REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. **Chair of the Faculty for Eating Disorders Royal College of Psychiatrists** 2. **Medicines and Healthcare Products Regulatory Agency** 3. [redacted], **Greater Manchester Health and Social Care Partnership / Integrated Care Board** 4. **Chief Excecutive Officer of NHS England**
	CORONER I am Joanne Kearsley, Senior Coroner for the Coroner area of Manchester North
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroner's and Justice Act 2009 and Regulations 28 and 29 of the Coroners (Investigations) Regulations 2013
3	**INVESTIGATION and INQUEST** On the 13th January 2023, I commenced an investigation into the death of Charlene Roberts, date of birth 12th March 1987 who died on the 12th January 2023 at Fairfield General Hospital. The medical cause of her death was confirmed as 1a) Cyclizine Toxicity 2) Aspiration Pneumonia, Anorexia and Factitious Disorder
4	**CIRCUMSTANCES OF DEATH** Charlene was an extremely complex patient who could be difficult to engage. She had a complex diagnosis of Anorexia (since early 2000s), Factitious disorder (2019) and cyclizine abuse (2019). All of these were linked to past trauma. It is recognised at the outset of this report that this is a rare presentation. Charlene was under the care of Greater Manchester Eating Disorder Service (Greater Manchester Mental Health Trust), the Community Mental Health Team for her Factitious Disorder (Pennine Care NHS Foundation Trust), a Dual diagnosis worker for her cyclizine abuse. Due to her eating disorder her weight and bloods were monitored by her GP in the community. However her physical health meant she was often admitted to the acute hospitals, in particular North Manchester General Hospital (Manchester Foundation Trust) and Royal Oldham Hospital (Northern Care Alliance.) [redacted]. She had initially been prescribed cyclizine around 2014 when she was an inpatient. The prescribing of cyclizine had continued unquestioned for over 5 years and at one point for reasons that could not be ascertained she was prescribed it intravenously. [redacted]. However she was consistently found interfering with cannulas and lines (PIC lines) when she was an inpatient and would inject cyclizine into them. It had been recognised by medical staff that she should not have lines inserted. If there was a clear medical reason for them to be placed when she was an inpatinet, she would require 1-1 observations. Her care had been escalated in 2022 to the Multi Risk Management process. It was accepted that Charlene was at a significant risk of death due to her eating disorder and her cyclizine abuse. Charlene had capacity to make decisions in relation to her use of cyclizine. She was not able to be detained under the Mental Health Act 1983. From mid 2022 until the time of her death all

professionals accepted that they had run out of ideas and options as to how to make progress with Charlene.

She was rejected from nearly 20 inpatient Specialist Eating Disorder Services predominantly due to the dual diagnosis of her substance abuse and eating disorder.

There was no treatment for her addiction to cyclizine, only psychological therapy to work on her addiction.

On the 10th January 2023 Charlene attended A&E at Fairfield General hospital to have her weekly bloods taken. This was a recent arrangement due to difficulties for the GP in finding somewhere for her to have bloods taken. Due to being compromised Charlene required ultrasound guidance to obtain bloods. She was physically unwell with a suspected infection and was admitted as an inpatient.

On the 12th January 2023 Charlene's condition deteriorated and she went into cardiac arrest. She died at 10:34am.

Following her death it was discovered she had left the ward on the 11th January 2023 and taken an uber taxi to a local pharmacist where she had purchased cyclizine. Her cause of death following examination was found to be due to cyclizine toxicity.

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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:-

1. Cyclizine

During the course of the Inquest a number of issues pertaining to cyclizine were raised. In considering these it is important to note that cyclizine is not tested for in routine toxicology testing so the prevelance of cyclizine abuse is not well understood. Many professionals who gave evidence had not worked with a patient with such an addiction previously. It was clear throughout the hearing that the knowledge of cyclizine varied amongst many professionals as to how it was prescribed and obtained.

Medicines and Healthcare Products Regulatory Authority

The court heard evidence that intravenous cyclizne is by prescription only but oral cyclizine can be purchased over the counter at a pharmacy. In order to purchase oral cyclizine in a pharmacy a pharmacist should seek information as to why it is required and should be present. Charlene's family gave evidence that following Charlene's death they had been able to obtain cyclizine in a pharmacy directly from a pharmacy assistant with no questions being asked of them.

Chair of the Faculty of Eating Disorders Royal College of Psychiatrists

The court was made aware of the research conducted in 2009 as published in the journal PNS, "Proceedings of the Nutrition Society", "Cyclizine dependence in patients with complex nutritional requirements" Thursby-Pelham, De Silva, Stroud and Fine, 23 July 2009. This identified cyclizine dependence in four female patients who all had complex nutritional problems.

Whilst it is acknowledged that this is one study and as stated cyclizine addiction is rare, it was not something which had been considered before Charlene's addiction by the Eating Disorder Service. For the Manchester Eating Disorder Service there is now a greater awareness of cyclizine. This may be important nationally given its use as an anti-emetic.

NHS England

Cyclizine is not a controlled drug. At one stage consideration was given to using the Controlled Drugs local intelligence network as convened by NHS England (Controlled Drugs (Supervision and Management of Use) Regulations 2013) to put an alert out to local pharmacies to warn them about Charlene's purchasing of cyclizine.

From the evidence there was a lack of clarity and understanding from professionals as to whether this local network could be used for drugs which are not controlled drugs. The fact that the legislation

	refers to controlled drugs may mean there is a lack of understanding about using this for system for non controlled drugs such as cyclizine. 2. Commissioned Pathway in Greater Manchester for the taking of bloods in community patients who are compromised. **Greater Manchester Integrated Care Board** During the course of the evidence the court heard evidence from the GP who was responsible for obtaining weekly bloods to monitor her eating disorder. There is no commissioned pathway in Rochdale for GPs to refer patients who require bloods but who are compromised and therefore hard to obtain blood from. As a result patients are attending A&E departments for these to be taken.
W	**ACTION SHOULD BE TAKEN** **In my opinion action should be taken to prevent future deaths and I believe each of you respectively 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 2 February 2024 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 namely:- The family of Charlene Roberts Greater Manchester Mental Health Trust Pennine Care NHS Foundation Trust NHS England 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 from. 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	Date 8th December 2023 Signed: