The Rotherham NHS
NHS Foundation Trust

Our reference [redacted]

Your reference [redacted]

Date 6th June

Address **Strictly Private and Confidential**
Mr M A Beresford
Assistant Coroner
South Yorkshire (East District)
Coroner's Court and Office
Doncaster Crown Court

Rotherham Hospital
Moorgate Road
Oakwood
Rotherham
S60 2UD

Telephone 01709 820000
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Via Email

Dear Mr Beresford

RE: Ms Hayley Clark – Regulation 28

Firstly, I wish to state on behalf of The Rotherham NHS Foundation Trust, how sorry we are for the shortcomings in practice relating to Ms Clark's care. We have taken the learning from our investigation and your concerns seriously in order to improve practice and take action to ensure that other patients do not have the same experience in future.

Turning to the specific issues that you identified in your conclusion at the inquest on the 12th of April 2016:

"There was a failure, on the part of the staff who prescribed and administered the paracetamol to Ms Clark, to recognise the need to adjust the dosage (in evidence the reduction was said to be 50%) to reflect Ms Clark's extremely low body weight"

I attach a copy of our additional action plan and can confirm that I am assured that the Patient Safety Group will oversee completion of the action plan. In the meantime please do not hesitate to contact me if you require any further information

Yours sincerely

Louise Barnett
Chief Executive

Enc

Louise Barnett
Chief Executive, The Rotherham NHS Foundation Trust

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ACTION PLAN - REGULATION 28

Action Plan: **Regulation 28 – Prevention of future deaths** **Management of oral paracetamol for adult patients of extremely low body weight.**	**Date Issued:** **30th May 2016 (Version 1)**	**Action Plan Lead:** **Chief Pharmacist and Assistant Director of Patient Safety**	**Action Plan Review Dates:** **Monthly by Medication Safety Group** **To be signed off by the Patient Safety Group by September 2016 provided evidence of all actions is available.**

This action plan is dated the 30th May 2016 and relates to concerns identified at the inquest into the death of Ms Hayley Clark who was admitted to The Rotherham NHS Foundation Trust (TRFT) with electrolyte imbalance. She had a medical background which included malnutrition, hypogammaglobulinemia, irritable bowel syndrome, anaemia and depression. As part of her pain management Ms Clark received paracetamol. However the dose administered was the standard adult dose and did not reflect Ms Clarks extremely low body weight. The overdose caused derangement of her liver function. The issue was identified and the paracetamol withdrawn and Parvolex administered. The cause of death which was recorded by HM Coroner as:

1a) Respiratory Failure
1b) Pulmonary oedema
1c) Severe multifactorial malnutrition
2) Acute Pyelonephritis, electrolyte imbalance, anaemia and immune deficiency.

Following the inquest HM Coroner identified:

- There was a failure on the part of the staff who prescribed and administered the paracetamol to recognise the need to adjust the dosage (in evidence the required reduction was said to be 50%) to reflect Mrs Clark's extremely low body weight.

ACTION PLAN – REGULATION 28

Objective	Action Required	Who will take the action?	What timescale has been set and agreed?
1. Ensure the Trust's Medicines Management Policy includes the safe prescribing and administration of medication for patients with extremely low body weight.	See notes in far right column regarding research undertaken to inform this action plan 1.1 Review of the Trust's Medicines Management Policy and/or the development of further local guidelines/Standard Operating Procedure or a Patient Group Directive which must include information for all prescribers of the need to be aware of possible dose reduction of drugs for patients with extremely low body weight.	Chief Pharmacist and the Trust's Pharmacist designated as the Medication Safety Officer / Assistant Director of Patient Safety and the Chair of the Medication Safety Group	As the British National Formulary (BNF) does not currently provide dosage reduction recommendations the Trust's Chief Pharmacist has sought advice from the Medicines and Healthcare products Regulatory Agency (MHRA) who have recently reviewed the publication of a paper from Birmingham Trust; whilst body weight alone is not considered a marker for an increased risk of oral paracetamol toxicity, an adult weighing less than 50kgs is more likely to have conditions that predispose them to liver damage from the paracetamol. A dose reduction to 2-3g total daily dose may be warranted. The MHRA are not currently recommending a change to the licences of oral paracetamol products, or a change to the packaging of the paracetamol products for the public to buy. Local guidelines /Standard Operating Procedure or a Patient Group Directive to be completed by September 2016
	1.2 A pharmacy medications information leaflet to be produced on reducing the dose of oral paracetamol for patients who weigh less than 50kgs and/or with medical conditions which may require consideration of dose reduction – malnutrition/anorexia or high alcohol consumption all of which are known indications for considering a dose reduction of oral paracetamol	Chief Pharmacist and the Trust's Pharmacist designated as the Medication Safety Officer	The Trust information leaflet must be approved by the Trusts Medication Safety Group by July 2016 and available on the Trust's intranet by August 2016. Information added to the Trust electronic information for junior medical staff by August 2016.

	1.3 Development of stickers to be used on the Trust's prescription charts to raise awareness and compliance with the dose reduction guidance of oral (and IV) paracetamol	Chief Pharmacist and the Trust's Pharmacist designated as the Medication Safety Officer.	The stickers must be approved by the Trust's Medication Safety Group by July 2016 and available by August 2016 or any delay in the production and compliance with this completion date escalated to the Trust's Medication Safety Group
2. Ensure all nursing and medical colleagues identify adult patients with extremely low body weight who may need adjustment in the dosage of oral paracetamol	2.1 All nursing and medical staff who prescribe and administer medication to be provided with information on how to adjust the dosage of paracetamol for adult patients with extremely low body weight	Chief Pharmacist and the Trust's Pharmacist designated as the Medication Safety Officer	This information for staff will be developed by 31 August 2016.
	2.2 A record of all staff who require and have received appropriate training - on dosage reduction; will be collated to ensure all appropriate nursing and medical colleagues have received this in the required timescale	Chief Pharmacist and the Trust's Pharmacist designated as the Medication Safety Officer	All staff requiring additional training will have received this by October 2016. Attendance will be collated at the time of attendance Training will also be on-going and provided on induction to appropriate colleagues (from September 2016)
	2.3 Review of documentation to ensure accurate recording of patients weight in the clinical records, nursing records and prescription charts	Heads of Nursing/Matrons/Ward Managers/Ward pharmacists	An audit of documentation of weights recorded in relevant nursing records and charts and on prescription charts will be undertaken by August 2016 and the results presented to the Patient Safety Group by September 2016
	2.4 Audit to be undertaken to assess the equipment available across the Trust for weighing patients.	Patient Safety Team with the Critical Care - outreach team	Audit to be completed by July 2016 and a business case for any additional equipment will be presented to the Trust's Medical Device Management Group (MDMG) by August 2016.

	2.5 A learning event to be held to discuss the details of this specific case	The Pharmacy Department and Patient Safety team will deliver the learning event session	A learning event session will have been delivered by 30th September 2016 as part of the SAFETEMBER safety work to be undertaken in September 2016. The changes in practice will be communicated in the Quarter 2 Patient Safety 'lessons learnt' newsletter due to be published September 2016.

Action Plan developed by: Osman Chohan Chief Pharmacist and Fiona Middleton Assistant Director of Patient Safety

Version Control: Version 1

Date: 30th May 2016

Circulation List: Divisional Clinical Directors, All Consultant colleagues, Clinical Pharmacists, Heads of Nursing, Matrons, Ward Managers Medical Education and Practice Development teams.