Bupa Care Services

Regulation 28 – Prevention of Future Death

Care Home: Ashley House

Resident: David Anthony Sketchley

Background: Circumstances of Death

Mr Sketchley was a resident at Ashley House Nursing Home, in Cirencester. On the 16th July 2017 he was seated in a commode chair. He attempted to raise himself from the chair and in the process he inadvertently dislodged the commode pan and flipped the seat on the chair. The commode chair was a bariatric chair with a horse shoe design. This design means there is a gap at the front of the seat and it appears on raising himself from the chair, one of Mr Sketchleys legs became lodged in the gap thus causing the pan to dislodge and the seat to flip up. His body then fell between the gap in the front of the chair and in doing so his anus was impaled on one of the supporting bars beneath the seat (no longer insitu). The injuries Mr Sketchley sustained caused his death the following day.

Actions that should be taken (identified by the coroner):

1. Inadequate Supervision :
    - During the incident an appropriate carer was absent during the incident
    - Lack of clarity in the care plan. His supervision needs were unclear, as were the definitions of supervision
2. Suitability of commode
    - There is insufficient to evidence of DAS suitability for a bariatric commode in terms of documented risk assessment
3. Bupa should consider undertaking a further investigation taking into account the following:
    - The initial investigation - Did not come to the conclusion on the level of supervision DAS required
    - The initial investigation - Did not take the opportunity to collaborate with the manufacturers of the commode
    - The initial investigation - Did not apparently attempt to determine exactly how the incident had occurred
    - The initial investigation - Did not inquire into the method by which the bariatric commode was considered suitable for DAS

- The initial investigation - What are the standards by Gloucester Care Services in relation to the assessments required when determining if a commode is suitable for a particular person : no evidence that these standards are reflected in Bupa practice

Bupa actions required:

1. Inadequate Supervision :

   Specifically; Safety, Moving Around, Going to the Toilet sections of the 'My day my life' documents do not currently highlight a supervision plan if a resident requires close monitoring and by whom and neither do any of the other sections. All sections ask what support a person requires but if a resident does require close supervision, none of the sections specifically ask what the plan would look like. None of the sections prompt staff to consider what an individualised definition of supervision is for the specific resident or who would supervise the resident.

   We now advocate the use of a two tier care documentation filing system which is a mandatory process and has been in use since 2017. The main care file is to be housed at the nurse's station and is where the care plans sit. The second file, which is known as the supplementary file is to be housed at the point of care delivery i.e. in a resident's bedroom. At the front of the supplementary file is a document named 'My Day, My Life, and My Portrait'. This document is designed to give an overview of the care needs an individual requires and is available at the point of care delivery, allowing care staff immediate access to imperative information regarding a resident's care needs. Therefore this document should be reviewed to incorporate an individual's supervision requirement, including who carries out the supervision, during each activity of daily living requirement. Supporting guidance and Resident Care policies will also need to be reviewed to incorporate this change .This work is currently underway and all clinical policies will be reviewed during 2018

2. Suitability of commode

   Each resident has their body mass index (BMI) established on admission by staff using the MUST nutritional screening tool, this is then reviewed on a monthly basis. The eating and drinking plan asks what support a person requires from us but there is no formal Bariatric Risk assessment, which should include assessment and requirement of specialised equipment. This assessment should form part of the 'My Day My Life' care documentation process and also be triangulated in the Resident Care policies and the Clinical Equipment policy. Therefore there is a requirement to develop a Bariatric Risk Assessment form and update the underpinning policies.

   A first draft of the Bariatric Risk Assessment form has been produced and was considered at the Clinical Governance Committee in April 2018. It will be re-submitted at the May committee following further review. The underpinning policies are also in the process of being updated.

3. Further investigation

Bupa will allocate resource to undertake further investigations into the issues highlighted above under point 3 by the coroner, which were not covered in the original investigation. Any findings from the new investigation will be discussed at the BCS Clinical Governance Committee and actions and learning's agreed.

Governance process

Any documents developed will be agreed and signed off by members of the Bupa Care Services Clinical Governance Committee

Cascade of learning's and Actions

Cascade of new documentation and learning's will be via Need2Read which is a weekly communication and the Quality Matters quarterly bulletin, both of which are cascaded via email to the Operational team and the Quality & Compliance team, including Home Managers and support teams who will then cascade at home level. All new or updated documents will be uploaded onto Bupa Oneplace which is an online electronic filing system available to all Bupa staff.

Review completed by:

[redacted] Head of Clinical Governance

3rd April 2018

PERFORMANCE HEALTH

performancehealth.co.uk
Main: +44 (0) 3448 730 035
Fax: +44 (0) 1623 557 769

Nunn Brook Road, Huthwaite,
Sutton-in-Ashfield,
Nottinghamshire, NG17 2HU, UK.

4th April 2018

Ms Caroline Saunders,
HM Assistant Coroner for Gloucestershire
Gloucester Coroner's Court
Corinium Avenue
Barnwood
Gloucester
GL4 3DJ

Dear Ms. Saunders,

Ref: The Late David Anthony Sketchley

Thank you for your letter dated the 9th March 2018 and the Prevention of Future Death Report related to the recent inquest which we have now considered.

On a personal level I am, of course, very regretful that one of our products was involved in this tragic incident and wish to restate my sympathies to Mr Sketchley's family which I conveyed in person at the conclusion of the resumed inquest.

I have carefully reviewed your findings in this case, and reflected on the evidence I heard during the inquest which provided a fuller, but still largely theoretical explanation of the exact incident.

The jury found that the main factors in the death were 1) Inadequate Supervision and 2) the Suitability of the commode. I agree that this commode was entirely unsuitable for Mr Sketchley, given his particular conditions.

After careful thought and comparison with other bariatric commodes on the market which also use a similar design and considering the long and uneventful history associated with the Atlantic Bariatric Shower Commode, our conclusion is that no design change is required.

Yours sincerely,

[redacted]
Managing Director

Company Registration No. 4374752
VAT Registration No. 945765283

Medicines & Healthcare products
Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Ms Caroline Saunders
HM Assistant Coroner for Gloucestershire
Gloucestershire Coroner's Court
Corinium Avenue
Barnwood
Gloucester
GL4 3DJ

MHRA
151 Buckingham Palace Road
London
SW1W 9SZ
United Kingdom

www.gov.uk/mhra

26 April 2018

Your ref: TJ/je
Our ref: 18337

Dear Ms Saunders,

Reference: Mr David Anthony SKETCHLEY

I write with reference to your Regulation 28 letter following the inquest into the death of Mr Sketchley. You requested that we take action to prevent similar events of this kind occurring.

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and is responsible for the regulation of medical devices and medicinal products.

The aim of the MHRA Devices Division is to take all reasonable steps to protect the public's health and safeguard the interests of patients and users by ensuring that medical devices and equipment meet appropriate standards of safety, quality and performance and that they comply with relevant Directives of the European Union.

One major area of the MHRA's responsibilities is the investigation of adverse incidents. An adverse incident is an event involving a medical device, which produces, or has the potential to produce, unwanted effects involving the safety of patients, users and other persons. These effects may arise from shortcomings in the device, its operating instructions, user practice or conditions of use.

Incident summary

Mr Sketchley sustained fatal injuries when he fell between the gap in the front of a commode chair he was using at the Ashley House Nursing Home in Cirencester. The commode chair was intended for bariatric use (manufactured by Performance Health) and Mr Sketchley's leg became trapped in the gap at the front of the seat when he dislodged the commode pan as he tried to stand.

From your communication, it would appear that there was no supervision in place at the time of the incident and that the risk assessment conducted for Mr Sketchley's use of this chair was inadequate.

Although the type of commode provided for Mr Sketchley may have been inappropriate and contributed to his death, there should have been a risk assessment conducted by the healthcare professionals with the responsibility for his care before its use. This is a key requirement for all

Occupational Therapy equipment and is always emphasised in the Instructions for Use issued by the manufacturers of such equipment and general guidance published by organisations such as the CQC. The MHRA is unable to comment on the level of supervision, or lack of it, that was in place for Mr Sketchley at the time of the incident that led to his death.

Classification of commodes as Medical Devices

Under the heading "Coroner's Concerns" in the Reg 28 report you have highlighted the fact that the MHRA (formerly the Medical Devices Agency) has downgraded the commode into a category which does not require investigation of incidents associated with the product. This is in fact incorrect, commodes are not regulated as medical devices in the UK, as they are regarded as aids to personal hygiene and do not perform the function of a medical device in accordance with the definitions contained in the Medical Device Directives.

Therefore, manufacturers of commodes are not obliged to report adverse incidents involving their products to the MHRA, as the Competent Authority for medical devices, under the vigilance process. In that respect, the evidence heard at the inquest into Mr Sketchley's death from Performance Health was correct.

However, the MHRA is prepared to receive reports of adverse incidents involving commodes (or similar products) from manufacturers, healthcare professionals, members of the public etc. Where we consider there is a safety issue that needs addressing we would pass the report to the appropriate Trading Standards Organisation to take any necessary action, as these products are outside our remit to take direct action against the manufacturer as they are not CE marked as medical devices.

Conclusion

Commodes and associated equipment are not regulated as Medical Devices in the UK and it is, therefore, outside the remit of the MHRA to take action with the manufacturer in this case. If a product of this type is regarded as unsafe in its design or construction the matter should be referred to the Trading Standards Organisation.

MHRA will continue to pass any reports of adverse incidents for commodes to the appropriate TSO and to endorse the general advice issued to healthcare professional using OT equipment and aids to daily living that it is essential to carry out a detailed risk assessment for each individual patient as to the suitability of the product before it is brought into use.

Yours sincerely,

Dr Ian Hudson
Chief Executive Officer
Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road, London, SW1W 9SZ

30 APR 2018

HSCA Further Information
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

Telephone: 03000 616161
Fax: 03000 616171

For attention of:
Ms Caroline Saunders
HM Assistant Coroner for Gloucestershire
Gloucestershire Coroner's Court
Corinium Avenue
Barnwood
Gloucester
GL4 3DJ

19 April 2018

Care Quality Commission
Our Reference: ENQ1-4973662699

Dear HM Assistant Coroner

Prevention of future death report following inquest into the death of Mr David Anthony Sketchley. D.O.B *(11/03/1933)*

We write to acknowledge receipt and provide a response to the prevention of future death report dated 9th March 2018 issued jointly to CQC and BUPA following the death of Mr David Anthony Sketchley. In the report you ask whether, in the light of the evidence provided, CQC and BUPA intend to commission a new investigation.

We can assure you that CQC is gathering information into the circumstances that contributed to Mr Sketchley's death in accordance with our regulatory powers.

As you may be aware since 1 April 2015 CQC has been given new powers to prosecute registered providers (operators of care homes and nursing homes) and registered managers for failures to provide safe care and treatment. The offence is found within Regulations 22 and 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The CQC does not have the power to prosecute individual care workers or nurses. Our prosecution powers are limited to failures at registered provider or registered manager level.

In order to successfully prosecute this offence CQC must establish to the criminal standard (beyond reasonable doubt) that;

- The registered provider or manager failed to provide safe care and treatment to the service user (service user is the language used in the legislation); and
- That the failure resulted in avoidable harm to the service user; or
- Resulted in a significant risk of exposure to avoidable harm.

Once the CQC has established these elements of the offence the burden then shifts to the registered provider or manager to establish on the balance of probabilities that they took all reasonable steps and exercised all due diligence to ensure safe care and treatment was provided.

In order to prosecute any offence the Code for Crown Prosecutors must be satisfied.

The Code has two stages; the evidential test and the public interest test. In order to satisfy the evidential test the CQC must be satisfied there is sufficient evidence to amount to a realistic prospect of conviction. If the evidential test is satisfied the public interest test must also be met; is it in the public interest to bring the case to Court? The public interest test cannot be considered unless the evidential test is satisfied.

You are aware that the CQC is gathering evidence into this matter with a view to deciding whether there has been a failure by BUPA and/or the Registered Manager to comply with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ('the Regulations'). We will update you when decisions have been made.

With regard to BUPA's investigation, we have no regulatory remit to judge the quality and effectiveness of the provider's investigation or require that they carry out an additional investigation into this concern. The BUPA investigation outcome came after our responsive inspection on 31 July 2017 of Ashley House Care Centre, Cirencester during which we gained assurances that action was being taken to prevent further similar incidents.

CQC will also contact BUPA to request a copy of their response to the prevention of future death report once the 56 days response time has passed. We will also be requiring regular updates from BUPA to monitor and ensure progress is being made to complete the action(s) they intend to take. Any information regarding these actions will be explored at the next inspection to ensure they have been effectively implemented and embedded in the work practices at Ashley House Care Centre, Cirencester to prevent future harm.

Please send any correspondence to:

By email: CQCInquestsandCoroners1@cqc.org.uk

By post: Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

Please include the reference number ENQ1-4973662699.

Yours sincerely

[redacted]
Head of Inspection