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Shared Insights

CQC enforcement and prosecution in the health and care sector

Panel of speakers

Carl May-Smith – Partner (Chair), Browne Jacobson
Kathryn Fearn – Director of Legal Services, Nottingham University Hospitals NHS Foundation Trust
Eleanor Sanderson – Barrister, Mayfair Place Chambers

Browne Jacobson

Introduction

This session focused on insights from our extensive experience of supporting health and care providers with CQC registration issues, enforcement action and prosecution.

We looked at the offences and thresholds for CQC prosecution and how to prepare for CQC investigations including responding to CQC information requests as well as avoiding urgent enforcement action and prosecution.

We were delighted to be joined to by guest speakers Kathryn Fearn, Director of Legal Services at Nottingham University Hospitals NHS Trust and Eleanor Sanderson, regulatory barrister at Mayfair Place Chambers. Eleanor shared the key risk indicators identified through her practice that would suggest a greater likelihood the CQC would decide to prosecute an offence. Kathryn shared her insights from her real world experience of CQC action from an in house perspective and practical strategies for managing investigations, enforcement and prosecution by the CQC.

Contents

How we can help

Our regulatory and inquest teams provide expert legal advice to organisations across the public and independent health and care sector. Please do contact us if we can assist.

Services we offer:

- Advising on proposed urgent action and assisting in the preparation of responses to Notices of Proposal;
- Appeals against Notices of Decision on urgent enforcement action to the First Tier Tribunal.
- Advising and representing organisations at Inquest, including preparation of witnesses.
- Assisting throughout investigation and prosecution – including drafting responses to requests for information and identifying gaps, advising on key risks and likelihood of further action, assisting with preparing responses under caution.
- Advising on Duty of Candour policies and procedures.
- Advising on liaison with external agencies, including commissioners and other stakeholders.
- Advising on liaison with the CQC and police, including where separate investigations are running in parallel.
- Our specialist Maternity team has a dedicated Maternity Services Resources Hub, a unique facility providing free resources and training materials to help maternity services improve and follow best practice. It includes support, advice and a number of training guides and videos for staff attending inquests
- Training packages for clinical or patient safety teams on topics such as creating a culture of candour, supporting staff to escalate concerns, complying with the Trust's statutory duties in relation to whistle-blowers, best practice when responding to complaints and supporting staff through legal processes.

CQC enforcement powers and the role of criminal prosecutions

Carl May-Smith – Partner,
Browne Jacobson

Carl opened the session covering CQC enforcement powers. Whilst the session focused predominantly on criminal prosecutions, Carl set out other enforcement action that may be taken by the CQC. This includes the addition of conditions to an organisation's registration, restrictions on intake of new patients, mandatory discharge of patients or, suspension or revocation of registration. When the CQC are considering urgent action the following process takes place:

1. CQC sends a letter of intent setting out its intended actions and the reasoning behind this.
2. The organisation has an opportunity to make representations against the proposed action.
3. The CQC send a Notice of Decision if it is to act.
4. The organisation can appeal to the First Tier Tribunal against that decision.

In respect of urgent enforcement action, this will be done quickly. It is not unusual for the CQC to give 24 to 72 hours for the Trust to respond to proposed action and to provide an action plan to address the areas of concern the CQC have highlighted with the aim of convincing the CQC not act. When responding to any letter of intent, an organisation should focus on:

- Setting out actions that are different to what is being done already – as the CQC have already taken the view that what is in place is not sufficient.
- Targeting the CQC concerns – e.g. if the CQC says there are staffing issues out of hours, the proposed actions should focus on out of hour staffing not staffing in general.
- Evidencing how those actions will be resourced/funded.
- Allocating a member of the leadership team as accountable for ensuring each action is completed.
- Ensuring the actions are sustainable on a longer term basis.

Once the CQC has made its decision, the organisation has the option to appeal but the decision remains in force whilst the appeal is considered. The CQC will also publish any action it takes against a provider.

CQC offences and prosecution

The key offences the CQC prosecute for are:

- Duty of Candour failures.
- Failure to provide safe care and treatment.
- Failure to properly have obtained consent (including failure to follow the Mental Capacity Act.
- Failure to provide safe care and treatment.

The latter is the offence we see most often prosecuted. To date, such prosecutions have only be brought against the provider or a Registered Manager, never directors. The failure to provide safe care or treatment must either have caused avoidable harm to have occurred; or created a significant risk of avoidable harm occurring.

It is a relatively low bar in terms of whether there is sufficient evidence for a prosecution to be brought. However, the CQC must consider two tests:

- **Evidential** – do they have enough evidence for a realistic prospect of success? Evidence the CQC will rely on will include post incident investigation reports, Coronial conclusions;
- **Public Interest** – Is it in the public interest to bring a prosecution? There is no determinative test for how the CQC (or any prosecutor) determines whether a matter is in the public interest to prosecute. However, there are key elements which can contribute to increasing the likelihood it will be considered in the public interest:

Trends in what the CQC prosecute for, and who the CQC decide to prosecute, have varied over the years. There was a period, four or five years ago, where we saw an increase in prosecutions of Registered Managers by the CQC and it does seem to be a focus of the CQC again – at least to interview under caution stage. Examples of cases we have seen prosecuted for the failure to provide safe care and treatment include:

- Patients accessing areas where they can fall or jump.
- Defective equipment which has not been maintained or subject to regular audit.
- Lack of training or ineffective training.
- Fire safety deficiencies.
- Failure to protect patients from other patients.
- Hot pipes.
- Legionella.

The investigation and prosecution process

The usual process is:

1. Initial enquiries such as request for medical records and copies of any post incident investigation. This can be followed up for further requests for information.
2. Invitation to interview under caution – usually this is by means of a written response from the Trust or Registered Manager to specific questions posed by the CQC. It is worth noting that the period of time between an initial request for information and an invitation to interview under caution can be lengthy.
3. The CQC makes a determination of whether to proceed with a prosecution. The CQC has three years from the date of the incident to bring a prosecution. The CQC notifies the organisation of its decision.
4. If the decision is to proceed to prosecution, the CQC lays an Information with the Court and a hearing date is set. The CQC will then share Initial Details of its Prosecution Case with the organisation (setting out the alleged failings by the organisation).
5. The organisation determines if they will plead guilty or not guilty. If the organisation pleads not guilty the case will proceed to trial. If the organisation pleads guilty the case proceeds to a sentencing hearing.

Consequences of a conviction

We have seen in recent years significant fines imposed on organisations. The level of fine will be dictated by the size of the organisation (i.e. its turnover), the level of harm risked and, the culpability of the organisation (e.g. the extent of its failings - which will consider what processes and procedures were in place, how these were embedded and whether the failing was one off or systemic). There is also considerable publicity in these cases. The proceedings are public and the CQC will publish details of prosecutions and the outcome of the sentencing hearing. These can, and often are, reported by both regional and national news outlets.

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Factors that can lead to a higher likelihood of prosecution from a regulatory barrister's perspective

Eleanor Sanderson – Barrister, Mayfair Place Chambers

Eleanor Sanderson, Barrister at Mayfair Place Chambers discussed key factors that she has seen in her practice that increases the likelihood of the CQC deciding to take a case to prosecution.

The most common question asked when it comes to patient safety incidents: will the CQC prosecute? Whilst this can, and often is, unpredictable, there are factors which can provide a steer when assessing whether or not the CQC is likely to proceed to prosecution.

The Inquest

In the context of a fatality, the Inquest can be determinative of whether or not the CQC are going to investigate, with a view to prosecute. CQC involvement and interest in Inquests can vary. During some Inquests, you might see the CQC present and more engaged at each stage of the Inquest whilst at others the CQC may keep more of a watchful eye at a distance. The features that tilt the balance of further investigation by the CQC are:

- The circumstances of the death and cause of death. For example, if the location of a death is a hospital setting but there is nothing attributable by the organisation to the circumstances of, or cause of, the death, it is less likely the CQC will investigate further.
- The conclusion: where there is a neglect conclusion, i.e. a failure in care or treatment that has contributed to the death, it is much more likely the CQC will look to bring a prosecution. To that end, the CQC are assisted by findings from the Coroner as it may inform what evidence the CQC will rely on.
- Prevention of Future Death ("PFD") reports: whilst not necessarily evidence of an offence having taken place (unlike a neglect verdict) the CQC may have regard to the PFD when considering whether it is in the public interest to bring a prosecution.

Systemic failings

The CQC are more likely to bring prosecutions where there is evidence of systemic failings i.e. there are key themes identified across several cases. This does not mean that action will not be taken in a case which appears to be isolated and individual to that one incident but, the likelihood of action is higher where there are systemic failings. Again, this can be highlighted through Inquests with repeated themes. Repeated failings can encourage the CQC to prosecute. If something that has cropped up again i.e. training or policy implementation, this makes it more likely to prosecute and easier to frame the allegation.

Actual or risk of harm

As covered by Carl, the offence is of actual harm or risk of harm. However, the greater harm that has occurred the greater the likelihood the CQC will prosecute e.g. a fatality or more serious harm has occurred.

How strong is the evidence of an offence?

The CQC will look at witness statements, Coronial conclusions and other post incident investigations.

The CQC - relative to other regulators – prosecute fewer cases, and concentrate on those where they believe the evidence appears to be strong. To that end, nearly all cases that have gone to prosecution have resulted in a guilty plea by an organisation. One has so far resulted in an acquittal after trial.

Eleanor's top tip – preparation!

Early preparation by an organisation is key! This includes understanding early what the issues are and taking an organisational view on what is accepted in respect of any suggested failings and what is being done to address them. Don't forget to prepare witnesses for what to expect during these processes and to understand what they have to say about what has taken place.

Key takeaways from an in-house perspective – managing CQC relationships and understanding risk

Kathryn Fearn – Director of Legal Services, Nottingham University Hospitals NHS Foundation Trust

Kathryn Fearn spoke about her experience within the legal department of several NHS Trusts over the last ten years and set out her top tips for managing CQC involvement and investigations.

Maintaining an open and candid relationship with the CQC

Kathryn set out the importance of maintaining an open and candid relationship with your CQC liaison team to build trust. In her experience, if the CQC are finding out issues for the first time through either Coronial referrals or seeing cases in the media and these have not been communicated to the CQC in advance, this can cause an increase in the level of scrutiny on an organisation across the board, and not just in respect of a specific incident.

In her legal team, they work closely with the Trust's Quality Assurance Team and have developed processes for early internal notification of any key cases which may attract criticisms, CQC or media interest to enable proactive conversations. The Quality Assurance team work hard to build those relationships with the CQC and have a keen eye for anything that may pique their interest – the processes the Trust has in place enables information flow and allows for proactively providing additional assurance to the CQC, when necessary.

Provide assurance and be robust around matters of improvement

Whilst it is important to respond to the specific questions being asked by the CQC, providing additional context or detail can be key. Often you may get queries about what happened in an incident or wanting information/policies about practice, so when answering these types of queries think about including:

1. What safety or preventative measures were in place at the time the incident happened (even if ultimately a view is taken that these did not work as intended).
2. What steps have been taken immediately to address the concerns. Think about the "so what" factor and whether there is any evidence that actions have been embedded e.g. audit data to show improvement in patient care. When talking about policies or guidelines check they are in line with national standards/policies and explain how they have been communicated to staff and how staff have been trained on any new aspects.
3. What is the position now (if this is different to points above) – this usually happens if the incident was quite historic and improvements have evolved over time.

Staff involvement and communication

This is a topic that comes up in nearly every investigation. The CQC will want to engage with staff who were involved in the care in question – this can be at various stages in the process and the purpose will be to take a witness statement or to confirm any statement provided at Inquest is accurate.

Clearly staff often find being involved in this process extremely distressing and unsettling, particularly if they have already been through a tough experience with other processes relating to the case (such as NMC or GMC involvement and Inquest proceedings). Establishing with the CQC how you are going to liaise with staff is important. For example, if possible, agreeing with the CQC that the Trust will be the intermediary for correspondence between the CQC and staff (being fully transparent with the CQC about the information provided to staff) allows the Trust to provide support to staff as needed.

Discussion

The session ended with a discussion on the following topics:

- Uncertainty around the impact of the Patient Safety Incident Response Framework.
- How the CQC process works alongside a police investigation. The CQC's first instinct will be to try to wait until police conclude their investigation and determine whether to prosecute any organisation or individual e.g. corporate or gross negligence manslaughter. However, the CQC are limited by a three year prosecution deadline which the police are not, which means we have more recently seen the CQC proceeding at least to interview under caution before the police have completed their own investigations.
- Delegates found pleasing external stakeholders can be difficult and flagged the importance of mitigating this with rapid escalation processes.
- The recent review of the operational effectiveness of the CQC and how it impacts on policy and decision making on enforcement action, particularly prosecution.
- Delegates affirmed the importance of maintaining relationships with the CQC and engagement with staff throughout the process.

Key takeaways

- The CQC can be notified of an incident that may require investigation through Inquests, statutory notifications made by the Trust, referrals by other regulator(s), and complaints by patients/family members.
- Organisations should have processes to monitor and escalate potential risk cases.
- When responding to urgent action, tailor the response and proposed actions to the issues being targeted – identify effective, sustainable actions.
- When responding the CQC's requests for information, sometimes additional context can be important. Answering too narrowly can create more scrutiny. For example, if training data looks low - is there a reason for this? Such as the training has been replaced by something new which has a higher training rate.
- If failings have been identified, develop a clear action plan to address those issues. This should include audits/checks to confirm not only that the initial action has been completed but that it is embedded into the organisation processes and that the organisation continues to monitor its effectiveness moving forward.

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