Doncaster and Bassetlaw Hospitals NHS
NHS Foundation Trust

Medical Director's Office

[redacted] **Medical Director (644156)**
[redacted] **Deputy Medical Director – Clinical Standards (642150)**
[redacted] **Deputy Medical Director – Professional Standards (642124 or 75 2275)**
[redacted] Clinical & Professional Standards Co-ordinator (642149)
[redacted] Executive PA to Medical Director (644148)

Our Ref [redacted]

16 August 2016

Mr M A Beresford
Assistant Coroner
South Yorkshire (East District)
Crown Court
College Road
Doncaster
DN1 3HS

Dear Mr Beresford

Re: Thomas William Pearson (Deceased)

Thank you for your letter to [redacted] dated 12 July 2016 and which has been forwarded to me for action.

I write in response to the Regulation 28 Report received following the inquest held on 24th June 2016.

I note the matters of concern identified in section 5 of the said report and particularly item 4 of that section namely '[redacted] *(Consultant Respiratory Physician) gave evidence at the inquest confirmed that fluticasone causes a reduction in the body's defence mechanisms and as a result carries with it an increased risk (estimated at 1.7 fold) increasing the risk of the patient developing pneumonia".*

The report also in section 5 states *"for a proportion of patients, the increased risk of developing pneumonia may be justified by the benefits that the use of fluticasone brings. However* [redacted] *stated that for the majority of patients, namely those without a raised eosinophil count (a group which included* [redacted] *fluticasone, whilst still carrying an increased risk of the development of pneumonia, would bring no benefits".*

[redacted] *went on to agree that is would be helpful for the use of inhaled steroids (in particular fluticasone) to be reviewed (paragraph 6, section 5).*

I now have had the opportunity of receiving a response from the respiratory team led by [redacted] Care Group Director.

[redacted] confirmed there has been a debate within the respiratory team at Doncaster and Bassetlaw NHS Trust regarding the matter. He advises that the wider respiratory community is aware of the ongoing international debate over the role of inhaled corticosteroids (ICS) in chronic obstructive pulmonary disease. The discussions took place between the respiratory physicians within the Trust since the inquest. Management of chronic obstructive pulmonary disease was the subject of a presentation in June 2015 prior to the conclusion of the inquest.

This issue of inhaled corticosteroid is a matter of international scientific debate at the moment. I understand that the consultant giving evidence pointed out that the respiratory community is on the verge of a reappraisal of the use of inhaled corticosteroid in chronic obstructive pulmonary disease as there remain many unanswered questions. I also understand that the consultant giving evidence did not suggest that the recurrent pneumonia suffered by the deceased led directly to the death.

It is important to stress that the international respiratory clinical and academic body still do not have a unified view on the matter. The national and international guidelines still recommend the use of inhaled corticosteroids in patients with chronic obstructive pulmonary disease (NICE 2010 (CG101), NICE Quality Standard (QS10) updated February 2016 and international guidelines – GOLD – Global Strategy for Diagnosis Management and Prevention of chronic obstructive pulmonary disease 2016. These acknowledge increased risk of pneumonia and the respiratory community within Doncaster is well aware of this. However it has been pointed out that whilst there is an increase in the incidence of pneumonia in patients using inhaled corticosteroids this is likely to be non-severe and non-fatal. Inhaled corticosteroids remain recommended as there is a reduction in the frequency of exacerbations of chronic obstructive pulmonary disease through their use. There is also evidence of improved lung function and quality of life with the use of such inhalers. Analysis through the Cochrane review concludes (March 2014) as follows;

"Budesonide and fluticasone, delivered alone or in combination with LABA, can increase serious pneumonias that result in hospitalisation of people. Neither has been shown to affect the chance of dying compared with not taking ICS. Comparison of the two drugs revealed no difference in serious pneumonias or risk of death. Fluticasone was associated with a higher risk of any pneumonia (i.e. cases that could be treated in the community) than budesonide, but potential differences in the definition used by the respective drug manufacturers reduced

our confidence in this finding. These concerns need to be balanced with the known benefits of ICS (e.g. fewer exacerbations, improved lung function and quality of life)".

It is accepted that there is a risk of patients having exacerbations of chronic obstructive pulmonary disease should inhaled corticosteroids be withdrawn and some of these exacerbations can be very significant. I understand that it has been suggested that a normal eosinophil count may identify a subset of patients who will not deteriorate on withdrawal. However I am advised by the respiratory team that there is no agreed consensus or international agreement on the validity of this assessment. On that basis therefore the eosinophil count cannot currently be recommended as a clinical tool to use in order to identify patients whose inhaled corticosteroids can be withdrawn. As there is no other reliable means of separating out those patients with an asthmatic component to their condition there is a significant worry that there is a sub set of patients with asthma/chronic obstructive pulmonary disease overlap syndrome (ACOS) who may be significantly compromised by withdrawal of inhaled corticosteroids.

To summarise the position therefore I am advised that the respiratory team is well versed with the current state of the evidence and are following appropriate current guidelines from learned societies. I have been reassured that the respiratory team work collaboratively in cohesive generic teams and a variety of topics are regularly discussed. At this point the team are unable to produce a useable local guideline given the current state of knowledge other than to be aware that possible options must be discussed with the patient while acknowledging that the evidence for withdrawal of inhaled corticosteroid currently remains unclear.

I trust this addresses the concerns that you have raised and provides reassurance that the respiratory unit at the Doncaster and Bassetlaw Hospitals Trust works within currently accepted guidance and are cognisant of the various debates that sometimes do arise in the management or patients occasioned by the various stages of knowledge before practice becomes generally accepted.

Please do not hesitate to refer back to me should there still be any outstanding concerns.

Yours sincerely

[redacted]
Deputy Medical Director - Clinical Standards

[redacted] Chief Executive
[redacted] Medical Director
[redacted] Deputy Director of Quality & Governance
[redacted] Consultant Physician/Care Group Director
[redacted] Acting Head Risk & Legal