the CQC's enforcement policy.

Since 1 April 2015 Care Quality Commission (CQC) has assumed lead enforcement responsibility for health and safety incidents where service users have died or sustained avoidable harm, or have been exposed to a significant risk of avoidable harm, as a result of a failure by the Registered Person to meet specified prosecutable regulatory standards, for instance to provide safe care and treatment. A Registered Person may be the Registered Provider and/or the Registered Manager.

Criminal prosecutions can be brought against registered providers, individual registered managers and directors of corporate providers. Prosecutions can arise from single specific incidents where the incident and resulting harm provides sufficient evidence of a serious breach of a prosecutable regulation by the Registered Person. Under Regulation 22(2) the relevant prosecutable regulations are:

- Regulation 12(1) RAR 2014 safe care and treatment
- Regulation 13(1) to (4) RAR 2014 safeguarding from abuse and improper treatment
- Regulation 14(1) RAR 2014 meeting nutritional and hydration needs

Healthcare Safety Investigation Branch (HSIB)

The HSIB's purpose is to:

- conduct thorough, independent, impartial and timely investigations into clinical incidents
- engage patients and relatives, NHS staff, and medical organisations throughout the investigation process

- help the patients and relatives understand ‘what happened?’ and what’s being done to prevent similar events in the future
- produce clearly written, thorough and concise reports with well-founded analysis and conclusions that explain the circumstances and causes of clinical incidents without attributing blame
- make safety recommendations to improve patient safety
- improve patient safety by sharing the lessons learned from investigations as widely as possible
- raise the standard of local investigations of healthcare safety incidents by establishing common standards and skills development

HSIB approach

The HSIB use a range of approaches in our investigations focusing on identifying risk and the causes of incidents.

Safety issues for potential investigations can be shared by individuals, groups or organisations. The decision to start an investigation could relate to a single event, a series of events or an issue discovered through current, ongoing investigations.

All HSIB cases are logged and stored on a database and become part of a process of review to help identify themes and patterns of safety issues over time.

Learning not blaming

The HSIB act independently and do not investigate on behalf of the families, staff, organisations or regulators. HSIB can make public safety recommendations to the healthcare sector.

HSIB staff are investigators not regulators, so don’t enforce regulations but do publish the response to recommendations. When it’s necessary HSIB ask the Care Quality Commission and other regulatory bodies to act via safety recommendations.

Annex 2: Contact details for all parties

Contact details redacted.