



## Frequently asked questions

### Update on 19 December 2019

The frequently asked questions have been updated below and are now accurate as of 19 December. New questions have been added marked with an asterisk\*\*. If you have any further questions please send these to the NHS England and NHS Improvement [customer contact centre](#): <https://www.england.nhs.uk/contact-us/> or via the patient group PINNT on [comms@pinnt.com](mailto:comms@pinnt.com) We will provide a further update on the situation in January 2020.

### Background

An inspection at the end of June 2019 by the Medicines and Healthcare Products Regulatory Authority (MHRA) at the Calea site identified a need for Calea to permanently change some aspects of the manufacturing process to ensure product safety for patients supplied with total parenteral nutrition bags.

Whilst no evidence was found of defective product on the market, the changes have led to supply problems which risks increased hospital admissions for patients as supplies run short. The replacement product, multi-chamber bags (MCBs), are being supplied where clinically appropriate to people who cannot have their usual compounded parenteral nutrition.

When the situation initially arose, an NHS action group was established to determine the effect this would have on those receiving parenteral nutrition. In order to deal with the issue as quickly as possible the NHS set up an incident management team to replace the action group. The NHS incident management team continue to work with Calea, MHRA and other key health sector partners (full details below).

### Frequently asked questions

**\*\*Progress at Calea seems to be slow, how long will this situation go on for?**

The NHS, the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Authority (MHRA), are working hard to ensure that safety is a priority. Whilst we all want to see a return to the production levels seen prior to June 2019, it is imperative that

the safety of all patients is not compromised. The situation, as outlined above, is expected to continue for several more months and well into 2020.

**\*\*Given how fragile the supply chain of parenteral nutrition is, what is being done to secure the longer-term supply of parenteral nutrition?**

We recognise we need to avoid a repeat of Calea's problems, so work is underway to examine longer-term solutions for the supply of parenteral nutrition to NHS patients.

The production of medicines and medical products including Home Parenteral Nutrition (HPN) is complex and highly regulated. Materials and processes must meet rigorous safety and quality standards. In England there are only a few manufacturers of parenteral nutrition and when one supplier experiences a problem with production such as the issue with Calea, it creates further pressure on the whole supply chain. Addressing the long-term supply issue with HPN for NHS patients is complex we are working with the Department of Health and Social Care (DHSC), NHS trusts, clinical experts and suppliers to explore a number of options. These include a review of the pathway of care and a review of pharmacy aseptic services in England, which the DHSC commissioned NHS England and NHS Improvement to undertake. The aim of the review is to develop recommendations to deliver a high quality, safe and resilient service able to meet both current need and cope with the increase in demand for aseptic production of chemotherapy, parenteral nutrition and other medicines.

**Why has Calea's ability to make parenteral nutrition changed?**

Following the MHRA inspection, Calea was required to make permanent changes to their compounding process. Calea have not yet been able to achieve previous levels of production whilst implementing necessary changes. However, there have been some improvements in this process and this has meant Calea is now able to gradually increase the amount of parenteral nutrition made. The company's processes will continue to be monitored to ensure compliance with all the required quality and safety standards.

**What fluids and replacement parenteral nutrition are those unable to have their compounded parenteral nutrition receiving?**

The NHS has been in regular contact, through local trusts or nutrition teams, with all patients who have been affected by this. Where this is clinically appropriate, some patients have been receiving a different type of parenteral nutrition than usual, multi-chambered bags or fluids, for example,

with vitamins and trace elements provided separately. You can be reassured that you will receive support and the best level of care when using a different feed than you are used to.

### **What is the impact of receiving a different type of parenteral nutrition?**

It depends on your circumstances. Some patients will have received a parenteral nutrition known as a multi-chamber bag (MCB) and, whilst providing most of the nutrition and minerals you need, it is not tailored to your individual requirements, meaning that you may need to administer an additional infusion of vitamins and trace elements. For some patients, their clinical needs mean that MCBs cannot be used. In these circumstances, patients will remain on individually tailored compounded bags. If you have any concerns about your treatment then please speak to your clinical team.

### **Why does my multi-chamber or fluid bag keep changing?**

Due to the unexpected nature of this incident, the initial stock levels of some multi-chamber bags (MCBs) and magnesium containing fluids within the UK was lower than required.

The NHS has been working with manufacturers, homecare companies and the MHRA to make sure that we have enough stocks going forward. You may have noticed that some bags were labelled in a foreign language, although the name of the bag will be clear to you. These bags have been imported from European countries where stock was available, and we can assure you the contents are the same as the product that is made for the UK.

The situation with out of stock MCBs should now be very rare and we are constantly monitoring the availability and use of the different MCB bags to try and ensure there are no supply issues.

### **What does additional infusions mean?**

Compounded parenteral nutrition includes vitamins and trace elements whereas multi-chamber bags (MCBs) do not. Those receiving MCBs are likely to need vitamins and trace elements which are given separately. Your nutrition team will look at your individual circumstances as it may be possible for you to have oral vitamins and minerals in this interim period. If you require intravenous vitamins and trace elements, these will be administered either by your nursing team or by you after training has been received and you are capable of managing this procedure.

If you have any concerns or questions about the vitamins and trace elements that you are taking either orally or through an intravenous (IV) drip please contact your nutritional team.

**My parenteral nutrition is set up by a homecare nurse. Will this change?**

If you are having home nursing support for your parenteral nutrition, this will continue. If required, you will have the infusions of vitamins and trace elements prepared and administered during your usual nursing visits. These nurses have undertaken additional training to make sure extra infusions are given safely.

**I do not have homecare nurses, I do my own procedures. What should I do?**

If you are self-caring for your parenteral nutrition, patients and carers will receive additional training, either via group training sessions or individually. You will be contacted by your specialist team to arrange this training which may be in your own home or at a location close to you.

You will have the opportunity to discuss this with your own nutrition team, before and during, these essential infusions. You will be fully supported, and any concerns will be addressed for as long as these infusions are required.

**Who is prioritising those people for compounded parenteral nutrition?**

Initially trusts were asked to prioritise the patients who required compounding slots as they are aware of all your clinical details.

We have now formed a clinical support group to oversee this process of allocations of compounding slots across England and Wales. This group comprises of healthcare professionals who are fully aware of the importance of patients receiving compounded parenteral nutrition.

Each NHS trust submits a list of those patients most in need of being considered for one of the compounding slots. The clinical support group then uses this information to allocate slots based on a set number of clinical priorities that are known to be more difficult to manage on multi-chamber bags. The submissions to the group are anonymous and they base their decision only on the medical evidence received.

## **What is the process of managing parenteral nutrition allocations?**

Processes are in place to ensure patients with the highest clinical need are allocated compounding slots and to ensure that this is undertaken fairly. This is supported by the clinical support group.

A protocol for this prioritisation process has been developed and issued to all trusts. This sets out the clinical priorities used to allocate new compounding slots to patients. It also details the process for trusts to follow when applying for a compounding slot for one of their patients.

A small number of compounding slots may become available if a hospital decides to remove a patient from compounding to a multi-chamber bag (MCB). The hospital can then decide to put another of their patients onto compounding.

While a number of hospitals have facilities capable of producing parenteral nutrition, many do not. The hospitals that are able to produce parenteral nutrition may be able to produce some extra compounded parenteral nutrition or manipulated MCBs (these are MCBs with vitamins and trace elements added) for Home Parenteral Nutrition (HPN) patients but have a very limited capacity to do this.

Those hospitals which cannot produce parenteral nutrition would order MCBs.

## **How many compounding slots are becoming available?**

This varies, but please be assured that when slots are available they are assigned to those with the greatest clinical need.

## **Are the new compounding slots with Calea or new homecare providers?**

Slots become available with Calea and other homecare providers. These compounding slots will be available to new Home Parenteral Nutrition (HPN) patients and those patients who are not managing on multi-chamber bags (MCBs). If you are a patient moving back from MCBs to compounded, you may get your HPN from a different provider than Calea. You will be informed about this in advance.

Due to the production issues at Calea described above, any patients being phased back into Calea compounding are being closely monitored to ensure the parenteral nutrition can be made and supplied to the patient on time and in full.

## **How long is this issue likely to last?**

It is expected that the issue will last well into 2020 but we continue to work with all partners to try and return to normality as soon as it is safe to do so.

## **How many patients are affected by this?**

Calea serves over 1,300 patients with parenteral nutrition - this number accounts for the UK and Ireland. Approximately 460 patients are currently affected in England by the reduction in capacity at Calea. The NHS is working very closely with Calea, MHRA, PINNT – the support and advocacy group for people on home artificial nutrition (parenteral nutrition), other homecare providers and suppliers of parenteral nutrition, as well as local nutrition teams to ensure that patients are aware of what is happening, have their care plans amended and if required, an alternative solution found.

## **Why did this incident happen?**

The parenteral nutrition market is very specialised and as a result has very few providers. Any disruption in the supply chain has a destabilising effect further down the line, which is what we have experienced with the reduction in supply from Calea. However, patient safety must always remain a priority which is why we are working with MHRA and Calea to resolve the on-site situation as well as searching the market across Europe to increase safe alternative products from elsewhere.

## **How do we know if the service from Calea is safe?**

Throughout this process, the NHS, the Department of Health and Social Care (DHSC) and the MHRA have been working with Calea to ensure that the company's processes comply with current guidance and that the service patients are receiving, improves. Currently we are having calls with Calea three times a week to continue to work on areas, and to ensure all issues are discussed and resolved as quickly as possible. This number increases to daily when required. This high level of contact with Calea will continue until we are satisfied that the service is of a high standard.

## **Who is representing the patients' voice in this issue?**

The NHS has engaged with the patient group, PINNT, as an expert body to represent the broad-ranging views of patients/parents/carers. PINNT has stated from the outset that they do not represent everyone affected by this situation. They have agreed to share all relevant updates on their website. Due to patient confidentiality there were no patient representatives on the

initial action group (which is no longer operational) nor is there a representative on the clinical support group.

### **What other support is available?**

We are working hard to make sure your care is maintained to the high standard you expect. NHS England and NHS Improvement continue to work closely with your nutrition support team to make sure you receive answers to any questions or concerns you may have.

If you would like to speak to someone, please contact your local nutrition support team in the first instance.

You can also send queries via the NHS England and NHS Improvement [customer contact centre](#).

or via PINNT on [comms@pinnt.com](mailto:comms@pinnt.com)