REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

*NOTE: This form is to be used **after** an inquest.*

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. The Chief Executive, Salford Royal Hospital, NHS Trust Hospital, Stott Lane, Salford M6 8HD 2. Dr June Raine CBE, The Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA), 151 Buckingham Palace Road, London SW1W 9SZ 3. The Chief Executive, Nursing & Midwifery Council, 23 Portland Place, London W1B 1PZ
1	**CORONER** I am Rachel Syed, HM Assistant Coroner for the Coroner Area of Manchester West.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3	**INVESTIGATION and INQUEST** On the 16th January 2019, I commenced an Investigation into the death of Victor James Hall, born on the 24th May 1934. The Investigation concluded at the end of the Inquest on the 16th October 2019. The medical cause of death was:- Ia Cardiac enlargement and coronary artery atheroma in combination with Chronic Obstructive Pulmonary Disease (COPD). The conclusion of the Inquest was that Mr Hall died from natural causes.
4	**CIRCUMSTANCES OF THE DEATH** 1. Victor James Hall (hereinafter referred to as "the deceased") died at the Salford Royal Hospital on 29th June 2018. 2. The deceased suffered from a number of underlying co-morbidities, namely Bronchiectasis, Chronic Obstructive Pulmonary Disease and Heart Disease and was fitted with pacemaker around 2010. 3. On the 25th June 2018, the deceased was admitted to the Salford Royal

Hospital with shortness of breath and an exacerbation of his Chronic Obstructive Pulmonary Disease. Mr Hall was diagnosed with Acute Kidney Injury and prescribed, 500mg of IV sodium bicarbonate, 1.4% every six hours.

4. A member of the pharmacy dispensing team, in error, manually dispensed Phosphate Polyfusor which was close to the sodium bicarbonate Polyfusors box and generated a label for Sodium Bicarbonate. The Pharmacist tasked with checking the dispensed medication, failed to identify the error, by checking the medication packaging against the prescription and label and authorised release for delivery to the Wards.

5. Two Ward Nurses, both responsible for checking and signing the prescription chart, failed to check the medication packaging, against the prescription and label and at around 23.30 on 28th June 2018, Mr Hall was infused with Phosphate Polyfusor. At approximately 01.20 on 29th June 2018, Mr Hall was found to be unresponsive and the Resuscitation Team was summoned. Despite resuscitation efforts, Mr Hall died on the same day.

6. The Post Mortem and Toxicology evidence concluded that Mr Hall could have died at any time from his underlying heart, lungs and kidney conditions and the medication error was not in keeping with levels associated with fatalities therefore had played no role in his death.

5 CORONER'S CONCERNS

During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you.

The **MATTERS OF CONCERN** are as follows:

During the Inquest, evidence was heard that:-

1.Salford Royal Hospital had undertaken an internal investigation and concluded that one of the root causes for the medication error, was the Phosphate Polyfusor product design.

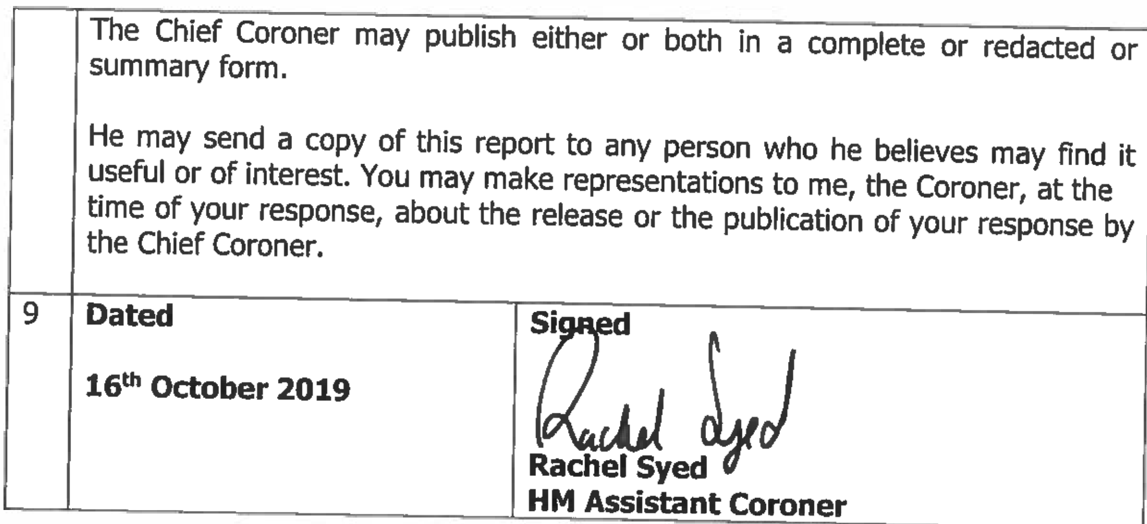
i. The Pharmacy and Nursing Matron Lead, concurred that the staff involved in the incident had relied on the word Polyfusor, without actually checking the medication packaging against the prescription chart and label. Salford Royal Hospital, wrote to the Medicines and Healthcare products Regulatory Agency (MHRA) in 2018, requesting the word Polyfusor be removed from the Phosphate design product packaging to prevent future medication errors. Despite repeated requests from Salford Royal Hospital for an MHRA update, the product design for Phosphate Polyfusor remains the same.

2. I request that The Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA) reviews the:

i. Product design on the Polyfusors in question

3.The Chief Executive, Nursing & Midwifery Council, 23 Portland Place, London

	W1B 1PZ reviews the: i.Guidance given to their members in relation to the administration of medication to consider and include the simplest of steps, namely that a Healthcare Professional should check the name of the medication on the prescription chart against the name of the medication on the packaging and labelling of the medication at the time of each administration of medication to ensure that the correct medication is always administered to a patient. ii.Guidance given to their members in relation to their duties, to accurately record and contemporaneously document the packaging, label an prescription checks they have undertaken to ensure the correct medication is always administered to a patient. 4.The Chief Executive, Salford Royal Hospital, NHS Trust Hospital, Stott Lane, Salford M6 8HD reviews the: i.Guidance and procedures in relation to the dispensing and transfer of medications from the Pharmacy Department to a ward, to include a system of checking medications against the packaging, labelling and prescription chart at the time of receipt by the ward. Furthermore, to consider documentary evidence of the fact that the medication packaging has been checked against the prescription chart and an acknowledgement of receipt of the correct medication by the pharmacy and ward staff, evidenced by a signature of the recipient. ii.Training, Auditing, Supervision and monitoring of all staff, particularly Nursing and Pharmacy staff, in relation to the above issues.
6	**ACTION SHOULD BE TAKEN** In my opinion urgent action should be taken to prevent future deaths and I believe that you have the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by **11th December 2019**. I, the Coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons:- 1. [redacted], Son of the deceased I am also under a duty to send the Chief Coroner a copy of your response.



	The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the Coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.	
9	**Dated** **16th October 2019**	**Signed** **Rachel Syed** **HM Assistant Coroner**