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Mr H G Mark Bricknell
Senior Coroner for County of Herefordshire
BY EMAIL
C/O Nigel Phillips
Coroner's Officer
coroners@herefordshire.gov.uk

28 April 2020

Dear Mr Bricknell

Re: Jake Perry; Regulation 28 Report to Prevent Future Deaths

I write in response to your Regulation 28 Report issued to Birmingham Women's and Children's NHS Foundation Trust on 1 April 2020, following the inquest into the tragic death of Jake Perry.

We would like to reiterate our sincere condolences to Jake's family, who sadly have lost a very special young person.

The matters of concern you raised in your Report refer to the variation of Parenteral Nutrition and communication of such. Specifically, you are concerned that secure procedures are required in connection with changes to Parenteral Nutrition and that consideration should be given to the production of a standard Parenteral Nutrition which is varied on specific instructions of the prescribing consultant. I will respond to each of your concerns in turn.

You are aware that immediately following this incident, the Trust commissioned an investigation into the care and treatment we provided to Jake. Following the investigation of this incident a significant amount of work has been undertaken by the Trust to improve our own internal processes. We have ensured that national guidance such as that the best practice guidance on Homecare medicines, issued in 2011 and known as 'the Hackett Report'¹, has been put into practice. For ease of reference, the relevant sections within the report are reproduced below:

¹ <http://media.dh.gov.uk/network/121/files/2011/12/111201-Homecare-Medicines-Towards-a-Vision-for-the-Future2.pdf>



5.15 Ensure governance arrangements in relation to patient safety state aspects of care for which the following are responsible

- Hospital
- Homecare Company
- GP
- Health professionals
- Patient
- Availability of backup advice and support

5.16 It should explain:

- How will the treatment plan be communicated to the patient, homecare company, GP other healthcare providers.
- How will the initial prescription and repeat prescriptions be produced, and who will check this prescription in the Trust before communicating to the home healthcare company.
- What level of clinical checking of the prescription and patient will the home healthcare company undertake.
- How will the clinical and laboratory monitoring be undertaken.
- What are the arrangements for patient safety incident reporting, performance monitoring and outcome monitoring?

All these reports should be shared with the Trust and then the NRLS.

The Trust should have a formal way of reviewing these reports and taking necessary action.

5.17 The home healthcare company should also provide to the Trust electronic copies of medicines policies, control of infection policies, and other policies impacting on patient safety and clinical effectiveness.

The Hackett Report was written generally, for all medicines delivered by homecare companies and not specifically for home Parenteral Nutrition. It has therefore taken some time to agree the details of such arrangements for this specialised area. There have been improvements at a national level, such as an agreed national template for the initial prescription and improved working with homecare suppliers to identify errors and learn from them.

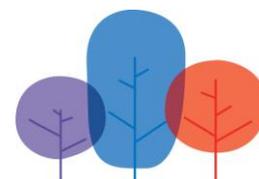
Improvements have also been made to the National framework. There is a national review being undertaken on the safety and resilience of aseptic services, including the production of home Parenteral Nutrition². Birmingham Women's and Children's NHS Foundation Trust has submitted evidence to this review on various aspects of paediatric services including the lessons learnt directly from Jake's case.

As you are aware, we have reflected upon Jake's sad and untimely death in detail and we have put measures in place in an attempt to prevent any recurrence of such an incident. In order to strengthen the measures we have put in place locally, the Trust considers that computerised prescription should be used throughout the ordering process of PN. However, unfortunately, the Trust is not in a position to effect such a change in the market; the requirement for a single format electronic prescription for PN would require a mandate by NHS England.

PN is an intravenous medication, with more than 50 ingredients and additives, and as such is liable to medication errors, especially in paediatric patients where all the calculations are weight-based. Computerised prescription, whether standardised or bespoke to the individual patient, ought to be used in the ordering process of PN. We therefore consider that computer assisted prescribing software for PN should become readily available, as a standard for all units set out in the national Home PN Framework as these programs can save time, decrease prescription and compounding errors, and improve the quality of nutritional care.

We have recommended a national standardised electronic prescribing system for Parenteral Nutrition as we noted that there needed to be improved communication between Trusts and suppliers, specifically with clarity on responsibilities. This issue was also highlighted within our RCA.

² <https://improvement.nhs.uk/resources/call-evidence-pharmacy-aseptic-services-review/>



Furthermore, the Trust's Chief Pharmacist has been asked by the Chief Pharmaceutical Officer of England to provide a synopsis of the lessons learnt in Jake's case for pharmacy professionals nationally. There are mechanisms for sharing such learning through a number of networks including the All England Chief Pharmacists' Network, Medication Safety Officer Network and through presentations at local and national professional meetings.

The findings will also be shared with the National Homecare Medicines Committee who have input into the national framework for the procurement of homecare products. The national lead for outsourced medicines has advised the Trust on improvements following the incident involving Jake's Parenteral Nutrition and will also receive a copy of the lessons learnt.

In response to your concern regarding the production of a standard Parenteral Nutrition which is varied on specific instructions of the prescribing consultant, I have discussed this matter with Dr Protheroe and can respond as follows;

There are two Parenteral Nutrition (PN) solutions available for use. Those are a) standard feeding regimens known as All-in-One (AIO) or multi-chamber bags (MCB) which contain all the required nutritional components, or b) individually compounded mixtures which are manufactured in a suitable pharmacy manufacturing unit and contain bespoke nutritional requirements for an individual patient.

Commercially prepared mixtures of vitamins and minerals are available and will provide well-balanced amounts of all essential vitamins and trace elements. These mixtures must be added to individually compounded bags of PN or AIO bags under controlled aseptic pharmaceutical conditions.

Standard PN bags are used for children and young people in hospital on a short term basis only. This is in order to reduce the risk of ordering errors, as well as the risk of compounding errors in the hospital pharmacy, which deals with many different PN prescriptions on a daily basis. These commercially batch-produced standardised PN bags require an addition of parenteral multi-vitamins shortly before infusion. This is a limitation that requires proper handling to assure aseptic conditions and to avoid errors and as a consequence is not an option available for home use. Moreover, the inclusion of various trace elements may shorten the shelf life of the standard bag.

Regular use of standard formulations in infants and children requiring PN for prolonged periods (such as those on home PN particularly over longer periods of time), may be less than optimal for growth and development and as a result, these patients require bespoke formulations of PN, as was the case with Jake.¹

There are a number of reasons why a patient will require individualised PN;

A] patients with chronic intestinal failure requiring long term home PN (HPN)

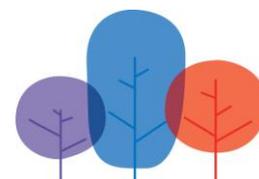
B] particularly where parenteral nutrition is a supplement to oral intake and

B] children and rapidly growing adolescents on HPN in order to meet their specific nutritional requirements.

Jake fulfilled all of these three criteria and consequently was prescribed individualised PN.³

As you heard in evidence provided at Inquest, an adequate supply of micronutrients is essential for patients on PN to prevent clinical deterioration. Specific patient related requirements for parenteral vitamins, trace elements and minerals vary among patients depending on their clinical and metabolic status and the need to replace any losses or prevent toxicity. It is for this reason that long-term PN patients, who have their PN administered at home, require a bespoke formulation rather than a standard preparation.

³ <https://www.bapen.org.uk/85-nutrition-support/parenteral-nutrition>



I hope that this information serves to adequately address your concerns. Jake's death has had a significant impact on staff caring for Jake and we are truly sorry for the errors in processes that led to Jake's death. Once again, I would like to offer my sincere condolences to Jake's family.

Yours sincerely



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Chief Medical Officer

Birmingham Women's and Children's NHSFT

ⁱ https://www.espen.org/files/ESPEN-Guidelines/Pediatrics/ESPGHAN_ESPEN_ESPR-guidelines-on-pediatric-parenteral-nutrition-Standard-versus-individualized-parenteral-nutrition.pdf

2018 ESPGHAN/ESPEN/ESPR guidelines on pediatric parenteral nutrition: Standard versus individualized parenteral nutrition

