Prevention of Future Death Notice Matters
of Concern

CCG Actions taken

- 7). The GPs relied upon the advice given by Enfield Clinical Commissioning Group (CCG) that the scriptswitch was simply the replacement of one branded product with another branded product of the same drug/device. This gave false reassurance. The CCG joint formulary committee introduced a new drug for GPs, but then gave the wrong advice to accompany this.
- 27th August 2015 North Central London Joint Formulary Committee (NCL JFC) agreed to replace Epipen with Emerade on the joint formulary.

1. The narrative verdict was discussed at the NCL Medication Safety Officer (MSO) Local

Network on 17th January 2020. The network agreed that a Medicines Safety Bulletin on

Adrenaline Auto Injectors (AAIs) would be distributed to GPs and other primary care healthcare

professionals. The NCL Medicines Safety Bulletin on Adrenaline Auto Injectors (AAI) dated 24th

January 2020 is attached as appendix 1. The bulletin was approved virtually by NCL Medication

Safety Officer (MSO) Local Network following the meeting on 17th January 2020 and distributed

- 8). The CCG failed to draw prescribers' attention to the need, following scriptswitch from EpiPen to Emerade, to reconsider the dose and to prescribe the higher dose of 500mcgs for patients at higher risk (which would have included Shanté).
- The Prevention of Future Death notice will be discussed at the next NCL Medication Safety Officer (MSO) Local Network on 4th April 2020 to consider if there is anything further that should be done.

9).The CCG failed to inform prescribers that the Emerade pen requires different training to the EpiPen because different AAIs do not operate in the same way. In fact, the CCG gave the opposite advice.

- 2. The Prevention of Future Deaths report has been shared with the Chair of the NCL Joint Formulary Committee (JFC) with a request that the committee ensures that they address the matters of concern at the next meeting on 20th April 2020.
- 3. Information circulated to GPs by Enfield CCG:

to Enfield GP practices on 30th January 2020.

i) 16th January 2017 - Scriptswitch message:

"Please switch EpiPen solution for injection auto-injectors 300 micrograms/0.3ml (1in 1,000) to Emerade solution for injection auto-injectors 300 micrograms/0.3ml (1 in 1,000). The Emerade® adrenaline auto-injector currently has the longest shelf life of all the Adrenaline auto-injector pens currently available 2.5 years (30 months) from date of manufacture compared to others that are 18 months from date of manufacture. If patients are switched to Emerade, it is advised that they are offered training in the use of the device. An on-line instruction video is available at the official Emerade® website along with a 'request button' for free training".

8 and 9 contd

ii) 2nd Sept 2017 – newsletter to GP practices distributed

The Enfield CCG Newsletter emailed to all GP practices included a link to Adrenaline auto-injectors updating advice after a European review - https://www.gov.uk/drug-safety-update/adrenaline-auto-injectors-updated-advice-after-european-review. The link references advice to healthcare professionals to "ensure that people with allergies and their carers have been trained to use the particular auto-injector that they have been prescribed—technique varies between injectors".

iii) 28th September 2018 – supply distribution alert

Supply Disruption Alert was emailed to all GP surgeries http://nww.enfield.nhs.uk/Docs/Referral%20Forms/EpiPen%20supply%20issue.pdf

The alert stated "The different brands of adrenaline auto-injectors are not used in exactly the same way and therefore specific training and advice is required for each of the devices- please see information on these alternative devices below". This alert helped to reinforce the view that training was required if a patient was changed from one device to another.

iv) 17th July 2019 – policy statement approved by Enfield CCG Medicines Management Committee

Policy Statement agreed by Enfield CCG Medicines Management Committee on the prescribing of adrenaline auto injectors (Appendix 2) was put on Enfield GP intranet and discussed with GPs at all the GP locality events.

v) 19th July 2019 – scriptswitch message

A Scriptswitch message on 300mcg AAIs was issued stating "Consider prescribing Emerade 500mcg if risk of severe anaphylaxis (for self-administration patients at risk of severe anaphylaxis).

vi) 30th January 2020 - Medicines Safety Bulletin

Following receipt of the narrative verdict Medicines Safety Bulletin (Appendix 1- as above) was circulated to Enfield GP practices and community pharmacists, and, was uploaded on the Enfield GP intranet site. The bulletin advises GPs to review the dosage and ensure it is appropriate for the patient's age and weight, and to seek specialist advice for high-risk patients.

8 and 9 contd.

vii) 4th March 2020 - scriptswitch message update was issued advising practices:

- All strengths of Emerade devices will be unavailable for the foreseeable future.
- Review patients to ensure Adrenaline auto-injector (AAI) appropriate according to current guidelines
- An alternative brand of AAI must be prescribed (Epipen or Jext)
- Dose should be checked to ensure it is appropriate for the patient especially in children as they age and increase in weight or for patients whose condition changes.
- Patients should be given robust training about carrying two AAI pens with them at all times, and administering the second dose 5-15 minutes after the first if their condition does not improve. (Document in patient notes that this advice has been given).
- Patient (or representative where appropriate) must be counselled on change of device and trained on how to use the new device.
- For children ensure an allergy action plan is in place and to ensure patient/carer can follow: https://www.bsaci.org/about/download-paediatric-allergy-action-plans

viii)

The Prevention of Future Deaths Report is included on the agenda of Enfield CCG's Medicines Management Committee for discussion with GPs and pharmacists on 31st March 2020.

ix) Ongoing Actions

Matters of Concern and opportunities for shared learning from incidents are raised during face to face practice meetings with GPs, community pharmacists, Primary Care Network pharmacists and other prescribers; GP Locality meetings and GP protected learning time events.

Enfield CCG has requested the Prevention of Future Deaths Notice is discussed at the following meetings to ensure that this incident can be shared and reviewed further and learning identified and shared across North Central London:

Medicines Safety Officers and Medical Devices Safety Officers (MDSO) meeting on 4th April 2020. This meeting is attended by Medicines Safety Officers from primary care and hospital trusts and is chaired by a GP; this group will help share learning across healthcare sectors.

8 and 9 contd.

- Enfield Medicines Management Committee 31st March 2020.
- North Central London Joint Formulary Committee on 20th April 2020.

CCG pharmacists to check what action they have taken regarding the NCL Medicines Safety Bulletin on Adrenaline Auto Injectors (AAI) have contacted all GP practices. This is being followed up with individual practice meetings, training meetings for GPs, training sessions for Primary Care Network pharmacists, and by CCG pharmacists working in practices. A record is in the process of being collated to capture actions by individual practices to ensure all patients regularly receive appropriate training in the use of their device and dosages have been reviewed. This process is due to complete by 30th April 2020.

An analysis of CCG actions that may have been contributory to this incident were lack of governance around scriptswitch messaging and newsletters sent to practices from the CCG Medicines Management team. Following the review of this case, it was identified that a more robust governance and decision making process was needed. Current measures to stop any reoccurrence include:

- checking and approval of scriptswitch messaging by senior pharmacists
- newsletters to be checked and approved by GP Clinical Lead

NCL primary care group has been set up to review the local formulary and scriptswitch messaging to standardize messages across NCL CCGs.

The CCG will now implement a post incident review and a report will be completed to ensure that all actions identified are implemented to prevent a recurrence of this nature. This will include a review of governance processes and decision-making points This report will go to the Quality and Safety Committee, which will oversee any recommendations and ensure implementation of all actions.