

RESPONSE TO REGULATION 28 CORONER'S REPORT TO PREVENT FUTURE DEATHS

1	<p>THIS RESPONSE IS MADE ON BEHALF OF Calderdale and Huddersfield NHS Foundation Trust</p>
2	<p>THIS REPORT IS BEING SENT TO: Calderdale and Huddersfield NHS Foundation Trust Leeds Teaching Hospitals NHS Trust [REDACTED] – Taycare Medical Limited, Unit 2, Royds Close, Leeds</p>
3	<p>CORONER Martin Fleming HM Senior Coroner for West Yorkshire Western</p>
4	<p>CORONER'S LEGAL POWERS I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulation 28 and 20 of the Coroners (Investigations) Regulations 2013</p>
5	<p>INVESTIGATION AND INQUEST On 15 October 2018 I opened an inquest into the death of Gladys May Sayles who, at the date of her death was aged 90 years old. The inquest was resumed and concluded on 9 July 2019.</p> <p>I found that the cause of death to be: - 1a – Fracture of C2 and C3 vertebrae</p> <p>I arrived at a conclusion of Accident</p>
6	<p>CIRCUMSTANCES OF DEATH At approximately 6:10pm on 26 August 2018, Gladys May Sayles was found collapsed with a head and neck injury after an unwitnessed fall in the kitchen of her home address at [REDACTED] West Yorkshire. Upon the arrival of the paramedics she was taken to Huddersfield Royal Infirmary, where a CT scan revealed that she had sustained fractures to her C2 and C3 vertebra.</p> <p>Although she was subsequently managed conservatively with a hard collar, she deteriorated such that she was discharged for palliative treatment on 3 October 2018 to Overgate Hospice, where she succumbed and died on 8 October 2018.</p> <p>Although I found that the hard collar did not play any part in the sad death communication and training issues with respect to the use of the hard collar were identified.</p>
7	<p><u>CORONER'S CONCERNS</u></p> <p>The MATTER OF CONCERN is as follows: -</p> <ul style="list-style-type: none"> • To review the existing guideline with respect to use of Aspen collars. • To review training with respect to the application and fixing of the collar in order to make it bespoke to patient's needs. • To consider the effectiveness of existing communications between Leeds General neurological unit, Huddersfield Royal Infirmary and the suppliers of collar's with respect to the fitting of the collar and patients general care.

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8	<p>ACTION SHOULD BE TAKEN</p> <p>In my opinion action should be taken to prevent future deaths and I believe that Calderdale and Huddersfield NHS Foundation Trust, Leeds Teachings Hospital NHS Trust and Taycare Medical Ltd, has the power to take such action. In circumstances it is my statutory duty to report to you.</p>
9	<p>RESPONSE</p> <p><u>PREAMBLE TO RESPONSE:</u> Evidence was heard at the inquest confirming that Leeds Teaching Hospitals Trust (LTHT) are the Trust responsible for the diagnosis, treatment and care plan for patients who have suffered a spinal injury. Taycare Medical Ltd (TML) are the healthcare organisation responsible for providing orthotic care to patients with a spinal injury. Calderdale & Huddersfield NHS Foundation Trust (CHFT) are responsible for managing the general care of patient with a spinal injury, whilst they are admitted to the trust.</p> <p><u>CONCERN 1 – GUIDANCE RELATING TO USE OF ASPEN COLLAR:</u> The use of an Aspen collar for treatment in a patient with a spinal injury is a decision that is made by LTHT.</p> <p>As CHFT do not make decisions on the use of an Aspen Collar for patients with spinal injuries we would not be in a position to fully address this concern. When a patient who requires a hard collar is nursed on a ward within the Trust, written guidance on the application of that collar and care and treatment are provided by TML.</p> <p><u>CONCERN 2 – TRAINING IN THE USE OF ASPEN COLLARS:</u> Although CHFT staff do not fit the Aspen Collar, this is undertaken by TML, CHFT staff are responsible for the general care of a patient, who requires an Aspen Collar; this will involve removing the collar and reapplying it.</p> <p>CHFT does not offer any formal training for application of Aspen Collars; however, bespoke training is provided by TML when a patient, who requires an Aspen Collar, is being cared for under CHFT. TML will also leave written instructions with the patient in relation to the application of the Aspen Collar, which CHFT staff will follow.</p> <p>On further discussion with staff who were caring for Mrs Sayles, CHFT can confirm that they were competent and confident in the use of Aspen Collars. Due to the low number of patients CHFT sees requiring an Aspen Collar, it is felt that bespoke training is the safest model of training delivery. Bespoke training when required ensures staff caring for a patient with an Aspen Collar understand how to remove and apply the Aspen Collar and can follow the written instructions left with the patient.</p> <p><u>CONCERN 3 – COMMUNICATION BETWEEN CHFT, LTHT AND TML:</u> When an Aspen Collar is required a referral is sent to TML to fit the collar. Should problems arise with the Aspen Collar when the patient admitted onto a ward at CHFT, CHFT staff will contact TML, via to telephone, regarding the problem encountered. Following this contact TML will attend the ward to reassess the patient.</p> <p>Should problems persistent CHFT staff will contact LTHT for further advice on the treatment and management for a patient with an Aspen Collar, explaining</p>

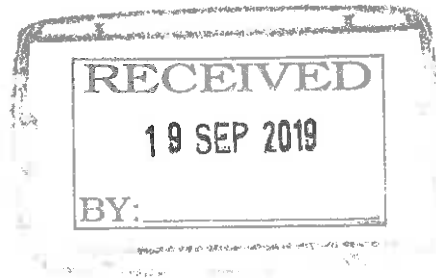
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	<p>the difficulties encountered. CHFT will follow the advice given by LTHT.</p> <p>In relation to Mrs Sayles' case, the orthotists at TML were contacted on seven occasions between 26 August 2018 (admission) to 5 September 2018 (discharge), when difficulties arose regarding Mrs Sayles' hard collar. On each occasion an orthotist attended the ward to assess Mrs Sayles on the same day they were contacted. LTHT were contacted on 21 September 2018 regarding the continuing concerns relating to the Aspen Collar and LTHT advised CHFT to remove the collar on 22 September 2018.</p> <p>CHFT have considered the effectiveness of communication between CHFT, LTHT and TML. From the Trust perspective communication has been timely, there have been no delays from calling TML to them being on site to offer recommendations and advice, and communication with LTHT has been clear, concise and informative.</p>
10	<p>THIS RESPONSE HAS BEEN PREPARED BY ██████████, Head of Legal Services and Complaints ██████████ Orthopaedic Consultant ██████████ Senior Ward Sister, Trauma and Orthopaedics</p>
11	<p>DATE OF RESPONSE 24 September 2019</p>

Suppliers of Orthotic Products and Services

Our ref: PNT/LET
Your ref: MDF-HK/-2471-2018
19 September 2019

Mr Martin Fleming
Senior Coroner
City Courts
The Tyris
Bradford
BD1 1LA



Dear Mr Fleming

**Re: Gladys May Sayles, deceased
Report to Prevent Future Deaths
Paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and
regulation 28 and 20 of the Coroners (Investigations) Regulations 2013**

I write further to your letter dated 26 July 2019 and Regulation 28 Report.

As you will be aware TayCare Medical Ltd was contracted by Calderdale and Huddersfield NHS Foundation Trust to supply and fit an Aspen Collar for Gladys May Sayles whilst she was in their care.

Whilst you have found that the hard collar did not play any part in the sad death you have indicated that communication and training issues with respect to the use of the hard collar were identified such that TayCare Medical Ltd has the power to take action to prevent future deaths.

As we were not present at the inquest, we do not have knowledge of what led to the Matters of Concern, but we respond to them as follows.

1. To review the existing guideline with respect to use of Aspen collars.

TayCare Medical Ltd follows rather than creates guideline with respect to use of Aspen collars.

In an NHS setting the decision to use an Aspen collar is taken by treating doctors. Whether that decision is based on a set of clinical guidelines is outside of TayCare's knowledge.

TayCare's role, upon receipt of a referral, is to supply and fit the collar once the decision to use it has been made.

Guidelines in terms of the fitting of the collar are provided by the manufacturer. I enclose instruction sheets for the Aspen Collar and Aspen Vista Collar. These are the guidelines we follow.

2. To review training with respect to the application and fixing of the collar in order to make it bespoke to patient's needs.

Aspen collars are an off the shelf product. There is no bespoke element to their construction and TayCare is not involved with their construction.

Following the manufacturer's instructions results in the appropriate fit for each patient. You will see from the instructions enclosed that appropriate fit is achieved by following, in particular, the sections on 'sizing', 'Position Front', 'Adjustments' and 'Proper Fit' (for the Aspen Collar) and 'sizing', 'tightening' and 'tips' (for the Aspen Vista).

To be an orthotist you need a recognised qualification from a national body called, The British Association of Prosthetists and Orthotists (BAPO). To gain this qualification you have to complete and pass a 3 year specialist course run by one of two universities – Salford and Strathclyde. During the course of that qualification the orthotist learns how fit hard collars. The BAPO website (www.bapo.com) gives further details, and confirms that:

"Orthotists are autonomous registered practitioners who provide gait analysis and engineering solutions to patients with problems of the neuro, muscular and skeletal systems. They are extensively trained at undergraduate level in mechanics, bio-mechanics, and material science along with anatomy, physiology and pathophysiology. Their qualifications make them competent to design and provide orthoses that modify the structural or functional characteristics of the patients' neuro-muscular and skeletal systems enabling patients to mobilise, eliminate gait deviations, reduce falls, reduce pain, prevent and facilitate healing of ulcers. They are also qualified to modify CE marked Orthoses or componentry taking responsibility for the impact of any changes. They treat patients with a wide range of conditions including Diabetes, Arthritis, Cerebral Palsy, Stroke, Spina Bifida, Scoliosis, MSK, sports injuries and trauma. Whilst they often work as autonomous practitioners they increasingly often form part of multidisciplinary teams such as within the diabetic foot team or neuro-rehabilitation team."

All of our orthotists are appropriately qualified and trained in this way. Furthermore, all of our new staff have a probationary period during which they have a mentor to ensure that they are operating correctly. During this probationary/training period we undertake mock fittings to assess their competence.

As orthotists, we are regulated by the health care and professions council (www.hcpc-uk.org) and to maintain the required registration must meet their Continuing Professional Development requirements.

I am therefore satisfied that all TayCare orthotists are appropriately trained with respect to the application and fixing of the collar in order to make it bespoke to patient's needs.

If it should ever be required, those engaged in fitting a collar will always have the manufacturers clear instructions with them. Every collar we supply is new and comes supplied with a copy of the applicable instructions. Those instructions are then left with the patient after fitting.

TayCare has no power to order, arrange or give training to NHS Staff.

3. To consider the effectiveness of existing communications between Leeds General neurological unit, Huddersfield Royal Infirmary and the suppliers of collar's with respect to the fitting of the collar and patients general care.

The initial communication TayCare Medical Ltd would receive would be the referral from the NHS Trust for the fitting of an Aspen Collar. This would contain the diagnosis of the patient and the request for the hard collar. Upon receipt of the referral an orthotist would attend the patient; this is usually the same day.

When the orthotist presents to the ward where the patient is situated, they would report to the sister in charge, and explain the reason for their visit. A nursing member of staff would accompany the orthotist to the patient.

The orthotist will explain in detail to the patient what the assessment and fitting involves. In a patient who does not have capacity, this would be explained to the patient's next kin, and in the absence of next of kin and capacity the collar will be fitted in the patient's best interest.

Once the orthotist is satisfied that the collar has been fitted correctly, a discussion takes place with the patient to once again to explain what has happened and the written instructions for the collar are left with the patient.

Appropriate notes are added directly and electronically to the Calderdale and Huddersfield NHS Foundation Trust's clinical record by the orthotist.

The collar purchased by the NHS is then NHS property and the patient remains under the care of the NHS. TayCare has no power to monitor the ongoing use, removal, refitting and adjustment of the collar thereafter.

However, we always leave our involvement as 'open review' because we are always happy to return to assist with any issues or concerns that arise. On occasions some patients may find that a further review is required. It may be that the collar requires replacement liners or the collar requires re-adjustment after removal and refitting by the care provider for washing/hygiene reasons. In these circumstances we may receive a referral from the hospital for a review and we are always happy to attend promptly to address any concerns.

I am satisfied that TayCare Medical Ltd already operate suitably and safely but if I have misunderstood the intent of your report then I would be happy to discuss the issues with you in more detail.

Yours sincerely




TayCare Medical Ltd

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