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Care Quality Commission

26 AUG 2014

Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

Telephone: 03000 616161
Fax: 03000 616171

www.cqc.org.uk

Christopher Dorries
HM Senior Coroner South Yorkshire (West)
Medico-legal Centre
Watery Street
Sheffield
S3 7ES

19 August 2014

BY EMAIL and POST

Re: Inquest into the death of Miss Lucy Moffatt

Dear Mr Dorries

Thank you for your letter dated 10 June 2014 in which you wrote to us under the provisions of Regulation 28 of the Coroners (Investigations) Regulations 2013 ('the Regulations') in relation to the inquest into the death of Miss Lucy Moffatt.

We are extremely saddened to learn of the death of Miss Moffatt and of the circumstances leading to her death. We are also very grateful for your report in requiring us to review what actions should be taken to prevent the occurrence or continuation of such circumstances in the future.

Please treat this letter as the formal response of the Care Quality Commission ('CQC') to your report dated 10 June 2014.

In your report and pursuant to the requirements of Regulation 29 of the Regulations you require the CQC to provide details of any action that has been taken or which is proposed to be taken in response to the concerns highlighted in your report, or an explanation as to why no action is proposed if appropriate.

In accordance with the evidence that was given at the inquest neither the registration assessor nor the compliance inspector in this case were specifically aware of the Department of Health Alert concerning the strength of window restraints referred to in Health Technical Memorandum (HTM) 55. The reason for this lies in the regulatory framework in which health and social care providers are registered to operate, and in accordance with the current registration and inspection CQC methodology. Under the current statutory and regulatory framework the primary responsibility for managing patient safety, and ensuring that such alerts are actioned, lies with the provider of health and social care providers. As you will be aware that framework is formed primarily of the Health and Social Care Act 2008 ('the Act'), as well as the Care Quality Commission (Registration) Regulations 2009 ('the Registration Regulations')

and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 ('the Regulated Activities Regulations').

Under Regulation 16 of the Regulated Activities Regulations, the registered person, that is Sheffield Crisis in this case, must make suitable arrangements to protect service users and others who may be at risk from the use of unsafe equipment by ensuring that equipment provided for the purposes of carrying out the regulated activity is properly maintained and suitable for its purpose, and used correctly. How this regulation is complied with will be taken into account by the CQC at registration and subsequent reviews of compliance. However, at this stage the CQC does not mandate exactly what systems or equipment or systems should be in place while the burden falls on the provider to ensure that they take account of Alerts such as HTM 55 in devising the particular window restrictor or that is used.

The CQC is committed to continuous improvement and takes extremely seriously the concerns that you raised. We consider that your concerns touch upon the broader question of the implementation and inspection of Safety Alerts more generally. Accordingly, in addressing your concerns we set out the steps that the CQC is undertaking to improve the effective implementation of Safety Alerts.

In seeking to address the concerns raised in your report we structure our response as follows:

1. Clarification of duties on providers to implement safety alerts;
2. CQC's regulatory role; and
3. Steps taken by the CQC to address the concerns set out in your report.

<u>1. Duties on providers to implement safety alerts</u>

The CQC recognises that Safety alerts as encompassing a variety of vital communications produced by the Medicines and Healthcare products Regulatory Agency (MHRA), the former National Patient Safety Agency (NPSA), NHS England and the Department of Health, including the following:

- National Patient Safety Agency (NPSA) safety alerts
- NHS England safety alerts and guidance
- Rapid response alerts.
- Emergency alerts.
- Drug alerts.
- Dear doctor letters.
- Medical device alerts.

We recognise that alerts cover a wide range of topics, from vaccines to patient identification and the types of alerts include Rapid Response Reports and Safer Practice Notices as well as Patient Safety Alerts.

The CQC also recognises alerts as important mechanisms to help providers learn lessons from each other and to improve the quality of care they provide. They also

offer providers an opportunity to demonstrate their accountability for the safety of people who use services.

You will be aware that patient safety alerts and other safety critical guidance are issued by the Central Alerting System ('CAS') by email. The system is currently hosted and administered by the Medicines and Healthcare products Regulatory Agency, while details of specific alerts can be accessed by the CAS website: (https://www.cas.dh.gov.uk/Home.aspx).

All alerts are issued to each organisation registered with CAS, regardless of whether or not they might be relevant. The number of alerts relevant to an organisation varies considerably depending on their size, nature of business and services they provide. Each alert indicates the type of organisations it is relevant to, but it is up to providers themselves to consider each alert for relevance and to update CAS accordingly. Meanwhile, each alert has an issue date, an 'acknowledged by' date and a completion deadline. A single alert may include a number of separate actions, each with different completion dates.

By way of background the Health and Social Care Act 2008 introduced a single registration system which applies to both healthcare and adult social services. Once registered with the CQC, providers such as Sheffield Crisis are required to comply with conditions placed on their registration, as well as under the Act, and the Regulated Activities and Registration Regulations. The Regulations set out the essential standards of quality and safety that service users have a right to expect. The Act requires the CQC to publish guidance about compliance with the requirements of the regulations and accordingly the CQC has published "Guidance about compliance, Essential standards of Quality and Safety" ('the Guidance') which provides advice to providers about how and what they need to do to comply with the Regulations in the form of outcomes and prompts.

The requirements on providers to deal with Alerts depends the nature of the provider and varies according to whether they are NHS Trusts, Primary Care contractors or other providers such as Crisis House, as follows:

1. NHS Trusts

All NHS trusts must be registered with the system to receive alerts, act on them and feed-back information on compliance. There are also more specific requirements for NHS trusts under the essential standards in outcomes 4M and 9J in relation to National Patient Safety Agency alerts.

- Outcome 4M constitutes a specific additional prompt for specific service types in the context of Outcome 4, which refers to Regulation 9 of the Regulated Activities Regulations dealing with the care and welfare of service users. It appears at page 69 of the current Guidance and sets out that service providers must make sure that people who use services benefit from a service that "*ensures that patient safety alerts, rapid response reports and patient safety recommendations issued by the National Patient Safety Agency (NPSA) and which require action are acted upon within required timescales*".

- Outcome 9J constitutes an additional prompt within the context of Outcome 9, which refers to Regulation 11 of the Regulated Activities Regulations dealing with the management of medicines. It appears at page 109 of the current Guidance and sets out as follows: *"Ensure that patient safety alerts, rapid response reports and patient safety recommendations disseminated by the National Patient Safety Agency and which require action are acted upon within required timescales"*.

2. Primary Care Contractors

NHS England has a responsibility to cascade alerts to their primary care contractors for action where appropriate and to monitor the implementation of alerts by contractors. This function had historically been managed by previous commissioning organisations and transferred to NHS England's Area Teams from the 1st April 2013.

Draft guidance has been prepared on this responsibility. We understand that that guidance includes as follows but we respectfully invite you to contact the NHS England for further details:

- Area Teams will be required to use CAS for issuing and responding to alerts, confirming that the alert has been received and cascaded onwards for action as appropriate.

- Implicit in this is the expectation that Area Teams will monitor the implementation of alerts, by primary care contractors, given their responsibility to ensure that the services they commission are safe. Each Area Team will have a designated CAS liaison officer (with appropriate back up cover) responsible for cascading alerts to primary care contractors and making responses on CAS.

- In relation to independent providers, Area Teams are only required to cascade alerts to independent contractors before signing off the alert 'Complete'. This must be within 5 working days. Feedback from independent contractors does not need to be included in the response to CAS but local processes should be in place to monitor their compliance with alerts to ensure that safe services are being commissioned. While not currently nationally mandated, these local processes should include compliance with relevant alerts being considered as part of regular assurance or contract review processes. The specification of a standard process for reviewing compliance is currently being considered.

3. Other providers

All other providers have been advised by CQC to register directly with CAS to receive alerts to ensure they are complying with the regulations. These providers would include providers such as Sheffield Crisis. However, the system's functionality does not allow them to feed-back information on compliance status to CAS in the same way as NHS providers. CQC has no role in distributing safety alerts to independent healthcare or adult social care

providers (as communicated by letter), unlike its predecessor, the Healthcare Commission or Commission for Social Care Inspection.

While independent healthcare and social care providers such as Sheffield Crisis are not mandated in the same way as NHS providers to implement alerts issued by CAS, they are required nevertheless to comply with requirements in the essential standards of quality and safety as set out in the Guidance. Providers are required to take into account the CQC's Schedule of Applicable Publications as detailed at Appendix B where they are required to do so within the context of relevant regulations. In particular:

1. Within the context of regulation 9 of the Regulated Activities Regulations (Outcome 4) dealing with the care and welfare of service users, providers must take account of relevant evidence based guidance about good practice and alerts published by expert and public bodies including the National Patient Safety Agency.

2. Within the context of regulation 15 of the Regulated Activities Regulations (Outcome 10) dealing with the safety and suitability of premises, providers must take account of alerts, responses, guidance and directives about all aspects of healthcare and social care premises published by agencies including the National Patient Safety Agency, the Department of Health and the Health and Safety Agency. Accordingly, as with all providers Sheffield Crisis had responsibility for taking into account the Health Technical Memorandum ('HTM') 55 which had been issued by the Department of Health. The Health and Safety Executive also first published August 2012 in Health Sheet Information Sheet No 5 guidance that incorporated at page 2 the concerns set in HTM55 as follows:

   "Control measures

   Suitable controls may include:
   - *fitting adequate window restrictors;*
   - *ensuring balconies have edge protection that is sufficiently robust, and of suitable design (including height, and the size of any openings in it), to prevent accidental falls;*
   - *fitting an adequate screen or barrier to prevent service user access to a window or balcony edge;*
   - *restricting access to upper floors.*

   Window restrictors

   - *Where vulnerable people have access to windows large enough to allow them to fall out and be harmed, those windows should be restrained sufficiently to prevent such falls. Window restrictors should:*
     - *restrict the window opening to 100 mm or less;*
     - *be suitably robust to withstand foreseeable forces applied by an individual determined to open the window further;*

- *be sufficiently robust to withstand damage (either deliberate or from general wear);*
- *be robustly secured using tamper-proof fittings so they cannot be removed or disengaged using readily accessible implements (such as cutlery) and require a special tool or key (see Department of Health Building Note 00-10 Part D Windows and associated hardware). Please note that 'safety restricted hinges' that limit the initial opening of a window can be overridden without the use of any tools and are not suitable in health and social care premises where individuals are identified as being vulnerable to the risk of falls from windows.*

Care providers should also:

- *ensure the window frames to which restrictors are fitted are sufficiently robust;*
- *consider any impact on the comfort of service users from reduced natural ventilation and provide adequate cooling where necessary (eg high-level and/or restricted aperture ventilation, fans or air conditioning). The NHS has produced guidance on dealing with extreme heat and heatwaves."*

3. Regulation 10 of the Regulated Activities Regulations (Outcome 16): dealing with assessing and monitoring the quality of service provision, providers must take account of relevant guidance, national reports and codes of conduct about risk management, monitoring quality and audit published by expert and professional bodies, including the National Patient Safety Agency.

Commissioners of NHS services from non-NHS providers also have a responsibility to ensure they are commissioning safe services. Accordingly, this would include ensuring that relevant safety alerts are implemented by any independent providers they contract with.

2. CQC's regulatory role

A new system of regulation came into force in April 2010, and providers were required to demonstrate compliance with the Registration Regulations. Whilst there were no specific regulations explicitly requiring compliance with safety alerts, this was included as something to be taken into consideration in the 'Guidance about compliance with Essential Standards of Quality and Safety' for all provider types with the exception of Shared Living and Extra Care providers.

The CQC tested both initial and ongoing compliance by establishing a dynamic Quality and Risk Profile (QRP) for each provider organisation. This included data that provided CQC with an insight into the risks of non-compliance with the regulations.

For the reasons stated above, compliance data from CAS did not feed into the early QRPs, but the data was subject to a number of data quality improvements by the

Department of Health and two new indicators were introduced in July 2010 as follows:

- Proportion of alerts acknowledged within deadline
- Proportion of alerts completed within deadline

You will of course be aware that compliance with safety alerts also had prominence in both the Francis review into failings that took place in Mid Staffordshire NHS Foundation Trust and in the subsequent Berwick report ' A promise to learn – a commitment to act', as follows:

- Francis Recommendation 41 set out as follows:

  "The Care Quality Commission should have a clear responsibility to review decisions not to comply with patient safety alerts and to oversee the effectiveness of any action required to implement them. Information-sharing with the Care Quality Commission regarding patient safety alerts should continue following the transfer of the National Patient Safety Agency's functions in June 2012 to the NHS Commissioning Board."

- The Berwick Report recommended that the CQC should hold Boards responsible for ensuring that recommendations from patient safety alerts are implemented promptly while NHS England should complete the re-design and implementation of a patient safety alerting system for the health care system in England. Finally, it was recommended that the CQC should assure that organisations respond effectively to these alerts except in the rare circumstances where organisations can demonstrate that implementation of an alert is not in the interests of specific patient groups.

The CQC responded to both of these recommendations in 'Hard Truths', the Government's response to Francis, as follows:

- The CQC already monitors compliance with patient safety alerts, such as those issued by the Medicines and Healthcare products Regulatory Agency, and is able to investigate further where it identifies the need to do so in order to hold providers to account for failures to act on them.

3. Steps being taken by the CQC to address the concerns set out in your report.

In response to the recommendations in both the Berwick and Francis reports we are taking the following actions which also take account of the concerns raise in your report:

1. The Care Quality Commission is currently exploring how it can give greater prominence to safety alerts in its revised surveillance and inspection model. However care is needed to be clear that providers retain accountability for implementing patient safety alerts. As set out already it is not the currently the

CQC's role to oversee providers' individual decisions or actions. Providers must be able to explain and account for how they act on safety alerts; the Care Quality Commission's role will be to assess their capability and performance in terms of whether it results in good quality care.

2. In 2013, CQC overhauled its approach to regulation and introduced a new system of assessment based around the 5 domains of safety, effective, caring, responsive and well led. This is underpinned by an assessment framework containing key lines of enquiry and prompts and an Intelligent Monitoring System of sentinel indicators to help identify risk.

3. The CQC also takes account of the work that is being undertaken by NHS England which has also been working on devising a new system of safety alerts, with three stages:

    - Stage 1: Alert: This alerts organisations to emerging risk. It will be issued very quickly once a new risk had been identified to allow rapid dissemination of information.

    - Stage 2: Notification: Provision of resources to help mitigate risk identified in stage 1

    - Stage 3: Notification: Directive makes it mandatory for organisations to have taken actions based on the stage 1 and stage 2 notifications and implement solutions or actions to mitigate that risk.

    The first new alerts under this system were issued in February 2014.

4. Compliance with safety alerts (from all sources) features in the assessment framework and is one of the things CQC inspectors are prompted to consider when undertaking an inspection. However, the initial version of the Intelligent Monitoring System did not include an indicator relating to compliance with safety alerts as the system was largely in abeyance due to the transfer of safety related responsibilities from the NPSA to NHS England. This has since been reviewed and from July 2014, a new composite indicator is to be included in the NHS acute Intelligent Monitoring System pertaining to compliance with safety alerts. The exact composition is yet to be finalised, but is likely to include components relating to:

    - outstanding alerts of those requiring action in the most recent 12 month period;

    - alerts outstanding for more than 12 months; and

    - timeliness of responses to safety alerts in the most recent 12 month period

5. As part of the CQC's commitment to continuous improvement the registration process is currently under review to ensure greater robustness of assessment. The inclusion of specific questions relating to the management of patient safety alerts is currently being considered as part of this review. Whether or

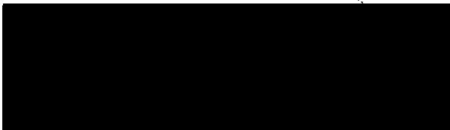
not registration with a national alerting system should be mandatory across all health and social care sectors is a topic for wider discussion that is taking place within the CQC and which would require a change to current legislation.

6. The CQC is also testing some pre-inspection methodology to provide additional intelligence to inspectors as part of inspection pre-planning and prior to going on site during the course of an inspection. We are currently piloting some pre-inspection where we will be testing the dissemination of safety alerts by assessing provider's policies and procedures around alerts, and the implementation of a sample of alerts selected on the basis of low compliance rates on the CAS, or intelligence that alerts have not been well implemented. By way of illustration we enclose the question/prompts that are being proposed for inspectors to look for in the provider's policy and procedures documentation, as well as the things to look for during inspection.

We greatly value the intelligence provided by your report and have endeavoured to address the concerns raised within it. The CQC is currently undertaking a detailed review designed to ensure that the valuable information provided by Regulation 28 reports, as well as from other sources of information, systematically and effectively feeds into our intelligent monitoring, inspection and registration processes.

Please do not hesitate to contact us with any further questions.

Yours faithfully



Deputy Chief Inspector – Adult Social Care (South Region and Registration)