East London NHS
NHS Foundation Trust

Title	Safe & effective use of medicines
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Presented to	Medicines Committee
Date	10th January 2024

Purpose of the Report:

This report provides a summary of medicines safety data that is collected in the Trust and is presented to the Medicines Committee for information. The committee is asked to consider the level of assurance provided by the report and decide whether further action is needed.

Strategic priorities this paper supports (Please check box including brief statement)

Improving service user satisfaction	☒	Improve service user-related outcomes by ensuring that they receive safe pharmaceutical care.
Improving staff satisfaction	☒	
Maintaining financial viability	☐	

Committees/Meetings where this item has been considered:

Date	Committee/Meeting
N/A	This report has not been considered in any other committees or meetings

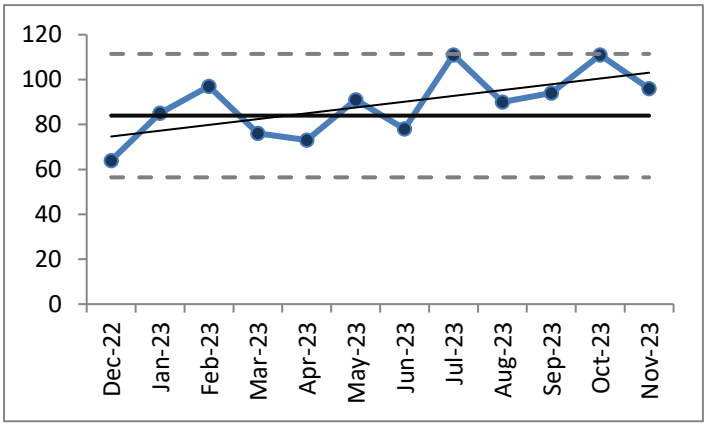
Equality Analysis	This report has no direct impact on equalities

Contents

East London NHS Foundation Trust

TRUSTWIDE INCIDENT REPORTING

Figure 1 Total number of medication incidents reported per month (Dec 22 – Nov 23)



Medication incident reporting fluctuates within control limits. Inphase incident reporting system went live 1st November 23. Reassuringly data demonstrates that reporting did not decrease in reponse to this system/process change.

Increased reporting trustwide which may be atrributed to greater awarenes of incident reporting amongst trust staff.

Figure 2- Total number of medication incidents reported per month (Dec 21 – Nov 23)

Over the last 2 years there has been a gradual increase in medication incident reporting trustwide (shown by data trendline); reflective of the increased awareness amongst staff to report and learn from incidents but also increase in trust services/expansion/geographical footprint.

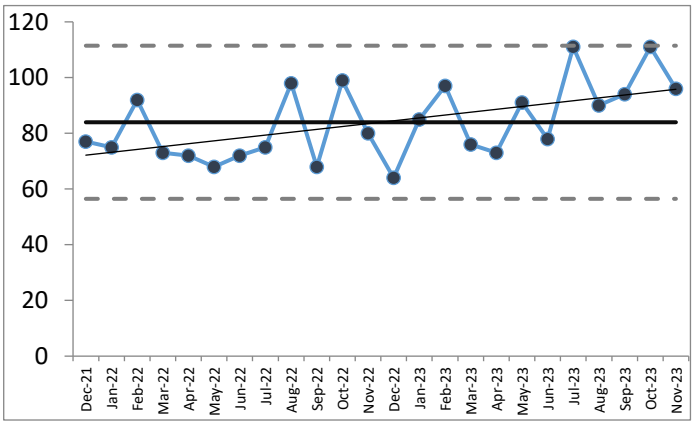
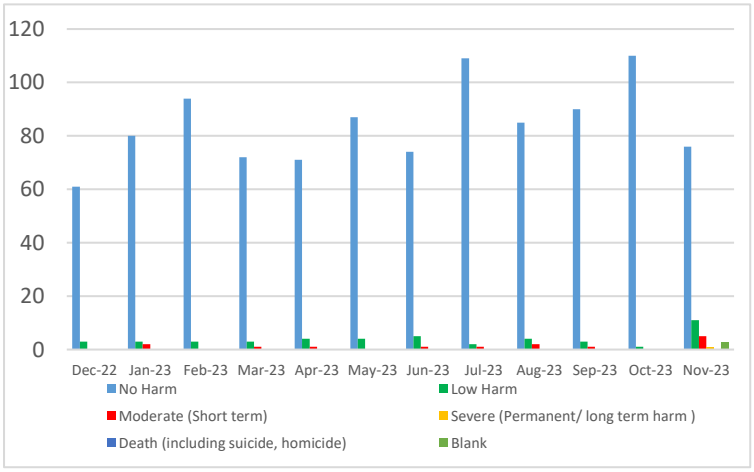


Figure 3 – Medication incidents broken down by type of harm (Dec 22- Nov 23)



Q3 23-24 (July-Sep 23) – 9 (3.16%) medication incidents categorised as LOW harm. 4 (1.40%) medication incidents categorised as MODERATE harm.

November- Inphase launch

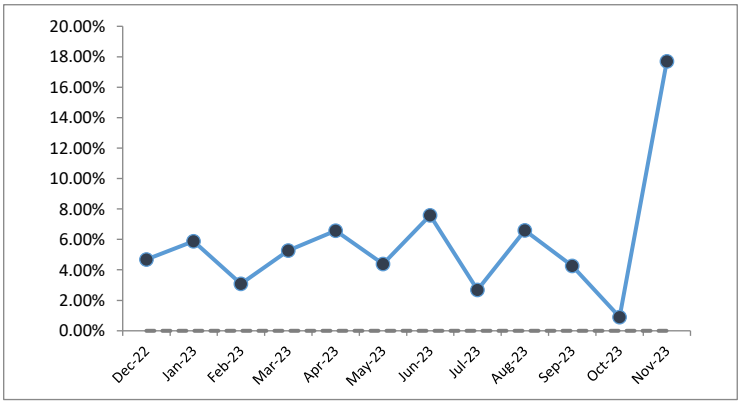
Increase in harm levels; 11% low, 5% moderate, 1% severe (11,5,1). Blank 3% (no longer mandatory). Continue to monitor. Is this increase due to system change i.e. is the incident reviewer still reviewing the reporter's harm selection? To raise with the Risk and Governance team.

1 Severe – external error see below

Palliative CHS patient unable to swallow analgesics or eat due to throat pain. Weak, sleepy and had been largely confined to his bed and not willing to go to hospital. GP contacted to visit as per request from DN and hospice. GP advised patient would have to register with a new practice as he'd moved address and is out of catchment. GP advised they would telephone but not visit. Follow up calls from CHS staff member to co-ordinate a visit from an A&E doctor and next day visit by a CHS nurse, hospice nurse and social worker. Other arrangements made for patient to be followed up the next day.

Figure 4 - % Medication incidents that resulted in patient harm (Dec 22 – Nov 23)

Medication Incidents resulting in patient harm (low and above) over the last 12 months is sitting at an average of 5.69%. November is skewed at 17.7%. As detailed above. This is to be monitored going forward to assess if this is related to Inphase implementation i.e. change of system/process. To follow up with the Risk & Governance Team.



Inphase Issues / Challenges – Medication Incident Reporting/Monitoring

- Inphase Reporter Builder Training videos are complex and not easily digestible for your average user, which has also been fed back by other departments. Risk and Governance Team aware.
- Abiola Ajayi-Obe is co-ordinating support to help build tailored medicine incident dashboards but may take time due to high demand for support. This may impact on producing tailored medicines incident reports required and also thematic analysis to identify medicines safety trends/themes.
- For example currently unable to extract a report for all incidents involving a particular high risk medicines.

Local Medicines Safety Updates

- The MSOs have a strong focus on Collaborative ICB / ICS working. Active Participation at the following forums:
  - NEL MSQG: North East London Medicines Safety Quality Group
  - NEL High Risk Medicines Network, also feeding into Valproate and Insulin subgroups
  - NEL Opioid Discharge Workstream – participation in NEL wide opioid discharge audit
  - BLMK Medicines Safety Group

- Internal Review and revision of EPMA reports and work being undertaken to transition some of these onto PowerBI
- Valproate Original Full Pack Dispensing

  Summary:

  MHRA (Oct 2023) raised concerns from patients/patient groups about warning information not always being provided and evidence continues to emerge suggesting that women are unaware of the significant risks posed to their unborn baby should they become pregnant whilst on valproate.

  As a result of this, changes have been made to the Human Medicines Regulation 2012 to make sure that all patient's, receive valporate-containing medicines in the Manufacturers original full pack and therefore will always receive information on the risks to the unborn child.

  The change in practice will ensure that patients (male and female) are provided with the specific warnings and pictograms on the labelling and a detachable patient card, along with the statutory patient information leaflet and additional patient booklet, which highlights the risks of taking valproate whilst pregnant. From the 8th January, valporate-containing medicines will be dispensed by the trust's pharmacy in the manufacturer's **original pack** unless there is an exceptional circumstance.

  Actions Taken
  - Memo is to be presented at Dec Medical Managers Meeting before finalisation.
  - RIO Electronic Valproate Pre Dispensing Risk Assessment draft has been finalised. To be completed in cases of exceptional circumstances for requests to deviate from full pack dispensing e.g. small supply in overdose risk
  - Valproate Policy to be amended Jan 2024 via chairs actions once above steps have been completed.

Key Medicines Incidents

1) Prescribing Error - Luton Directorate - Inpatient Setting – Drug: Methadone
   Service user prescribed 40mg methadone. However, patient had not been taking the methadone in community for the past 2-3 weeks. Risk of overdose/sedation, enhanced by co-prescribing of benzodiazepines. Error was detected by a pharmacist during medicines reconciliation. Medication discontinued, alongside other medication amendments and patient was placed on appropriate monitoring/observations by the clinical team.
   The incident is to be shared with the lead pharmacist to disseminate at directorate level for shared awareness/learning and also within pharmacy teams to highlight the importance of prioritising medicines reconciliation for high risk medicines.

2) Administration Error - Forensics Directorate - Inpatient Setting – Drug: Aripiprazole
   Nursing staff checked the 'white board' saw patient X was due his depot medication and administered the injection as per 'white board' and not in accordance with EPMA. The administration was not checked or documented against EPMA (not administered legally in accordance with a prescription/drug chart). EPMA was working and available during this the time frame of this incident. Following on from this, realised depot was administered incorrectly 2 days early and the incorrect dose (300mg instead of 400mg).
   Constructive discussion amongst lead clinical pharmacists regarding appropriate use of the 'white board' as acknowledge there is a use/function for them but not as means of identifying dose administrations. Lead pharmacists to share the learning with their directorates and clinical pharmacy teams and be vigilant of which wards have white boards and if these are being used appropriately.

NATIONAL PATIENT SAFETY ALERTS

1) **Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients (Nov 2023)**
   See separate paper presented by MSOs.

2) **Potential contamination of some carbomer-containing lubricating eye products with Burkholderia cenocepacia – measures to reduce patient risk (Dec 2023)**
   Do not stock or supply specified products. Alert Actioned.

3) **Potential for inappropriate dosing of insulin when switching insulin degludec (Tresiba) products (Dec 2023)**

- Shortage of Tresiba® (insulin degludec) FlexTouch® 100units/ml solution for injection 3ml pre-filled pens. Some patients may have been switched to Tresiba® (insulin degludec) FlexTouch® 200units/ml solution for injection 3ml pre-filled pens.
- Tresiba® FlexTouch® pen delivery devices dial up in unit increments rather than volume. However, a small number of patients have been incorrectly advised to administer half the number of units. Risk of incorrect dosing and one known case of a patient requiring hospital treatment for DKA because of a reduced insulin dose
- MSOs have formulated an action plan which has been forwarded to Risk and Governance

ELFT Action	Co-ordinated by named person:	Relevant to NPSA action	Status
A. Inpatients MSO to identify current inpatients prescribed Insulin Degludec (Tresiba). Diabetes Nursing team to follow up for review and counsel patients as per NPSA alert.	Vikram Totaram Lead Diabetes Inpatient Specialist Nurse	1	Complete
B. ELFT GP practices • Digital patient searches to identify patients • Ensure communication is disseminated to GPs to implement this alert.	Lead Pharmacist Primary Care (Quynh Nguyen)	1-5	Complete
C. Primary Care Patients under non-ELFT GP practices will be responsible for implementing this alert. However, our nursing staff and pharmacy technicians need to be informed of this alert so they can effectively counsel any patients they come across in community. • Alert to be communicated to Lead CHS nurses to disseminate to nursing staff and also to CHS pharmacy teams	-Lead CHS Pharmacists Saema Arain (Bedfordshire) Fatima Hafesji/Charity Okoli (Tower Hamlets) Nathaniel Addo (Newham)	1	Complete
D. EMPA • To action a drug alert on EPMA system to reflect no new initiations and to contact specialist diabetes to review	MSOs/EPMA lead pharmacist (Lewis Pope)	1,6	Complete
E. Trustwide Clincal Alert to be circulated to raise awareness	MSO/comms team	-	Complete

NATIONAL MEDICINES SAFETY UPDATES

MHRA Drug Safety Update October 23

- ***Isotretinoin (Roaccutane▼): introduction of new safety measures, including additional oversight of the initiation of treatment for patients under 18 years of age.***
  - 2 independent prescribers need to agree the initiation of isotretinoin in patients under 18 years
  - new counselling requirements about potential mental health and sexual function side effects
  - assessment of mental health and sexual function before starting treatment and monitoring of mental health and sexual function during treatment
  - new roles and responsibilities for healthcare professionals
  - new regulatory risk minimisation materials

- ***Valproate: dispense full packs of valproate-containing medicines***

Following a consultation, the Government has amended the Human Medicines Regulations 2012 (HMRs) to require manufacturer's original full pack dispensing of valproate-containing medicines.

Unless there are exceptional circumstances, valproate-containing medicines must always be dispensed in the manufacturer's original full pack from 11 October 2023. You must either round up or down so that the patient receives their supply in the manufacturer's original full pack and ensure that they receive an amount that is as close as possible to that prescribed. You must not subsequently re-package any valproate-containing medicine into plain dispensing packaging.

The aim of amendments to require manufacturer's original full pack dispensing of valproate-containing medicines is to ensure that women always receive information about the harms of valproate during pregnancy. This will further decrease the number of babies who are exposed to valproate in pregnancy.

MHRA Drug Safety Update November 23

- ***Ozempic▼(semaglutide) and Saxenda (liraglutide): vigilance required due to potentially harmful falsified products*** Falsified Ozempic and Saxenda products have been found in the UK, including falsified pens containing insulin, which may lead to patient harm.

Advice to remain vigilant for symptoms linked to hypoglycaemia in patients who may have obtained a falsified product and provide appropriate treatment for any patient who may have inadvertently administered insulin via these products

- ***E-cigarette use or vaping: reminder to remain vigilant for suspected adverse reactions and safety concerns and report them to the Yellow Card scheme***

MHRA Drug Safety Update December 23

- ***Aripiprazole (Abilify and generic brands): risk of pathological gambling***

Healthcare professionals prescribing aripiprazole are reminded to be alert to the risk of addictive gambling and other impulse control disorders. Healthcare professionals should advise patients, their families and friends to be alert to these risks

- ***Vitamin B12 (hydroxocobalamin, cyanocobalamin): advise patients with known cobalt allergy to be vigilant for sensitivity reactions***

Healthcare professionals prescribing vitamin B12 products to patients with known cobalt allergy should advise patients to be vigilant for signs and symptoms of cobalt sensitivity and treat as appropriate.