

tolerance of less than 50yards. Past medical history was noted as coronary artery bypass graft (CABG) by 5 vessels in 2013. An angiogram in 2014 showed nature right coronary artery to have severe disease, left main stem distal disease and competitive flow in left anterior descending coronary artery. Patent saphenous vein grafts to D1 plus posterior descending artery, left internal mammary artery and right internal mammary artery graft patents (*'may not be adequate'*). Normal myocardial perfusion scan. [Personal information redacted by] was recorded to be a smoker of 7 per day and alcohol intake was minimal. Vital signs were recorded as:

Date and Time	Temperature	Pulse	Blood Pressure	Respirations	SaO <sub>2</sub>	NEWS
19/2/18 @ 22:10	36.6°C	105	114/79	30	93% 15 l O <sub>2</sub>	10
23:20	36.3	121	133/115	35	91% 15L	10

Management plan was for chest x ray, record intake and output. A urinary catheter was recommended by declined by [Personal information redacted by]. His blood results were reviewed and ECG was noted to be normal.

Nursing notes 23:40 document a further episode of chest pain. Diamorphine 2.5 mgs was administered intravenously and furosemide 50mgs given intravenously. An ECG was repeated. A repeat troponin was taken and a BNP (NT-proB-type Natriuretic Peptide (BNP) is a blood test which identifies a hormone produced by your heart; it can be increased if patients have heart failure and other cardiac problems).

Initial ECG was unremarkable; however repeat ECG showed ST elevation, at 23:06, which was not actioned.

At 00:00 it is noted that [Personal information redacted by] continued to have chest pain, medics were contacted and ED nurses awaited response. At 00:50 nursing documentation highlights medics reviewed [Personal information redacted by]. ECG and a venous blood were carried out. At the time [Personal information redacted by] was reported to have stated he did not have chest pain.

Date and Time	Temperature	Pulse	Blood Pressure	Respirations	SaO <sub>2</sub>	NEWS
20/2/18 @ 00:30	36.5°C	120	149/103	35	87% 15 l O <sub>2</sub>	10

A retrospective note by nursing staff stated that [Personal information redacted by] had requested to sit in chair as he was experiencing chest tightness and increased shortness of breath from admission due to CCF. [Personal information redacted by] was seen by medical team who were aware that [Personal information redacted by] was experiencing increased shortness of breath. Nurses were to continue with the clinical observations. An arterial blood gas was obtained. [Personal information redacted by] was reported to state he was feeling worse with shortness of breath. A further venous blood gas and ECG were carried out. These were shown to medical SHO (Doctor 3). [Personal information redacted by] was reviewed by Doctor 3 and Doctor 2 who were reported to be happy to continue to monitor [Personal information redacted by] at present. [Personal information redacted by] continued to be restless and wanting to sit on the chair and pulling his oxygen mask off. He was advised to keep the mask on as it would help with the breathing. [Personal information redacted by] appeared to deteriorate at approximately 02:15 when he became unresponsive in the chair vomiting haematemesis.

A retrospective note from the medical staff confirmed [Personal information redacted by] had a pulseless electrical activity (PEA) cardiac arrest, cardiopulmonary resuscitation (CPR) was commenced, [Personal information redacted by] intubated and after 25 minutes (4 bolus of adrenaline) there was return to spontaneous circulation. He was transferred to theatres for stabilisation.

Post initial resuscitation the issues were 1) Frank pulmonary oedema, hypoxic. 2) inferolateral changes on ECG 3) RUMA on echocardiogram 4) metabolic acidosis. [Personal information redacted by] remained

haemodynamically unstable; he had a further period of cardiac arrest and despite maximum efforts, Personal information redacted by died at 05:21.

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## SECTION 3 - LEARNING SUMMARY

## 13. WHAT HAS BEEN LEARNED:

**Patient factors**

Personal information redacted by was a 45 year old male with a significant cardiac history including coronary artery bypass surgery with five vein graphs in 2013. An angiogram in 2014 showed native right coronary artery to have severe disease, left main stem distal disease and competitive flow in left anterior descending coronary artery. Patent saphenous vein grafts to D1 plus posterior descending artery, left internal mammary artery and right internal mammary artery graft patents ('may not be adequate').

Myocardial Perfusion Imaging in 2016 showed minor ischaemia at apex plus fixed defects elsewhere. *He had* preserved LV function 2016. Personal information redacted by had previously attended Antrim Area Hospital cardiology clinic in 2017. A clinic letter indicates that he was discharged from this clinic following consultation with his consultant.

**Task factors**

NEWS recording was not in keeping with Trust guidance on frequency. NEWS of 7 or there should be continuous monitoring of vital signs (including blood sugar), during continuous monitoring, all vital signs should be recorded on the NEWS chart every 15 minutes. This did not happen.

**Communication**

The review team noted that nursing and medical documentation did not appear to be contemporaneous.

The review team noted a lack of medical documentation in relation to the ECG and assessment of Personal information redacted by at 23:20. Medical staff did not document all the assessments at this time. The 23:20 and subsequent ECG's was not signed as having been reviewed.

**Work environment**

The hospital was busy with a total of 277 ED attendances in 24 hours, 43 admissions and 5 transfers to other hospitals. The 4 hour ED performance of 64.7% reflecting overcrowding in the Emergency Department.

**Conclusion**

Following discussion with the doctors involved in Personal information redacted by, the review team has spoken with Doctor 2 and Doctor 3. The ECG from 19/2/18 at 23:06hrs was reviewed. Drs 2 and 3 accept there was a new inferior elevation with reciprocal changes. Doctors 2 and 3 felt that primary PCI activation was not indicated as the patient had no chest pain. Drs 1 and 2 are very clear that the patient did not have chest pain. The review team pointed out that the patient would only have been fit for emergency cath lab activation if he had been intubated and ventilated, due to florid pulmonary oedema. The review team accepted that this was not a clear cut decision for emergency cath lab activation, given the lack of chest pain and florid pulmonary oedema. The review team mentioned that the nursing notes stated that Personal information redacted by did have chest pain and required diamorphine. The review team pointed out that while the decision to refer for emergency cath lab activation is not straightforward in this case, given the ECG in question, the case should have been discussed with the cardiologist on call for CAH.

Doctor 2 and Doctor 3 accept this and have reflected on the ECG in question and have

recognised the changes. There was no shockable rhythm. The cardiac arrest was PEA and this could have been due to the gross pulmonary oedema.

The review team spoke with Doctors 1 and 2 about the documentation they were advised that if a sick patient has been assessed, that assessment has to be documented clearly. The review team acknowledge the very busy work environment that night which may have contributed to the lack of documentation.

14. WHAT HAS BEEN CHANGED or WHAT WILL CHANGE?

15. RECOMMENDATIONS (please state by whom and timescale)

**Recommendation 1**

The Trust should ensure that documentation meets the standards outlined by the GMC and NMC guidance, including ensuring decision making is accurately and contemporaneously documented. This could be incorporated in to medical induction for trainee doctors.

**Recommendation 2**

The Trust must promote the National Early Warning Score, recording observations and appropriate escalation as per Trust Guidance.

**Recommendation 3**

Consideration should be given to implement annotation of ECG by medical staff when reviewing same.

16. INDICATE ANY PROPOSED TRANSFERRABLE REGIONAL LEARNING POINTS FOR CONSIDERATION BY HSCB/PHA:

17. FURTHER REVIEW REQUIRED? YES / NO  
Please select as appropriate

If 'YES' complete SECTIONS 4, 5 and 6.

If 'NO' complete SECTION 5 and 6.

**SECTION 4 (COMPLETE THIS SECTION ONLY WHERE A FURTHER REVIEW IS REQUIRED)**

18. PLEASE INDICATE LEVEL OF REVIEW:  
LEVEL 2 / LEVEL 3  
Please select as appropriate

19. PROPOSED TIMESCALE FOR COMPLETION:  
DD / MM / YYYY

20. REVIEW TEAM MEMBERSHIP (If known or submit asap):

21. TERMS OF REFERENCE (If known or submit asap):

<b>SECTION 5</b>	
<b>APPROVAL BY RELEVANT PROFESSIONAL DIRECTOR AND/OR OPERATIONAL DIRECTOR</b>	
22.NAME:	23.DATE APPROVED:
24.DESIGANTION:	

<b>SECTION 6</b>
25.DISTRIBUTION LIST:

**Checklist for Engagement / Communication  
with Service User<sup>1</sup>/ Family/ Carer following a Serious Adverse Incident**

Reporting Organisation SAI Ref Number:		HSCB Ref Number:	
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SECTION 1			
INFORMING THE SERVICE USER <sup>1</sup> / FAMILY / CARER			
1) Please indicate if the SAI relates to a single service user, or a number of service users.  Please select as appropriate (✓)	Single Service User		Multiple Service Users*
	Comment: <i>*If multiple service users are involved please indicate the number involved</i>		
2) Was the Service User <sup>1</sup> / Family / Carer informed the incident was being reviewed as a SAI?  Please select as appropriate (✓)	YES		NO
	If YES, insert date informed:		
	If NO, please select <u>only one</u> rationale from below, for <b>NOT INFORMING</b> the Service User / Family / Carer that the incident was being reviewed as a SAI		
	a) No contact or Next of Kin details or Unable to contact		
	b) Not applicable as this SAI is not 'patient/service user' related		
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user		
	d) Case involved suspected or actual abuse by family		
	e) Case identified as a result of review exercise		
	f) Case is environmental or infrastructure related with no harm to patient/service user		
	g) Other rationale		
If you selected c), d), e), f) or g) above please provide further details:			
3) Was this SAI also a Never Event? Please select as appropriate (✓)	YES		NO

4) If <b>YES</b> , was the Service User <sup>1</sup> / Family / Carer informed this was a Never Event?  Please select as appropriate (✓)	<b>YES</b>	If <b>YES</b> , insert date informed: DD/MM.YY	
	<b>NO</b>	If <b>NO</b> , provide details:	
<b>For completion by HSCB/PHA Personnel Only (Please select as appropriate (✓))</b>			
Content with rationale?	<b>YES</b>		<b>NO</b>

**SHARING THE REVIEW REPORT WITH THE SERVICE USER<sup>1</sup> / FAMILY / CARER**  
(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)

5) Has the Final Review report been shared with the Service User <sup>1</sup> / Family / Carer?  Please select as appropriate (✓)	<b>YES</b>		<b>NO</b>	
	If <b>YES</b> , insert date informed:			
	If <b>NO</b> , please select <b>only one</b> rationale from below, for <b>NOT SHARING</b> the SAI Review Report with Service User / Family / Carer:			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed <i>(if you select this option please also complete 'I' below)</i>			
	d) No contact or Next of Kin or Unable to contact			
	e) No response to correspondence			
	f) Withdrew fully from the SAI process			
	g) Participated in SAI process but declined review report			
	<i>(if you select any of the options below please also complete 'I' below)</i>			
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user <sup>1</sup> family/ carer			
	i) case involved suspected or actual abuse by family			
j) identified as a result of review exercise				
k) other rationale				
l) If you have selected c), h), i), j), or k) above please provide further details:				
<b>For completion by HSCB/PHA Personnel Only (Please select as appropriate (✓))</b>				
Content with rationale?	<b>YES</b>		<b>NO</b>	

**SECTION 2**

**INFORMING THE CORONERS OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)** (complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death?  Please select as appropriate (✓)	<b>YES</b>		<b>NO</b>	
	If <b>YES</b> , insert date informed:			
	If <b>NO</b> , please provide details:			
2) If you have selected 'YES' to question 1, has the review report been shared with the Coroner?  Please select as appropriate (✓)	<b>YES</b>		<b>NO</b>	
	If <b>YES</b> , insert date report shared:			
	If <b>NO</b> , please provide details:			

3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? Please select as appropriate (✓)	<b>YES</b>		<b>NO</b>		<b>N/A</b>		<b>Not Known</b>	
	If <b>YES</b> , insert date informed:							
	If <b>NO</b> , please provide details:							

<b>DATE CHECKLIST COMPLETED</b>	
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<sup>1</sup> Service User or their nominated representative

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ID	Incident date	Directorate	Division	Site	Loc (Exact)	Description	Drug administered	Correct drug	Action taken	Incident affecting	Incident type tier one	Incident type tier two	Incident type tier three	Consequence	Impact	Likelihood	Severity	Risk rating
Personal Information redacted by the USI	25/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	1 East Maternity/Gynaecology	pt rash/urticaria with amoxicillin co-amoxiclav in 2005 and 2009 confirmed with gp. On niecr as allergic to these but s/e not recorded. Pt states she doesn't take penicillin. on allergy status on kardex states patient has had pen allergy but has previously had penicillin?	Amoxicillin		kardex review by dr amoxicillin stopped pt had only 1 dose	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Contraindication due to history of allergy	Insignificant	insignificant	catastrophic	possible	extreme
	25/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	PT was sent to A&E due to query urosepsis, was returned without further investigations and prescribed an antibiotic the patient was allergic to.	Co-Amoxiclav		Urgent bloods taken upon return, escalated to duty MO and she attended A&E to raise concerns. Patient then required medical admission for blood transfusion.	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Contraindication due to history of allergy	minor	catastrophic	possible	extreme	
	25/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	1 East Maternity/Gynaecology	Pt prescribed tazocin allergic to penicillin on kardex not on niecr received one dose of tazocin. Patient doesn't take penicillin as says it causes a rash. Antibiotics changed by dr.	Tazocin		antibiotic changed	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Contraindication due to history of allergy	Insignificant	insignificant	catastrophic	possible	extreme
	02/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Doxycycline prescribed and administered (one dose). Later found documentation of doxycycline allergy in GP record although not nature of reaction. NOT documented on NH kardex	Doxycycline		Nurse in area of ED aware. Admitting team aware	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Contraindication due to history of allergy	Minor	minor	catastrophic	possible	extreme
	15/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Female Medical	Patient treated for hyperkalemia appropriately as ECG changes. Clear documentation of monitoring required in medical notes and handed over to nurse caring for patient including BM monitoring. Last BM recorded 3am = 4.8. Cardiac arrest at 6.35am with hypoglycaemia 1.9. Lack of BM and physical observations in patient overnight which should have been hourly and 4hourly respectively.  Patient also on warfarin. No recorded prescription for 14/4/19. F1 was informed by nursing staff that warfarin dose had been held 14/4/19 - this was not the case and patient had prescription for 14/4/19.	Warfarin	Warfarin	Discussed with Consultant Dr A and Ward Sister H. Advised Datix to be completed as per Dr A.	Patient Incidents	Diagnostic Processes/Procedures	Monitoring/On-going Assessment of Patient Status	Failure/in sufficient response to significant change in patient status	Major	catastrophic	catastrophic	possible	extreme

Personal information redacted by the USA

28/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	4 North	Patient arrived to emergency theatre. Upon check-in it was noted that the insulin protocol had been started and running at ward level, however both the fluids and the actrapid had been removed from their pumps and patient transported to theatre with item placed on her bed. Actrapid syringe was attached to patients IV line, not in a pump and not clamped off. This posed a potential risk that some of the insulin could have been administered accidentally in transit and not under any controls.	Insulins		4 North. Syringe immediately clamped off and nurse accompanying patient was informed that this was not appropriate and potentially dangerous. Explanation given by ward staff member that it was done as the new hospital beds did not have drip stands. I informed nurse that in future the pumps could be set onto the patients bed or pushed behind the bed on a standard drip stand. BM to be checked in theatre.	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect rate of administration	Moderate	insignificant	major	possible	high
26/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	Patient prescribed Enoxaparin BD Missed dose on 26.04.19 at 10am Missed dose on 27.04.19 at 10am Patient was in recovery ward on 26.04.19	Enoxaparin	Enoxaparin	Night duty staff escalated to doctor on 27.04.19 Nil ordered	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Minor	insignificant	major	unlikely	high
24/04/2019	Acute Services	Surgery and Elective Care	Daisy Hill Hospital	Female Surgical/Gynaecology	Patient had her 10am dose clexane 40mgs which was increased after ward round to 120mgs in view of patients weight. Patient was prescribed stat dose of clexane 80mgs which I missed...forgotten about until noted at 5pm medicine round due to business of bay	Enoxaparin	clexane	Dr looking after patient informed, dose to be omitted as due again 10pm	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Failure to administer	Insignificant	insignificant	major	possible	high
10/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	Medication omitted on 2 mornings which should have been given as same prescribed. Medication was a critical medication.	Dabigatran	Dabigatran	Pharmacist on ward notified, patient notified, nil ordered. Apology given to patient. Nursing notes updated. Nurse in charge notified. Datex completed.	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Failure to administer	Minor	insignificant	major	unlikely	high
16/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	PATIENT ADMITTED TO 3SOUTH TODAY FROM EMERGENCY DEPARTMENT. PATIENT HAS NO ENGLISH, SON PRESENT WHO HAS GOOD ENGLISH. PATIENT HAD ATTENDED ED ON 15/4/19 WITH ABDOMINAL PAIN AND DISCHARGED WITH CO-CODAMOL. ON ADMISSION ON REVIEW OF ANALGESIA IT WAS DISCOVERED THAT THE PATIENT HAD TAKEN 20 TABLETS IN 24HRS	Co-Codamol		MEDICAL STAFF INFORMED COMMENCED ON MANAGEMENT OF PATIENTS 8-15HRS AFTER INGESTION PROTOCOL COMMENCED ON N-ACETYLCYSTEINE INFUSION(PARVOLEX) MONITOR OBS HOURLY BLOODS INCLUDING OVERDOSE,LFTS, U+E, CRP,COAG,INR AMYLASE AND FBP SENT VBG DONE INSTANTLY	Patient Incidents	Medication/Biologicals/Fluids	Medication advice	Unclear advice	Minor	minor	major	possible	high

26/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	3 North Winter Ward	On Friday 26th night duty a patients insulin prescription sheet was taken from charts at bottom of bed to have insulin prescribed. Dr was contacted by co-ordinator to prescribe same. Same was not prescribed until 0.230hrs. the particular insulin was not available in 4 different wards so Pharmacist was contacted. Pharmacist stated that a long acting insulin should not be prescribed at that time of morning and to contact Dr to inform him of same. Dr decided to HOLD same. At 0500hrs while writing Nursing report I noted that this patient was not a DIABETIC „BUT HER ADDRESSOGRAPH WAS ON ANOTHER PATIENTS INSULIN SHEET on inside page. On removing addressograph another addressograph was underneath. Dr informed of same. I personally have been very fortunate as that prescription of insulin could have been given to the wrong patient because of several circumstances. It has been a MAJOR reminder of how easily a serious incident could have occurred.	Insulins	SR INFORMED	Personal Inform	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Incorrect patient	insignificant	major	possible	high	
07/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	General Male Medical	Patient was prescribed Novorapid 60 units at 08:00, 12:00, 17:00 & 22:00hrs. Developed hypoglycemia on 2 occasions as a result at 06:25 & 05:30hrs. Patient informed DR he takes Novorapid at 22:00hrs at home with his supper.	Insulins	Insulins	Highlighted in medical notes that Patient was only ever advised Novorapid 60 units with breakfast, lunch and evening meal. Patient advised of correct timing of his insulin. Ward manager informed and DR's who prescribed Novorapid to be informed.	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Incorrect frequency of dose	Minor	minor	major	possible	high
15/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	1 North Cardiology	Patient had attended PCI or stenting 1 stent to LCX and 1 stent to LAD last 12/04/19. It was written in the post cath notes that he is for Clopidogrel for 3/12 to stop 12/07/19. He was then loaded with 300mg on the 12/04/19 as a STAT dose but was not prescribed or written in the antiplatelet prescription page. So it was missed on the 13/04 and 14/04.	Clopidogrel	Clopidogrel	Clinical sister, SHO, and patient informed. The said tablet was prescribed and given. Apologise to the patient. Ward manager informed as well.	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Delay in prescribing	Insignificant	insignificant	major	possible	high
25/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	Theatres 1-4 CAH	Drugs stored in anaesthetic trolley by mistake (Amoxicillin & Thiopentone), resulting in potential confusion and drug mismatch due to lookalike packaging (with FLucloxacillin), see photos attached. List of drug that are required in ATICS SHSCT drug trolley is tightly regulated and this is a near miss (no incident happened)	Thiopental	Flucloxacillin	Amoxicillin and Thiopentone removed from the trolley, education to staff.	Patient Incidents	Anaesthetic Care	Other Anaesthetic Incident	Other anaesthetic care incident	Minor	insignificant	major	possible	high

Personal information recorded by the UOI	Date	Service	Department	Location	Incident Description	Medication	Incident Type	Severity	Impact	Prevention	Resolution	Outcome	Rating	
	26/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH No octaplex in department. Octaplex used on Thur 25th April night duty, only 2 vials used. s/n Lynsay Trimble contacted labs to inform only 2 used and would they like all vials returned as per normal protocol. s/n advised by lab staff to only return the used vials in the box and to keep unused vials of octaplex in resus fridge. same was done as per lab staff advice.	octaplex	Organisational Incidents	Minor	insignificant	Delayed delivery to unit/ward	Box with used vials returned to lab with porter Aaron. Aaron informed by lab staff that he did not need to bring any octaplex back to A&E as they had some in fridge and that the box did not need to be returned either. sat 27th night duty SR Roisin O'Neill contacted Haem labs to enquire about octaplex box and octaplex mediation. was informed by lab staff that box was not in labs and more than likely the box has been misplaced when with porter.	major	possible	high
	03/04/2019	Acute Services	Pharmacy	Daisy Hill Hospital	Pharmacy Dispensary AC@HT Rx for several items was presented to Pharmacy for dispensing. All items dispensed except the Enoxaparin inj. Missed at labelling, dispensing & final check. Discovered the following day by AC@HT pharmacist.	Enoxaparin	Patient Incidents	Minor	insignificant	Preparation/Formulation Omitted Ingredient	Continued need for Enoxaparin confirmed with Dr (only 3 days rather than original 5) by AC@HT pharmacist. These were dispensed using the original Rx.	major	unlikely	high
	30/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH Pt was not written up for any enoxaparin on admission (until I raised this issue at the post-take ward round), nor was the VTE assessment form completed, despite pt being short of breath and subsequently being diagnosed with bilateral pulmonary emboli. (Patient admitted as per NIECR on 29-Apr-2019 2:04 PM, and decision to admit was 29-Apr-2019 11:00 PM, again as per NIECR. It is therefore my view that the patient missed one dose.)	Enoxaparin	Patient Incidents	minor	major	Prescribing Processed Medication not prescribed	Enoxaparin treatment dose prescribed at post-take ward round. Datix completed.	major	possible	high
	21/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	South Medical 1 Pt. is on IV Tazocin & IV Terlipressin due at 0600 (21/04/19). Same were missed by the Agency Nurse.	Tazocin	Patient Incidents	insignificant	major	Administration to Patient Incorrect frequency of dose (omitted dose)	Doctors has been informed by the day staff.	major	possible	high
	05/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	North 4 Patient reviewed surgically in ED and started by surgical doctor J McConville on ibuprofen orally. (Patient was on rivaroxaban also).	Ibuprofen	Patient Incidents	Minor	minor	Prescribing Processed Contraindication due to interactions with other medications	Discovered when pt returned to ED a few days later,(no bleed), and IR1 completed.	major	possible	high
	23/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH medication not given critical med	apixaban	Patient Incidents	Minor	insignificant	Administration to Patient Failure to administer	dr informed and medication prescribed as a stat dose and give to patient	major	unlikely	high

<p>Personal Information</p>	<p>21/04/2019</p>	<p>Acute Services</p>	<p>Surgery and Elective Care</p>	<p>Craigavon Area Hospital</p>	<p>Trauma Ward</p> <p>Phone call to DN team from CAH Trauma ward on 20-04-2019 requesting DN to administer twice daily clexane and 4pm insulin. Advised there was no twilight cover 20-04-2019 and referral could not be accepted until 21-04-2019. Trauma ward phoned back to say that they had assessed Patient and that he was independent with both administration of clexane and insulin and that there was no need for any DN referral. DN called morning of 21-04-2019 just to check that patient was getting on OK at home with his medications. This patient has a diagnosis of metastatic breast cancer. On arrival to the house this morning patient disclosed that he forgot to take his claxane last night as he was tired and had fallen asleep, just having been discharged from hospital. I asked patient if it was OK if I observed him self administration cleaxne. He agreed that was OK. It quickly became apparent that in fact patient is unable to safely administer dose of clexane. Hand dexterity is problematic. Also, more importantly the dose is 90mg. The clexane comes in 1ml syringes and requires the administrator to adjust the dose by expelling the correct amount in order to achieve the correct dose prescribed. Patient was unable to read the small print numbers and would be unable to self administer same. DN team will also continue to support Patient with insulin administration daily at 4pm as dose has been significantly reduced due to recent hypo and due to patient vagueness at times potential risk of insulin not being correctly.</p>	<p>Enoxaparin</p>	<p>Spoke at length with Patient. Patient agreeable that he unable to manage clexane and insulin independently and that he needs assistance. Patient happy for DN team to help. There is twilight cover for the nighttime clexane up to and including 01-05-2019. Twilight referral made for the night time clexane.</p>	<p>Patient Incidents</p>	<p>Medications/Fluids</p>	<p>Administration to Patient</p>	<p>Inappropriate/incorrect Self Administration</p>	<p>Insignificant</p>	<p>Insignificant</p>	<p>major</p>	<p>possible</p>	<p>high</p>
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Personal information redacted by the UGJ	12/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Urgent referral received 3:30pm Friday 12th April for administration of insulin and enoxaparin. Blood glucose 14.6mmol/l at 08.35 or 12/4/19	Insulins	Telephoned GP for more details and it transpired that patient was in A&E for injuries following a fall and had a fractured humerus. He was discharged home and no referral made to DN to administer, even though patient is right handed and it was his right arm that was effected therefore unable to continue self administering insulin and enoxaparin. He had not had either medication from 1st April due to his injury and this was only discovered at an outpatients appointment on Friday. Authorization received from GP and attended to patient to administer Insulin as prescribed with consent and reported backed to GP. Shared care now between District Nursing and Twilight team for administration of enoxaparin.	Patient Incidents	Medication/Biologicals/Fluids	Post-administration Patient Monitoring	Incorrect/insufficient handover/transition	Minor	insignificant	major	possible	high
	08/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Pharmacy Aseptic Unit	when dispensing prednisolone tablets at oral chemo scripts in pharmacy cah I discovered there was 25mg tablets in a 5mg pack	Prednisolone	took the 25mg tablets out and check bn and expiry date and put them into correct pack from shelf. I alerted the rest of the technician team and my line manager	Patient Incidents	Medication/Biologicals/Fluids	Dispensing Processes	Incorrect dose		insignificant	moderate	possible	medium
	30/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Bronte Ward	A supply of clozapine 25mg, for a named patient, was found in the non stock drawer on Bronte. inside the skilnet labeled Clozapine 25mg was a strip containing 12 clozapine 25 mg and 2 strips containing a total of 13 clozapine 100mg. (this patient is still an in patient on bronte ward they have not left . The reason we have labelled stock is that he transferred from Rosebrook ( Their clozapine is named patient and labelled and supply made in line with bloods- due to them not having a pharmacist ) to Bronte ward. In bronte ward we keep stock of 25mg and 100mg tablets. As the box in question was stored in the non stock and not currently in use we have no way of knowing what patient may have been affected ( there have been 4 patients on clozapine during that time) and if they were affected or if the 100mg were stuffed into the 25mg box since being put back into non stock. )	Clozapine	The skilnet was removed from the non stock drawer, the pharmacist was informed and a Datix was filled in. A staff nurse was also informed. The pharmacist checked the blood results from the patient that was named on the skilnet to see if any harm had come to the patient in question.	Patient Incidents	Medication/Biologicals/Fluids	Storage Processes (in pharmacy or on unit)	Incorrect storage environment		insignificant	moderate	possible	medium

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14/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	<p>Patient attended ED on Sunday 14th April, in department from 02.56 until 19.20 then transferred to 2 North.</p> <p>Pharmacist med hx completed on 2 North at ~ 12.00 on Monday 15th April and noted that patient had been receiving Humalog insulin bd instead of preadmission Humalog Mix 25. Preadmission doses were Humalog Mix 25 22units am and 14 units pm.</p> <p>Patient received Humalog 24 units am and 14 units teatime on 14th April, and 24 units am on the 15th.</p> <p>Humalog Mix 25 was referenced on patient's Kardex but Humalog prescribed on insulin chart.</p>	Insulins	Humalog Mix 25	<p>Medical and nursing staff informed when discrepancy noted and patient's BM checked, found to be 3.0 and glucojuice given.</p> <p>Checked again repeatedly thereafter and remained normal.</p>	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Incorrect medication/fluid	Minor	minor	moderate	possible	medium
10/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	<p>Patient admitted 9/4/19 with slurred speech and unsteadiness. Found to have lithium toxicity (lithium level = 1.58)</p> <p>Medicines reconciliation carried out by ward pharmacist. Noted patient was prescribed Naproxen 500mg BD by GP for back pain on 25/3/19. Further supply given by CAH CDU on 5/4/19.</p>	Lithium		<p>Lithium held on admission (awaiting repeat levels).</p> <p>Naproxen stopped.</p> <p>Patient informed of interaction between NSAIDs and lithium.</p> <p>Interaction to be documented on discharge letter for GP info.</p>	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Contraindication due to interactions with other medications	Minor	minor	moderate	possible	medium
20/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	1 South Medical	<p>Pt is on Insulin at 10pm, same was missed by the Agency Nurse last Saturday 20/04/19.</p>	Insulins	tresiba	<p>Doctors has been informed.</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Failure to administer		insignificant	moderate	possible	medium
26/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Female Medical	<p>Apixaban prescribed for the wrong patient on a medicine kardex and on their discharge letter.</p> <p>Patient was not administered and did not receive any apixaban. Error discovered by pharmacist on checking discharge letter.</p>	apixaban		<p>Discharge prescription received for above patient by ward pharmacist on Friday afternoon 26/04/19.</p> <p>Patient was newly prescribed Apixaban. The letter detailed this was prescribed for paroxysmal AF.</p> <p>On checking the patients notes there was no detail on AF during the admission. The FY1 stated that she had checked with the Registrar who had verbally told her the patient had AF and that was why he had prescribed apixaban.</p> <p>After a second check of the patients notes the pharmacist rejected the letter back to the doctor as felt that if patient had AF and a decision was made to start anticoagulation then it should be documented in patient notes.</p> <p>The FY1 contacted the Registrar a second time and it was then discovered that Apixaban had been prescribed for the wrong patient.</p> <p>FY1 amended patients</p>	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Incorrect patient	Moderate	insignificant	moderate	possible	medium

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25/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	CEAW	ward contacted by patient who had been discharged with chloramphenicol 5, ear drops which he had administered to eye, patient should have had 0.5% eye drops (Ear drops 5% were clearly prescribed on discharge prescription, ear drops were dispensed and labelled to instill into the affected ear)	chloramphenicol	Chloramphenicol	Dr contacted, bed manager contacted- advice return to A+E Patients partner spoken to on phone as patient had gone to bed-eye had been well washed many times with water pain relief given stated patient not keen to return to A+E at present but will return if symptoms worsen advised to dispose of ear drops and not to use again- will get script for eye drops from GP	Patient Incidents	Medication/Bloods	Prescribing Process	Incorrect route	Minor	minor	moderate	possible	medium
12/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	1 South Medical	while administering morning medication, patient was prescribed Amlodipine 10mg, tablets in the patients drawer where those transferred with patient from CAH. The box was Amlodipine 5mg, when taking the strip out and checked against Kardex it was not Amlodipine it was Amiloride 5mg. The patient had come from 1 South and this was the first time on this ward that this medication was due, last dose was given in 1 South.	Amlodipine	Amlodipine	Reported near miss and correct drug then taken from treatment room and administered correctly.	Patient Incidents	Medication/Bloods/Fluids	Administration to Patient	Incorrect medication/fluid	Minor	insignificant	moderate	possible	medium
05/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Pharmacy Aseptic Unit	Lenalidomide 25mg OD day 1-21 prescribed, calculation using Cockcroft and Gault determined patient's renal function to be 46.6ml/min. As per chart when renal function <50ml/min 10mg OD is recommended.	lenalidomide	lenalidomide	I contacted prescriber Returned chart Dose and electronic prescription authorisation form (ePaf) amended Lenalidomide 10mg OD dispensed Mandeville contacted to make patient aware when relative came to collect medication that dose was changed.	Patient Incidents	Medication/Bloods/Fluids	Prescribing Process	Incorrect dose		insignificant	moderate	possible	medium
10/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	1 East Maternity/Gynaecology	AT THE BEGINNING OF MY AFTERNOON WARD ROUND I WITNESSED THAT THE PATIENTS INSULIN (Lantus), A CRITICAL MEDICATION, HAD NOT BEEN SIGNED AS ADMINISTERED THAT MORNING. I QUESTIONED THIS WITH THE STAFF ON DUTY AS IT HAD BEEN DOCUMENTED IN THE NURSING NOTES THAT IT HAD IN FACT BEEN ADMINISTERED. FOR MY OWN REASSURANCE I CONTACTED THE STAFF NURSE WHO HAD BEEN WORKING THERE AND SHE ADVISED IN FACT IT HAD NOT BEEN GIVEN. I ALSO CONTACTED THE STUDENT NURSE WHO HAD WRITTEN IN THE NOTES AND SHE WAS ABLE TO CONFIRM IT HAD NOT BEEN GIVEN.	Insulins		I SPOKE WITH DOCTOR WHO ADVISED TO GIVE INSULIN AT THIS TIME AS IT IS A CRITICAL MEDICATION	Patient Incidents	Medication/Bloods/Fluids	Administration to Patient	Failure to administer	Minor	insignificant	moderate	possible	medium

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27/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Female Medical	<p>On nightshift, one of the nurses came and got me and said one of the patients relatives would like a word about medication. The family were polish and didn't speak great English. Went in and grabbed the clip board along with the kardex and opened it. Patient was prescribed 250mg of Keppra to go via PEG, and he had said that the dose is wrong. The father had a pen already in his hand and I thought he was just showing me on the kardex the dose, but in face he changed the 2 to a 7, as he said the dose was 750mg instead of 250mg. He also stated that the drug should be given at 2100 instead of 2200. Now, on the other side of the kardex, there was a scribble out and a dose written in the margin of the kardex.</p>	Levetiracetam	Levetiracetam	<p>Contacted night sight and explained the situation, as the father wanted SN to open the locker and give the medications. Didn't do this, as he would have given the new dosage of the Keppra with out it being prescribed. Night sight bleeped the Doctor who came onto the ward and SN explained the situation. She then went and spoke to the family, and spoke to the Reg that clerked the patient in the night before, and clarified the dose of the Keppra, which was in fact 750mg which was changed by the GP as the patient was having more recurrent seizures.</p>	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Incorrect dose	Insignificant	insignificant	moderate	possible	medium
26/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	3 North Winter Ward	<p>late prescription of insulin resulted in held dose of insulin. Linked with datix <span style="background-color: black; color: black;">[redacted]</span></p>	Insulins	SOLOSTAR TOUJEO	doctors informed	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Medication not prescribed	Minor	insignificant	moderate	possible	medium
17/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Missed 6am madopar	Co-Beneldopa		<p>doctor informed and stat prescribed datix completed documented in notes</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Minor	insignificant	moderate	possible	medium

04/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	<p>bank staff nurse on duty 3 south 3-4/4/19 concerns</p> <p>issue 1: Patient [redacted] did not receive critical medicine epilim 200mg/5ml reason on kardex patient refused.</p> <p>issue 2: patient [redacted] Fasting for theatre (IVF prescribed and not erected overnight) Patients enoxaparin 20mg was to be omitted and crossed out on kardex. (staff gave and signed for this)</p> <p>issue 3 [redacted] Patient had an occluded airway, De-saturating, large mucus plug removed from airway this morning. care overnight by SN (NO Tracheostomy suction record completed (that can be found)6 am nebulizer's not given (as per kardex)no documentation about patients airway management.</p>	Enoxaparin		<p>Following am handover I was made aware that [redacted] did not receive critical meds. I spoke with Sn Topsy and was informed that patient was agitated. I discussed other options ie iv/pr meds and whom she had escalated this problem to. No escalation of management of same done overnight.</p> <p>regarding suctioning of [redacted] I have been informed in handover that SN topsy stated no suction required.</p> <p>the other 2 issues have been highlighted to me by SN taking over patients care this am so I have not addressed these with SN Topsy.</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Contraindication due to medical condition	Minor	insignificant	moderate	possible	medium
26/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	<p>patient was being nursed in green area. she was surgical waiting a long period of time for bed on ward. Due to staff shortages supernumary newly qualified nurse was nursing patient. 2pm IV amoxicillin missed on Kardex.</p>	Amoxicillin		<p>nurse informed myself at 6pm. surgical dr informed and stat dose prescribed and given</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Insignificant	insignificant	moderate	possible	medium
19/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	<p>Infection control reviewed patients kardex on ward level and there was no signature for Vancomycin 125mg on the 18/4/19 @06:00, 22:00 and 06:00 on the 19/4/19</p>	Vancomycin	Vancomycin	<p>FY1 aware stat doses prescribed Sister in Charge informed</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Administered but drug chart not signed	Insignificant	insignificant	moderate	possible	medium
20/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	<p>Patient missed a dose of Vancomycin on the 20/4/19 @2200hrs</p>	Vancomycin	Vancomycin	<p>Sister in charge informed</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Insignificant	insignificant	moderate	possible	medium
25/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	<p>Pt had Levetiracetam stopped on previous admission due to adverse effect and Lacosamide started in lieu. This admission pt was written up for both levetiracetam and lacosamide, and received two doses of levetiracetam. Pt appeared drowsy and pt has ongoing skin problems.</p>	Levetiracetam		<p>I informed medical consultant, I completed datix and informed patient's son. Levetiracetam stopped on Kardex.</p>	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Contraindication due to history of allergy	Minor	minor	moderate	possible	medium
27/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	1 South Medical	<p>Medication not given for 11 doses.</p>	rifaximin	rifaximin	<p>Nurse in charge informed. medical doctor informed.</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Minor	minor	moderate	possible	medium

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	08/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	2 North Respiratory	WRONG N-G FED GIVEN	Enteral Feed Product	Enteral Feed Product	FEED STOPPED AND CORRECT FEED ORDERED FROM PHARMACY WRONG FEED REMOVED FROM WARD	Patient Incidents	Medication/Biology/Fluids	Administration to Patient	Incorrect medication/fluid	Minor	minor	moderate	possible	medium
	28/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	S/N CC approached me this morning (29/4/19) to say that patient [redacted] did not have her Tegretol 200mg signed for yesterday morning 28/04/2019	Carbamazepine	tegretol	checked patients kardex, all other medications have been signed for. Checked patients notes to see who was looking after patient 28/4/19 and will speak with S/N involved. No harm came to patient.	Patient Incidents	Medication/Biology/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Insignificant	insignificant	moderate	possible	medium
	20/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Rehabilitation Ward	palliative patient discharged from hospital on 19th April on syringe driver. Twilight called that evening to give breakthrough meds, no prescription or drugs sent home, family had to call back to collect same in ward as it wasn't ready when pt was going home. DN called Saturday to replenish driver, no prescriptions sent home, only photocopy of original. patient was in a lot of pain and vomiting, was also agitated at this time. patients zimmer frame was not sent home either. (Prescription clinically checked in dispensary at 16.30 and labelled generated within 30 minutes. ECM states patient discharged at 17.00 so must have been discharged before discharge prescription was ready)			Contacted ward and arranged family to collect original prescription. Line manager informed	Patient Incidents	Medication/Biology/Fluids	Administration to Patient	Failure to administer		minor	minor	possible	medium
	25/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	1 East Maternity/Gynaecology	pt was to be restarted on 24/04 rivaroxaban 15mg od but started on rivaroxaban 15mg bd patient did not receive bd dose as picked up on ward whilst reviewing on the morning of 25/04 bisoprolol 7.5mg also missing from kardex.	rivaroxaban		kardex amended to od rivaroxaban as per medical team bisoprolol prescribed by medical team	Patient Incidents	Medication/Biology/Fluids	Prescribing Processes	Incorrect frequency of dose		insignificant	moderate	possible	medium
	29/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Missed 6am IV amoxicillin	Amoxicillin		reported to nurse in charge. dr made aware. next dose given	Patient Incidents	Medication/Biology/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Minor	insignificant	moderate	possible	medium
	20/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Emergency Department DHH	Patient seen in ED and discharged with antibiotics for chest infection at 18.10. Daughter rang department at 2100 to query antibiotics, notes pulled and discovered patient given incorrect medications.	Flucloxacillin	Clarithromycin	Patient's welfare established. explained error in medications to daughter and asked to return to department for correct discharge medication. daughter will return in am. Nurse in charge informed. Dr in charge of patient care informed.	Patient Incidents	Medication/Biology/Fluids	Administration to Patient	Incorrect medication/fluid	Minor	insignificant	moderate	possible	medium

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05/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	Haematology Clinic	Patient with EBV + LPD/Hodgkins Disease, prescribed Gemcitabine chemotherapy C3D15 for 05/04/19 with HB 63,Plt 46, WBC 2.4, ANC 1.3. Got 2 units RBC on 04/04/19 but no follow up bloods ordered.	Gemcitabine	Gemcitabine	Spoke to prescribing consultant and expressed my concern with the patients blood counts, in particular her PLT count. He was happy to treat as it was only single agent gemcitabine. Having already spoken to the patients nurse who had administered the blood and said she was very sleepy and not in great condition, I requested that he have repeat bloods taken before the treatment was made up. He agreed if that was what I wanted. SN brought patient up for bloods and HB85, PLT 34, ANC 1.37. I contacted the consultant again and he agreed to defer treatment.	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Contraindication due to medical condition		insignificant	moderate	possible	medium
16/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Pharmacy Dispensary	Final checking ACAH prescription. Daptomycin had no fridge labels on containers or in tray. ACAH team contacted dispensary to check if prescription had been refrigerated prior to transport to South Tyrone. Advised that it hadn't.	Daptomycin		ACAH contacted MI to seek advice if could still be used which it could.	Patient Incidents	Medication/Biologicals/Fluids	Storage Processes (in pharmacy or on unit)	Medication stored at wrong temperature	Minor	insignificant	minor	possible	low
05/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	Antenatal Clinic	medicine fridge has repeatedly been reported on estates and in march was reported on medical equipment repair forum. fridge is reading high and insulin needs stored in same.			re referred on request platform and Ruth McCauley telephoned but not in office. Michelle Portis Aware.	Organisational Incidents	Medication/Biologicals/Fluids	Storage Processes (in pharmacy or on unit)	Refrigeration failure	Insignificant	insignificant	minor	possible	low
07/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	2 West Maternity Post Natal	Infant in 2West missed dose of gentamicin due to work load of Paeds SHO. Antibiotic was due at 2000 on 7/4 but was not given until night SHO realized it was missed at 0600. Parents of baby have been notified of error and antibiotics was given as soon as error was realized. No harm has come to child but if baby had been more unwell this may have been very important.	Gentamicin	Gentamicin	I have explained to parents the error and informed consultant Dr Hogan.	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Medication not prescribed	Insignificant	insignificant	minor	possible	low
05/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	patient admitted to ward from ED earlier today and when administering 10pm meds noted that temazepam 10mg was prescribed for 10am and same given in ED this Am. Night co-ordinator informed and F1 changed prescription to 10pm.	Temazepam	Temazepam	As above and no sedation given at 10pm.	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Incorrect timing of dose	Insignificant	insignificant	insignificant	possible	low

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25/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Patient was prescribed 500mg IV paracetamol as wait was ?48kgs unable to get accurate weight as #NOF. Half of 100ml bottle was put through the IV pump. The patient was brought to xray and paracetamol was disconnected as 50mls had been administered. Staff nurse came back from break and reconnected paracetamol once the patient had returned from xray, unaware that only half the bottle was to be administered therefore patient received 1gram paracetamol IV.	Paracetamol	Paracetamol	Sister in charge was informed as well as medical DR. Reassurance given from DR as this was the patient's first dose of paracetamol	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect dose	Minor	insignificant	insignificant	possible	low
02/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	1 North Cardiology	Phonecall recieved from ED at approx 23.00 to handover patient, staff nurse stated that all night time medications, including evening insulin and IV Antibiotics were given. When administering morning antibiotics, it was noticed that night time oral medications were not given, they were coded '6' however this was not handed over.	all night medications	Bumetanide	informed to the charge nurse.	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Failure to administer	Minor	insignificant	minor	possible	low
24/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Pharmacy Dispensary	New ongoing script sent to pharmacy to be dispensed, dosing times had changed and I made a note of original time on script ward, I contacted the ward to verify time change but I forgot to remove one of the times and as a result patient received Quetiapine M/R TID instead of BD. When script was being prepared on 01/05/2019 checker noticed difference between script and kardex and asked me to clarify. I realised my error and contacted Bluestone pharmacist for advice. She spoke to patient's Consultant who had seen her this week and said patient was ok but to reduce back to twice a day. No harm came to patient	Quetiapine	Quetiapine	Patient's Consultant made aware of error	Patient Incidents	Medication/Biologicals/Fluids	Dispensing Processes	Incorrect frequency		insignificant	minor	possible	low
02/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Patient prescribed 1000mls 0.9% Normal Saline over 6 hours. Ivf commenced by SN at 2030 as per fluid balance chart. Staff Nurse on duty tonight went into patient at 2130 and IVF finished. No IV pump used to administer IVF.	Sodium Chloride		Advised patient of same. Sister in charge aware. Datix completed.	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect rate of administration	Minor	minor	minor	possible	low
04/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Patients kardex written in ED as per repeat ECR list - solifenacin had recently been stopped and changed to fesoterodine but solifenacin was prescribed on kardex.	solifenacin	fesoterodine	Admitted to 3 north and error found by pharmacist completing med rec. solifenacin stopped and fesoterodine recommenced	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Incorrect medication/fluid	Minor	insignificant	insignificant	possible	low
26/04/2019	Acute Services	Pharmacy	Daisy Hill Hospital	Pharmacy Dispensary	A prescription for Bisoprolol was labelled with the correct strength (1.25mg) but Bisoprolol 2.5mg was dispensed. The same person had both labelled and dispensed the item.	Bisoprolol	Bisoprolol	This was detected at the final check. The member of staff was informed and the correct strength dispensed.	Patient Incidents	Medication/Biologicals/Fluids	Dispensing Processes	Incorrect dose	Minor	insignificant	minor	possible	low

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11/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	CEAW	On Thursday 11/4/19 I noticed Pt was prescribed enoxaparin 40mg nocte as VTE prophylaxis. Her eGFR was < 30 but there was no weight. I discussed the need to reduce to 20mg nocte if the patient was between 50-100kg with the ward doctor and requested he ensure the review of this medication when the nurse weighed the patient. There was concern that the pt was not steady enough to stand on the scales but the nurse said she would attempt with another nurse. The ward doctor was aware and I documented in the notes that I had requested he review this medication. I return to the ward on Monday 15/4/19 and neither the ward doctor or medical team have reviewed the enoxaparin despite me having documented in the medical notes and on the kardex the need to review this medication. A weight was obtained on the 11/4/19 and documented on the front of the kardex.	Enoxaparin		The pts eGFR has now risen over 30 from 13/4/19. Note made in medical notes to keep eGFR and enox under review. Above discussed with ward doctor.	Patient Incidents	Medication/Bloods/Fluids	Prescribing Process	Incorrect dose	Minor	insignificant	minor	possible	low
09/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	4 South	When administering morning medications noticed Ramipril 15mg was prescribed. Discussed with patient and discovered Lisinipril was meant to be prescribed. same not administered and doctors made aware to review medications	Ramipril	Lisinipril	Ward sister aware of same. admitting ward made aware of same apparently medication was not prescribed at this time as patient had gone to theatre first on list spoke to fy1 unable to ascertain where drug prescribed /? in theatre or recovery unable to locate prescribing doctor as no bleep number on kardex and signature hard to decipher	Patient Incidents	Medication/Bloods/Fluids	Prescribing Process	Incorrect medication/fluid	Minor	insignificant	minor	possible	low
15/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	PATIENT WAS PERSCRIBED LONGTEC 5MG FOR #ANKLE PAIN IN ED. STAFF WERE UNABLE TO ADMINISTER THIS TO PATIENT AS THERE WAS NONE AVAILABLE IN THE DEPARTMENT. LAST DOSE OF LONGTEC WAS ADMINISTERED BY THE DAY STAFF TO ANOTHER PATIENT AT 11.30 THAT MORNING AS PER THE BOOK .	Oxycodone		SR INFORMED- NIL ADVISED. SHORTEC GIVEN TO PATIENT IN ED INSTEAD. ASKED THE WARD IF IT CAN BE GIVEN WHEN HE GOES TO THE WARD. WARD HAPPY TO DO THIS. PATIENT INFORMED.	Patient Incidents	Medication/Bloods/Fluids	Administration to Patient	Failure to administer	Insignificant	insignificant	minor	possible	low
05/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	morning medications were omitted by myself by accident. medications omitted include: aspirin 75mg, omeprazole 40mg, pabrinex 2 pairs, Librium 30mg.	Pabrinex IM/IV	Pabrinex IM/IV	first realized medications were omitted at 14.00. Informed medical doctor and nurse in charge and had relevant medications prescribed as stat dose and gave 14.00 medications as prescribed. patient also informed	Patient Incidents	Medication/Bloods/Fluids	Administration to Patient	Failure to administer	Minor	insignificant	minor	possible	low

Personal Information redacted by the UOI	Date	Service	Medicine and Unscheduled Care	Craigavon Area Hospital	Department	Description of Incident	Drug	Manufacturer	Details	Patient Incidents	Medication/Fluids	Administration to Patient	Failure to Administer	Severity	Impact	Frequency	Preventable	Outcome
	02/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	2 North Respiratory	Patient only received 4 applications of a possible 12 applications of DAKTACORT CREAM staff made aware that it was stored in fridge but have continued to mark kardex as drug unavailable yet 6 tubes were available and kardex marked "FRIDGE"	Daktacort	Daktacort	Again mentioned to staff that cream was available in FRIDGE.	Patient Incidents	Medication/Fluids	Administration to Patient	Failure to administer	Minor	minor	minor	possible	low
	24/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	Trauma Ward	Patient was admitted to the trauma ward on 19/4/19, the patient was prescribed tramadol 100mg BD. The patient takes Maxitram SR 100mg BD at home.	Tramadol	Tramadol MR	Pharmacist informed, Maxitram SR 100mg prescribed, nurse in charge informed, patient informed	Patient Incidents	Medication/Fluids	Prescribing Process	Incorrect formulation	Insignificant	insignificant	minor	possible	low
	18/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	1 East Maternity/Gynaecology	Patient on gynae ward had been in recovery ward for a number of days 15-17/04 then gynae from the night 17/04 written up for longtec 5-10mg bd in regular section by anaesthetist. Doses given in both wards, gynae ward stated dose but not recovery. Also jentaduo prescribed which pharmacy do not stock contains two separate meds which should be prescribed separately if patient does not have their own pods. this had been given in recovery even though patient did not have their own supply but once in gynae rewritten as separate meds.	Oxycodone		Rewrote Kardex with set dose of longtec not a range, spoke to gynae sister and recovery sister. Anaesthetist not on site at present will contact when on site.	Patient Incidents	Medication/Fluids	Prescribing Process	Incorrect dose		insignificant	minor	possible	low
	15/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Emergency Department DHH	IV FLUIDS-1 LITRE OF HARTMANS INFUSING AT INCORRECT RATE, RUNNING AT 125 MLS PER HOUR BUT SHOULD BE 167 MLS PER HOUR.	Sodium Lactate, Compound	HARTMANS	ADJUSTED TO CORRECT RATE	Patient Incidents	Medication/Fluids	Administration to Patient	Incorrect rate of administration	Insignificant	insignificant	minor	possible	low
	12/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	stat dose of Paracetamol administered and then patient also received regular Paracetamol at 1800hrs with only 2hr20 from stat dose.	Paracetamol		patient and nurse in charge informed	Patient Incidents	Medication/Fluids	Administration to Patient	Incorrect frequency of dose (extra dose)	Insignificant	insignificant	minor	possible	low
	23/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	4 South	Patient's potassium on 23/4 low at 3.3. Sando-K prescribed at dose of TT BD. Not written correctly on kardex and two doses missed before mistake noticed. Start date was 23/04/19 but boxed off on kardex from 19/04 PM to 21/4/19. (Potassium on 24/4/19 came back at 3.7 and so Sando-K discontinued anyway). (Further information: They had put the start date as 23/4 and put lines after the 3 days of treatment on the kardex as normal. However, they hadn't read the dates already written at the top of the kardex columns which started at the 19/4 and so the lines through the boxes on the kardex started from the 22/4 even though treatment should have begun on 23/4)	Potassium Chloride		Spoke to FY1. As potassium was back within normal range, they were happy to discontinue the Sando-K anyway.	Patient Incidents	Medication/Fluids	Prescribing Process	Incorrect duration of treatment	Minor	minor	minor	possible	low
	03/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Pharmacy Aseptic Unit	the wrong drug strength was dispensed. Ondansetron 8mg dispensed instead of ondansetron 4mg tablets.	Ondansetron	Ondansetron	prescription was taken back and the correct strength was dispensed.	Patient Incidents	Medication/Fluids	Dispensing Process	Incorrect dose		insignificant	insignificant	possible	low

14/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	PATIENT RECEIVED DOSE OF PARACETAMOL 1G IV AT 06.30 AND 08.00 ON 14/4/2019. FIRST DOSE ADMINISTERED FROM ED FLIMSY AND SECOND DOSE ADMINISTERED FROM DRUG KARDEX.	Paracetamol	Paracetamol	MEDICAL DOCTOR INFORMED - NO FURTHER PARACETAMOL TO BE GIVEN TODAY	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (extra dose)	Insignificant	insignificant	minor	possible	low
14/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Pharmacy Dispensary	Patient was seen by MO, fit for discharge. There were changes to her medications. She used a Medidose and required it to be renewed. With some Persuasion Pharmacy agreed to dispense her meds in a new Medidose. The letter was written and the drug Kardex sent to pharmacy around lunch time. Around 4.30 pm her family arrived to take her home. Pharmacy were rang but they did not answer the phone. Without being able to contact the Pharmacy Department I then rang the on call Pharmacist Richard. He was unable to contact them either. At 18.40 after several phone calls Richard agreed to Phone Maria McNally who had been on duty earlier. She stated the Meds had been dispensed. I sent staff around the hospital trying to find the medication, without result. Richard later came in around 19:30 and found the meds in Pharmacy.			Pharmacist on Call rang when unable to contact Pharmacy Department. Bed Manager informed. Porters asked who delivered the Pharmacy. Family kept informed	Patient Incidents	Medication/Biologicals/Fluids	Delivery Processes	Delayed delivery to unit/ward	Minor	minor	minor	possible	low
24/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	PATIENT ON CRITICAL MEDS OUT OF HOURS PHARMACY CONTACTED AND MEDICATIONS PERSCRIBED STAT. MEDICATIONS GIVE AS LISTED. AT 3AM PATIENT DISCLOSED THAT HE THINKS HIS NEICE GAVE HIM HIS TABLETS ? 6TABS ? SAME MEDICATION	Lithium	Lithium	SPOKE WITH PATIENT SENIOR DOCTOR AWARE MDICAL DR INFOMED HOURLY OBSERVATIONS	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Unauthorized self-medication	Insignificant	minor	minor	possible	low
09/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Emergency Department DHH	Patient given Apixiban by staff but daughter had already given patient her dose for this evening and didn't tell staff.	apixiban	apixiban	daughter contacted. Informed of risks associated with bleeding. consultant aware. no action required.	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Unauthorized self-medication	Insignificant	insignificant	minor	possible	low
26/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	North Cardiology	Patient discharged from 1 North CAH to Crozier House Intermediate Care facility on Fri 26/4/19. When discharge medication along with letter was being checked on admission a Senior Care Worker noticed that some of the medication in the bag didn't have any labels with the patients name or directions for use on them and others did. There were 6 boxes of medications without a label. These include: Atorvastatin 40mg, Bisoprolol 1.25mg, Folic Acid 5mg, Bumetanide 1mg, Pivemcillinam 200mg and Warfarin 1mg. All of the above medication was on the discharge letter. (JAC Pharmacy system - labels generated for 10 items including these 6 medicines on 26/4/19, indicating that these unlabelled medicines were ward stock that had been supplied on discharge from the bedside locker)	Bisoprolol	Bisoprolol	Informed pharmacy on the next working day and unlabelled medication removed.	Patient Incidents	Medication/Biologicals/Fluids	Other Medication/Biologicals/Fluids Incident	Other medication/fluids incident	Insignificant	insignificant	insignificant	possible	low

25/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Pharmacy Dispensary	no pharmacist cover in the emergency department on 25/04/19 23 trolley waits			pharmacy contacted no cover available delay in patients receiving critical medications	Organisational Incidents	Service Disruptions (environment, infrastructure, human resources)	Service Provision Insufficiencies/Failures/closures							not a medication incident asked to resubmit for any omitted/delayed doses
15/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Female Medical	Patient transferred to Cath lab from Female Medical, DHH without a nursing handover and/or transfer sheet, Nursing notes and Medicine kardex.			Registrar A contacted by Dr M as ward was not answering phone, medication list advise given over the phone. Ward was then contacted to send kardex and nursing notes. This still had not happened by 1700hours. Ward contacted again to email kardex to ward manager of cath lab so new one could be re-issued.	Patient Incidents	Communication	Between Different Teams	Omission of important facts	Minor					Kardex unavailable
08/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Pharmacy Dispensary	Patient brought POD into hospital (ward 2 south stroke) of Captopril 12.5mg (along with other meds). Captopril POD was issued by community pharmacy on 22/3/19 but the contents expired 31/3/19.	Captopril		Spoke to the patient and explained to him as well as contacting the community pharmacy and highlighting this to them. Also informed the ward Pharmacist.	Patient Incidents	Medication/Biologicals/Fluids	Dispensing Processes	Expired product	Insignificant					community pharmacy
09/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Female Medical	Patient transferred from DHH to Cath lab for a TOE. no nursing notes including kardex transferred with patient. Medications due when Patient in cathlab care. This was not handed over or documented.			When first noted, DHH hospital contacted to confirm that the kardex was still on female medical ward and asked what medications were prescribed. Nurse in charge informed, Sr W informed. Dr bleeped on [redacted] to rewrite kardex.	Patient Incidents	Documentation	Other Documentation Incident	Other documentation incident	Moderate					Kardex unavailable
11/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Emergency Department DHH	Strip of Lyrica 25mg (with 2 tablets missing, therefore 12 tablets remaining) found beside computer in Minors area of ED in brown envelope with "ED" written on same.	pregabalin lyrica		Reported to Sr. in charge and ED manager. ED pharmacist bleeped and informed of same. Drugs locked away in Control Drug cupboard by 2 members of staff. Datix submitted.	Organisational Incidents	Medication/Biologicals/Fluids	Storage Processes (in pharmacy or on unit)	Non secure storage of controlled substances	Minor					controlled drugs

Personal information redacted by the USI	20/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	CEAW	When we were carrying out medications of patient A we went to check a CD drug, the entry and count of the drug was incorrect (the drug was Plexia 100mg sr.) Upon reading back through the entries it was noticeable that there was an entry missing and an entry incorrect which was giving the wrong count of tablets.	tapentadol	bed manger informed- Paula MC Cann Pharmacist informed Claire Murphy	Patient Incidents	Documentation	Controlled drug registers	Ambiguous/incorrect/incomplete	Minor	controlled drugs				
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Personal information redacted by the USI	08/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	tapentadol 50mg ordered from pharmacy. 3 tablets in stock in controlled drug cupboard. 10 tablets were ordered and collected from pharmacy. When signing the medication into the controlled drug book it was recorded as 15 tablets received by two registered nurses which brought the total to 18. At handover from day to night staff, drugs were checked and no discrepancies noted. When signing the drug out for a patient it was noticed there was only 13 tablets.	tapentadol palexia	When noticed, contacted sister in charge of day shift who informed the ward manager. Noticed at this time that only 10 tablets were dispensed from pharmacy therefore this was the reason for the wrong amount of medication recorded in CD book.	Patient Incidents	Documentation	Controlled drug registers	Controlled drug (CD) record keeping error	Insignificant	controlled drugs				
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ID	Incident date	Directorate	Division	Site	Loc (Exact)	Description	Drug administered	Correct drug	Action taken	Incident affecting	Incident type tier one	Incident type tier two	Incident type tier three	Consequence	Impact	Likelihood	Severity	Risk rating
Personal information redacted by the USI	25/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	PT was sent to A&E due to query urosepsis , was returned without further investigations and prescribed an antibiotic the patient was allergic to.	Co-Amoxiclav		Urgent bloods taken upon return , escalated to duty MO and she attended A&E to raise concerns. Patient then required medical admission for blood transfusion.	Patient Incident	Medication/Biologicals/Fluids	Administration to Patient	Contraindication due to history of allergy		minor	catastrophic	possible	extreme
	02/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Doxycycline prescribed and administered (one dose). Later found documentation of doxycycline allergy in GP record although not nature of reaction. NOT documented on NH kardex	Doxycycline		Nurse in area of ED aware. Admitting team aware	Patient Incident	Medication/Biologicals/Fluids	Prescribing Process	Contraindication due to history of allergy	Minor	minor	catastrophic	possible	extreme
	15/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Female Medical	Patient treated for hyperkalemia appropriately as ECG changes. Clear documentation of monitoring required in medical notes and handed over to nurse caring for patient including BM monitoring. Last BM recorded 3am = 4.8. Cardiac arrest at 6.35am with hypoglycaemia 1.9. Lack of BM and physical observations in patient overnight which should have been hourly and 4hourly respectively.  Patient also on warfarin. No recorded prescription for 14/4/19. F1 was informed by nursing staff that warfarin dose had been held 14/4/19 - this was not the case and patient had mechanical heart valve. There was no prescription for 14/4/19.	Warfarin	Warfarin	Discussed with Consultant Dr A and Ward Sister H. Advised Datix to be completed as per Dr A.	Patient Incident	Diagnostic Processes/Procedures	Monitoring/On-going Assessment of Patient Status	Failure/in sufficient response to significant change in patient status	Major	catastrophic	catastrophic	possible	extreme
	16/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	PATIENT ADMITTED TO 3SOUTH TODAY FROM EMERGENCY DEPARTMENT. PATIENT HAS NO ENGLISH, SON PRESENT WHO HAS GOOD ENGLISH. PATIENT HAD ATTENDED ED ON 15/4/19 WITH ABDOMINAL PAIN AND DISCHARGED WITH CO-CODAMOL. ON ADMISSION ON REVIEW OF ANALGESIA IT WAS DISCOVERED THAT THE PATIENT HAD TAKEN 20 TABLETS IN 24HRS	Co-Codamol		MEDICAL STAFF INFORMED COMMENCED ON MANAGEMENT OF PATIENTS 8-15HRS AFTER INGESTION PROTOCOL COMMENCED ON N-ACETCYSTEINE INFUSION(PARVOLEX) MONITOR OBS HOURLY BLOODS INCLUDING OVERDOSE,LFTS, U+E, CRP,COAG,INR AMYLASE AND FBP SENT VBG DONE INSTANTLY	Patient Incident	Medication/Biologicals/Fluids	Medication advice	Unclear advice	Minor	minor	major	possible	high

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26/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	3 North Winter Ward	On Friday 26th night duty a patients insulin prescription sheet was taken from charts at bottom of bed to have insulin prescribed. Dr was contacted by co-ordinator to prescribe same. Same was not prescribed until 0.230hrs. the particular insulin was not available in 4 different wards so Pharmacist was contacted. Pharmacist stated that a long acting insulin should not be prescribed at that time of morning and to contact Dr to inform him of same. Dr decided to HOLD same. At 0500hrs while writing Nursing report I noted that this patient was not a DIABETIC ,, BUT HER ADDRESSOGRAPH WAS ON ANOTHER PATIENTS INSULIN SHEET on inside page. On removing addressograph another addressograph was underneath. Dr informed of same. I personally have been very fortunate as that prescription of insulin could have been given to the wrong patient because of several circumstances. It has been a MAJOR reminder of how easily a serious incident could have occurred.	Insulins		SR INFORMED REBECCA WILLS	Patient Incidents	Medication/Bloods/Fluids	Prescribing Processes	Incorrect patient	insignificant	major	possible	high	
07/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	General Male Medical	Patient was prescribed Novorapid 60 units at 08:00, 12:00, 17:00 & 22:00hrs. Developed hypoglycemia on 2 occasions as a result at 06:25 & 05:30hrs. Patient informed DR he takes Novorapid at 22:00hrs at home with his supper.	Insulins	Insulins	Highlighted in medical notes that Patient was only ever advised Novorapid 60 units with breakfast, lunch and evening meal. Patient advised of correct timing of his insulin. Ward manager informed and DR's who prescribed Novorapid to be informed.	Patient Incidents	Medication/Bloods/Fluids	Prescribing Processes	Incorrect frequency of dose	Minor	minor	major	possible	high
15/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	1 North Cardiology	Patient had attended PCI or stenting 1 stent to LCX and 1 stent to LAD last 12/04/19. It was written in the post cath notes that he is for Clopidogrel for 3/12 to stop 12/07/19. He was then loaded with 300mg on the 12/04/19 as a STAT dose but was not prescribed or written in the antiplatelet prescription page. So it was missed on the 13/04 and 14/04.	Clopidrogel	Clopidrogel	Clinical sister, SHO, and patient informed. The said tablet was prescribed and given. Apologise to the patient. Ward manager informed as well.	Patient Incidents	Medication/Bloods/Fluids	Prescribing Processes	Delay in prescribing	Insignificant	insignificant	major	possible	high

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26/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	<p>No octaplex in department.</p> <p>Octaplex used on Thur 25th April night duty, only 2 vials used. s/n Lynsay Trimble contacted labs to inform only 2 used and would they like all vials returned as per normal protocol . s/n advised by lab staff to only return the used vials in the box and to keep unused vials of octaplex in resus fridge. same was done as per lab staff advice.</p>	octaplex		<p>Box with used vials returned to lab with porter Aaron. Aaron informed by lab staff that he did not need to bring any octaplex back to A&amp;E as they had some in fridge and that the box did not need to be returned either.</p> <p>sat 27th night duty SR Roisin O'Neill contacted Haem labs to enquire about octaplex box and octaplex mediation. was informed by lab staff that box was not in labs and more than likely the box has been misplaced when with porter.</p>	Organisational Incidents	Medication/Biologicals/Fluids	Delivery Processes	Delayed delivery to unit/ward	Minor	insignificant	major	possible	high
30/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	<p>Pt was not written up for any enoxaparin on admission (until I raised this issue at the post-take ward round), nor was the VTE assessment form completed, despite pt being short of breath and subsequently being diagnosed with bilateral pulmonary emboli.</p> <p>(Patient admitted as per NIECR on 29-Apr-2019 2:04 PM, and decision to admit was 29-Apr-2019 11:00 PM, again as per NIECR. It is therefore my view that the patient missed one dose.)</p>	Enoxaparin		<p>Enoxaparin treatment dose prescribed at post-take ward round. Datix completed.</p>	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Medication not prescribed		minor	major	possible	high
21/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	1 South Medical	<p>Pt. is on IV Tazocin &amp; IV Terlipressin due at 0600 (21/04/19). Same were missed by the Agency Nurse.</p>	Tazocin		<p>Doctors has been informed by the day staff.</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)		insignificant	major	possible	high
23/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	<p>medication not given critical med</p>	apixaban	apixaban	<p>dr informed and medication prescribed as a stat dose and give to patient</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Failure to administer	Minor	insignificant	major	unlikely	high

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12/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Urgent referral received 3:30pm Friday 12th April for administration of insulin and enoxaparin. Blood glucose 14.6mmol/l at 08.35 on 12/4/19	Insulins		Telephoned GP for more details and it transpired that patient was in A&E for injuries following a fall and had a fractured humerus. He was discharged home and no referral made to DN to administer, even though patient is right handed and it was his right arm that was effected therefore unable to continue self administering insulin and enoxaparin. He had not had either medication from 1st April due to his injury and this was only discovered at an outpatients appointment on Friday. Authorization received from GP and attended to patient to administer Insulin as prescribed with consent and reported backed to GP. Shared care now between District Nursing and Twilight team for administration of enoxaparin.	Patient Incidents	Medication/Biologicals/Fluids	Post-administration Patient Monitoring	Incorrect/insufficient handover/transition	Minor	insignificant	major	possible	high
14/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Patient attended ED on Sunday 14th April, in department from 02.56 until 19.20 then transferred to 2 North. Pharmacist med hx completed on 2 North at ~ 12.00 on Monday 15th April and noted that patient had been receiving Humalog insulin bd instead of preadmission Humalog Mix 25. Preadmission doses were Humalog Mix 25 22units am and 14 units pm. Patient received Humalog 24 units am and 14 units teatime on 14th April, and 24 units am on the 15th. Humalog Mix 25 was referenced on patient's Kardex but Humalog prescribed on insulin chart.	Insulins	Humalog Mix 25	Medical and nursing staff informed when discrepancy noted and patient's BM checked, found to be 3.0 and glucojuice given. Checked again repeatedly thereafter and remained normal.	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Incorrect medication/fluid	Minor	minor	moderate	possible	medium
10/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Patient admitted 9/4/19 with slurred speech and unsteadiness. Found to have lithium toxicity (lithium level = 1.58) Medicines reconciliation carried out by ward pharmacist. Noted patient was prescribed Naproxen 500mg BD by GP for back pain on 25/3/19. Further supply given by CAH CDU on 5/4/19.	Lithium		Lithium held on admission (awaiting repeat levels). Naproxen stopped. Patient informed of interaction between NSAIDs and lithium. Interaction to be documented on discharge letter for GP info.	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Contraindication due to interactions with other medications	Minor	minor	moderate	possible	medium
20/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	1 South Medical	Pt is on Insulin at 10pm, same was missed by the Agency Nurse last Saturday 20/04/19.	Insulins	tresiba	Doctors has been informed.	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Failure to administer		insignificant	moderate	possible	medium

<p>Personal Information redacted by the USI</p>	<p>26/04/2019</p>	<p>Acute Services</p>	<p>Medicine and Unscheduled Care</p>	<p>Daisy Hill Hospital</p>	<p>Female</p>	<p>Apixaban prescribed for the wrong patient on a medicine kardex and on their discharge letter. Patient was not administered and did not receive any apixaban. Error discovered by pharmacist on checking discharge letter.</p>	<p>apixaban</p>	<p>Discharge prescription received for above patient by ward pharmacist on Friday afternoon 26/04/19. Patient was newly prescribed Apixaban. The letter detailed this was prescribed for paroxysmal AF. On checking the patients notes there was no detail on AF during the admission. The FY1 stated that she had checked with the Registrar who had verbally told her the patient had AF and that was why he had prescribed apixaban. After a second check of the patients notes the pharmacist rejected the letter back to the doctor as felt that if patient had AF and a decision was made to start anticoagulation then it should be documented in patient notes. The FY1 contacted the Registrar a second time and it was then discovered that Apixaban had been prescribed for the wrong patient. FY1 amended patients</p>	<p>Patient Incidents</p>	<p>Medication/Bloods</p>	<p>Prescribing Processes</p>	<p>Incorrect patient</p>	<p>Moderate</p>	<p>insignificant</p>	<p>moderate</p>	<p>possible</p>	<p>medium</p>
<p>12/04/2019</p>	<p>Acute Services</p>	<p>Medicine and Unscheduled Care</p>	<p>Craigavon Area Hospital</p>	<p>1 South</p>	<p>while administering morning medication, patient was prescribed Amlodipine 10mg, tablets in the patients drawer where those transferred with patient from CAH. The box was Amlodipine 5mg, when taking the strip out and checked against Kardex it was Amiloride 5mg. The patient had come from 1 South and this was the first time on this ward that this medication was due, last dose was given in 1 South.</p>	<p>Amlodipine</p>	<p>Reported near miss and correct drug then taken from treatment room and administered correctly.</p>	<p>Patient Incidents</p>	<p>Medication/Bloods</p>	<p>Administration to Patient</p>	<p>Incorrect medication/fluid</p>	<p>Minor</p>	<p>insignificant</p>	<p>moderate</p>	<p>possible</p>	<p>medium</p>	

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27/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Female Medical	On nightshift, one of the nurses came and got me and said one of the patients relatives would like a word about medication. The family were polish and didn't speak great English. Went in and grabbed the clip board along with the kardex and opened it. Patient was prescribed 250mg of Keppra to go via PEG, and he had said that the dose is wrong. The father had a pen already in his hand and I thought he was just showing me on the kardex the dose, but in fact he changed the 2 to a 7, as he said the dose was 750mg instead of 250mg. He also stated that the drug should be given at 2100 instead of 2200. Now, on the other side of the kardex, there was a scribble out and a dose written in the margin of the kardex.	Levetiracetam	Levetiracetam	Contacted night sight and explained the situation, as the father wanted SN to open the locker and give the medications. Didn't do this, as he would have given the new dosage of the Keppra with out it being prescribed. Night sight bleeped the Doctor who came onto the ward and SN explained the situation. She then went and spoke to the family, and spoke to the Reg that clerked the patient in the night before, and clarified the dose of the Keppra, which was in fact 750mg which was changed by the GP as the patient was having more recurrent seizures.	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Incorrect dose	Insignificant	insignificant	moderate	possible	medium
26/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	3 North Winter Ward	late prescription of insulin resulted in held dose of insulin. Linked with datix <small>irrelevant information</small>	Insulins	SOLOSTAR TOUJEO	doctors informed	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Medication not prescribed	Minor	insignificant	moderate	possible	medium
17/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Missed 6am madopar	Co-Beneldopa		doctor informed and stat prescribed datix completed documented in notes	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Minor	insignificant	moderate	possible	medium
26/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	patient was being nursed in green area. she was surgical waiting a long period of time for bed on ward. Due to staff shortages supernumary newly qualified nurse was nursing patient. 2pm IV amoxicillin missed on Kardex.	Amoxicillin		nurse informed myself at 6pm. surgical dr informed and stat dose prescribed and given	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Insignificant	insignificant	moderate	possible	medium
25/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Pt had Levetiracetam stopped on previous admission due to adverse effect and Lacosamide started in lieu. This admission pt was written up for both levetiracetam and lacosamide, and received two doses of levetiracetam. Pt appeared drowsy and pt has ongoing skin problems.	Levetiracetam		I informed medical consultant, I completed datix and informed patient's son. Levetiracetam stopped on Kardex.	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Processes	Contraindication due to history of allergy	Minor	minor	moderate	possible	medium
27/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	1 South Medical	Medication not given for 11 doses.	rifaxamin	rifaxamin	Nurse in charge informed. medical doctor informed.	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Minor	minor	moderate	possible	medium
08/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	2 North Respiratory	WRONG N-G FED GIVEN	Enteral Feed Product	Enteral Feed Product	FEED STOPPED AND CORRECT FEED ORDERED FROM PHARMACY WRONG FEED REMOVED FROM WARD	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect medication/fluid	Minor	minor	moderate	possible	medium

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20/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Rehabilitation Ward	palliative patient discharged from hospital on 19th April on syringe driver. Twilight called that evening to give breakthrough meds, no prescription or drugs sent home, family had to call back to collect same in ward as it wasn't ready when pt was going home. DN called Saturday to replenish driver, no prescriptions sent home, only photocopy of original. patient was in a lot of pain and vomiting, was also agitated at this time. patients zimmer frame was not sent home either. (Prescription clinically checked in dispensary at 16.30 and labelled generated within 30 minutes. ECM states patient discharged at 17.00 so must have been discharged before discharge prescription was ready)			Contacted ward and arranged family to collect original prescription. Line manager informed 24/04/19 when back on duty	Patient Incidents	Medication/Bloods/Fluids	Administration to Patient	Failure to administer		minor	minor	possible	medium
29/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Missed 6am IV amoxicillin	Amoxicillin		reported to nurse in charge. dr made aware. next dose given	Patient Incidents	Medication/Bloods/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Minor	insignificant	moderate	possible	medium
20/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Emergency Department DHH	Patient seen in ED and discharged with antibiotics for chest infection at 18.10. Daughter rang department at 2100 to query antibiotics, notes pulled and discovered patient given incorrect medications.	Flucloxacillin	Clarithromycin	Patient's welfare established. explained error in medications to daughter and asked to return to department for correct discharge medication. daughter will return in am. Nurse in charge informed. Dr in charge of patient care informed.	Patient Incidents	Medication/Bloods/Fluids	Administration to Patient	Incorrect medication/fluid	Minor	insignificant	moderate	possible	medium
05/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	patient admitted to ward from ED earlier today and when administering 10pm meds noted that temazepam 10mg was prescribed for 10am and same given in ED this Am. Night co-ordinator informed and F1 changed prescription to 10pm.	Temazepam	Temazepam	As above and no sedation given at 10pm.	Patient Incidents	Medication/Bloods/Fluids	Prescribing Processes	Incorrect timing of dose	Insignificant	insignificant	insignificant	possible	low
25/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Patient was prescribed 500mg IV paracetamol as wait was ?48kgs unable to get accurate weight as #NOF. Half of 100ml bottle was put through the IV pump. The patient was brought to xray and paracetamol was disconnected as 50mls had been administered. Staff nurse came back from break and reconnected paracetamol once the patient had returned from xray, unaware that only half the bottle was to be administered therefore patient received 1gram paracetamol IV.	Paracetamol	Paracetamol	Sister in charge was informed as well as medical DR. Reassurance given from DR as this was the patient's first dose of paracetamol	Patient Incidents	Medication/Bloods/Fluids	Administration to Patient	Incorrect dose	Minor	insignificant	insignificant	possible	low

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02/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	1 North Cardiology	Phoncall recieved from ED at approx 23.00 to handover patient, staff nurse stated that all night time medications, including evening insulin and IV Antibotics where given. When administering morning antiboics, it was noticed that night time oral medications were not given, they where coded '6' however this was not handed over.	all night medications	Bumetamide	informed to the charge nurse.	Patient Incidents	Medications/Fluids	Administration to Patient	Failure to administer	Minor	insignificant	minor	possible	low
02/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Patient prescribed 1000mls 0.9% Normal Saline over 6 hours. Ivf commenced by SN at 2030 as per fluid balance chart. Staff Nurse on duty tonight went into patient at 2130 and IVF finished. No IV pump used to administer IVF.	Sodium Chloride		Advised patient of same. Sister in charge aware. Datix completed.	Patient Incidents	Medications/Fluids	Administration to Patient	Incorrect rate of administration	Minor	minor	minor	possible	low
04/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	Patients kardex written in ED as per repeat ECR list - solifenacin had recently been stopped and changed to fesoterodine but solifenacin was prescribed on kardex.	solifenacin	fesoterodine	Admitted to 3 north and error found by pharmacist completing med rec. solifenacin stopped and fesoterodine recommenced	Patient Incidents	Medications/Fluids	Prescribing Processes	Incorrect medication/fluid	Minor	insignificant	insignificant	possible	low
15/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	PATIENT WAS PERSCRIBED LONGTEC 5MG FOR #ANKLE PAIN IN ED. STAFF WERE UNABLE TO ADMINISTER THIS TO PATIENT AS THERE WAS NONE AVAILABLE IN THE DEPARTMENT. LAST DOSE OF LONGTEC WAS ADMINISTERED BY THE DAY STAFF TO ANOTHER PATIENT AT 11.30 THAT MORNING AS PER THE BOOK .	Oxycodone		SR INFORMED- NIL ADVISED. SHORTEC GIVEN TO PATIENT IN ED INSTEAD. ASKED THE WARD IF IT CAN BE GIVEN WHEN HE GOES TO THE WARD. WARD HAPPY TO DO THIS. PATIENT INFORMED.	Patient Incidents	Medications/Fluids	Administration to Patient	Failure to administer	Insignificant	insignificant	minor	possible	low
05/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	morning medications were omitted by myself by accident. medications omitted include: aspirin 75mg, omeprazole 40mg, pabrinex 2 pairs, Librium 30mg.	Pabrinex IM/IV	Pabrinex IM/IV	first realized medications were omitted at 14.00. Informed medical doctor and nurse in charge and had relevant medications prescribed as stat dose and gave 14.00 medications as prescribed. patient also informed	Patient Incidents	Medications/Fluids	Administration to Patient	Failure to administer	Minor	insignificant	minor	possible	low
02/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	2 North Respiratory	Patient only received 4 applications of a possible 12 applications of DAKTACORT CREAM staff made aware that it was stored in fridge but have continued to mark kardex as drug unavailable yet 6 tubes were available and kardex marked "FRIDGE"	Daktacort	Daktacort	Again mentioned to staff that cream was available in FRIDGE.	Patient Incidents	Medications/Fluids	Administration to Patient	Failure to administer	Minor	minor	minor	possible	low
15/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Emergency Department DHH	IV FLUIDS-1 LITRE OF HARTMANS INFUSING AT INCORRECT RATE, RUNNING AT 125 MLS PER HOUR BUT SHOLDVE BEEN 167 MLS PER HOUR.	Sodium Lactate, Compound	HARTMANS	AJUSTED TO CORRECT RATE	Patient Incidents	Medications/Fluids	Administration to Patient	Incorrect rate of administration	Insignificant	insignificant	minor	possible	low
14/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	PATIENT RECVEIVED DOSE OF PARACETAMOL 1G IV AT 06.30 AND 08.00 ON 14/4/2019. FIRST DOSE ADMINISTERED FROM ED FLIMSY AND SECOND DOSE ADMINISTERED FROM DRUG KARDEX.	Paracetamol	Paracetamol	MEDICAL DOCOTOR INFORMED - NO FURTHER PARACETAMOL TO BE GIVEN TODAY	Patient Incidents	Medications/Fluids	Administration to Patient	Incorrect frequency of dose (extra dose )	Insignificant	insignificant	minor	possible	low

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14/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Pharmacy Dispensary	Patient was seen by MO, fit for discharge. There were changes to her medications. She used a Medidose and required it to be renewed. With some Persuasion Pharmacy agreed to dispense her meds in a new Medidose. The letter was written and the drug Kardex sent to pharmacy around lunch time. Around 4.30 pm her family arrived to take her home. Pharmacy were rang but they did not answer the phone. Without being able to contact the Pharmacy Department I then rang the on call Pharmacist Richard. He was unable to contact them either. At 18.40 after several phone calls Richard agreed to Phone Maria McNally who had been on duty earlier. She stated the Meds had been dispensed. I sent staff around the hospital trying to find the medication, without result. Richard later came in around 19:30 and found the meds in Pharmacy.			Pharmacist on Call rang when unable to contact Pharmacy Department. Bed Manager informed. Porters asked who delivered the Pharmacy. Family kept informed	Patient Incidents	Medication/Biologicals/Fluids	Delivery Processes	Delayed delivery to unit/ward	Minor	minor	minor	possible	low
24/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	Emergency Department CAH	PATIENT ON CRITICAL MEDS OUT OF HOURS PHARMACY CONTACTED AND MEDICATIONS PERSCRIBED STAT. AT 3AM PATIENT DISCLOSED THAT HE THINKS HIS NEICE GAVE HIM HIS TABLETS ? 6TABS ? SAME MEDICATION	Lithium	Lithium	SPOKE WITH PATIENT SENIOR DOCTOR AWARE MDICAL DR INFOMED HOURLY OBSERVATIONS	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Unauthorized self-medication	Insignificant	minor	minor	possible	low
09/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Emergency Department DHH	Patient given Apixiban by staff but daughter had already given patient her dose for this evening and didn't tell staff.	apixiban	apixiban	daughter contacted. Informed of risks associated with bleeding. consultant aware. no action required.	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Unauthorized self-medication	Insignificant	insignificant	minor	possible	low
26/04/2019	Acute Services	Medicine and Unscheduled Care	Craigavon Area Hospital	1 North Cardiology	Patient discharged from 1 North CAH to Crozier House Intermediate Care facility on Fri 26/4/19. When discharge medication along with letter was being checked on admission a Senior Care Worker noticed that some of the medication in the bag didn't have any labels with the patients name or directions for use on them and others did. There were 6 boxes of medications without a label. These include: Atorvastatin 40mg, Bisoprolol 1.25mg , Folic Acid 5mg, Bumetanide 1mg, Pivemcillinam 200mg and Warfarin 1mg. All of the above medication was on the discharge letter. (JAC Pharmacy system - labels generated for 10 items including these 6 medicines on 26/4/19, indicating that these unlabelled medicines were ward stock that had been supplied on discharge from the bedside locker)	Bisoprolol	Bisoprolol	Informed pharmacy on the next working day and unlabelled medication removed.	Patient Incidents	Medication/Biologicals/Fluids	Other Medication/Biologicals/Fluids Incident	Other medication/biologicals/fluids incident	Insignificant	insignificant	insignificant	possible	low

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25/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Pharmacy Dispensary	no pharmacist cover in the emergency department on 25/04/19 23 trolley waits			pharmacy contacted no cover available delay in patients receiving critical medications	Organisational Incidents	Service Disruptions (environment, infrastructure, human resources)	Service Provision Insufficiencies/Failures/closures							not a medication incident asked to resubmit for any omitted/delayed doses
15/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Female Medical	Patient transferred to Cath lab from Female Medical, DHH without a nursing handover and/or transfer sheet, Nursing notes and Medicine kardex.			Registrar A contacted by Dr M as ward was not answering phone, medication list advise given over the phone. Ward was then contacted to send kardex and nursing notes. This still had not happened by 1700hours. Ward contacted again to email kardex to ward manager of cath lab so new one could be re-issued.	Patient Incidents	Communication	Between Different Teams	Omission of important facts	Minor					Kardex unavailable
09/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Female Medical	Patient transferred from DHH to Cath lab for a TOE. no nursing notes including kardex transferred with patient. Medications due when Patient in cathlab care. This was not handed over or documented.			When first noted, DHH hospital contacted to confirm that the kardex was still on female medical ward and asked what medications were prescribed. Nurse in charge informed, Sr W informed. Dr bleeped on [redacted] to rewrite kardex.	Patient Incidents	Documentation	Other Documentation Incident	Other documentation incident	Moderate					Kardex unavailable
11/04/2019	Acute Services	Medicine and Unscheduled Care	Daisy Hill Hospital	Emergency Department DHH	Strip of Lyrica 25mg (with 2 tablets missing, therefore 12 tablets remaining) found beside computer in Minors area of ED in brown envelope with "ED" written on same.	pregabalin	lyrica	Reported to Sr. in charge and ED manager. ED pharmacist bleeped and informed of same. Drugs locked away in Control Drug cupboard by 2 members of staff. Datix submitted.	Organisational Incidents	Medications/Biology/Fluids	Storage Processes (in pharmacy or on unit)	Non secure storage of controlled substances	Minor					controlled drugs

ID	Incident date	Directorate	Division	Site	Loc (Exact)	Description	Drug administered	Correct drug	Action taken	Incident affecting	Incident type tier one	Incident type tier two	Incident type tier three	Consequence	Impact	Likelihood	Severity	Risk rating
	28/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	4 North	Patient arrived to emergency theatre. Upon check-in it was noted that the insulin protocol had been started and running at ward level, however both the fluids and the actrapid had been removed from their pumps and patient transported to theatre with item placed on her bed. Actrapid syringe was attached to patients IV line, not in a pump and not clamped off. This posed a potential risk that some of the insulin could have been administered accidentally in transit and not under any controls.	Insulins		4 North. Syringe immediately clamped off and nurse accompanying patient was informed that this was not appropriate and potentially dangerous. Explanation given by ward staff member that it was done as the new hospital beds did not have drip stands. I informed nurse that in future the pumps could be set onto the patients bed or pushed behind the bed on a standard drip stand. BM to be checked in theatre.	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect rate of administration	Moderate	insignificant	major	possible	high
	26/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	Patient prescribed Enoxaparin BD Missed dose on 26.04.19 at 10am Missed dose on 27.04.19 at 10am Patient was in recovery ward on 26.04.19	Enoxaparin	Enoxaparin	Night duty staff escalated to doctor on 27.04.19 Nil ordered	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Minor	insignificant	major	unlikely	high
	24/04/2019	Acute Services	Surgery and Elective Care	Daisy Hill Hospital	Female Surgical/Gynaecology	Patient had her 10am dose clexane 40mgs which was increased after ward round to 120mgs in view of patients weight. Patient was prescribed stat dose of clexane 80mgs which I missed...forgotten about until noted at 5pm medicine round due to business of bay	Enoxaparin	clexane	Dr looking after patient informed, dose to be omitted as due again 10pm	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Failure to administer	Insignificant	insignificant	major	possible	high
	10/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	Medication omitted on 2 mornings which should have been given as same prescribed. Medication was a critical medication.	Dabigatran	Dabigatran	Pharmacist on ward notified, patient notified, nil ordered. Apology given to patient. Nursing notes updated. Nurse in charge notified. Datex completed.	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Failure to administer	Minor	insignificant	major	unlikely	high
	25/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	Theatres 1-4 CAH	Drugs stored in anaesthetic trolley by mistake (Amoxicillin & Thiopentone), resulting in potential confusion and drug mismatch due to lookalike packaging (with FLucloxacillin), see photos attached. List of drug that are required in ATICS SHSCT drug trolley is tightly regulated and this is a near miss (no incident happened)	Thiopental	Flucloxacillin	Amoxicillin and Thiopentone removed from the trolley, education to staff.	Patient Incidents	Anaesthesia Care	Other Anaesthetic Incident	Other anaesthetic incident	Minor	insignificant	major	possible	high
	05/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	4 North	Patient reviewed surgically in ED and started by surgical doctor J McConville on ibuprofen orally. (Patient was on rivaroxaban also).	Ibuprofen	rivaroxaban	Discovered when pt returned to ED a few days later,(no bleed), and IR1 completed.	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Process	Contraindication due to interactions with other medications	Minor	minor	major	possible	high

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21/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	Trauma Ward	<p>Phone call to DN team from CAH Trauma ward on 20-04-2019 requesting DN to administer twice daily clexane and 4pm insulin. Advised there was no twilight cover 20-04-2019 and referral could not be accepted until 21-04-2019. Trauma ward phoned back to say that they had assessed Patient and that he was independent with both administration of clexane and insulin and that there was no need for any DN referral. DN called morning of 21-04-2019 just to check that patient was getting on OK at home with his medications. This patient has a diagnosis of metastatic breast cancer. On arrival to the house this morning patient disclosed that he forgot to take his claxane last night as he was tired and had fallen asleep, just having been discharged from hospital. I asked patient if it was OK if I observed him self administration cleaxne. He agreed that was OK. It quickly became apparent that in fact patient is unable to safely administer dose of clexane. Hand dexterity is problematic. Also, more importantly the dose is 90mg. The clexane comes in 1ml syringes and requires the administrator to adjust the dose by expelling the correct amount in order to achieve the correct dose prescribed. Patient was unable to read the small print numbers and would be unable to self administer same. DN team will also continue to support Patient with insulin administration daily at 4pm as dose has been significantly reduced due to recent hypo and due to patient vagueness at times potential risk of insulin not being correctly.</p>	Enoxaparin		<p>Spoke at length with Patient. Patient agreeable that he unable to manage clexane and insulin independently and that he needs assistance. Patient happy for DN team to help. There is twilight cover for the nighttime clexane up to and including 01-05-2019. Twilight referral made for the night time clexane.</p>	Patient Incidents	Medications/Fluids	Administration to Patient	Inappropriate/incorrect Self Administration	Insignificant	Insignificant	major	possible	high
25/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	CEAW	<p>ward contacted by patient who had been discharged with chloramphenicol 5, ear drops which he had administered to eye, patient should have had 0.5% eye drops (Ear drops 5% were clearly prescribed on discharge prescription, ear drops were dispensed and labelled to instill into the affected ear)</p>	chloramphenicol	<p>Dr contacted, bed manager contacted- advice return to A+E Patients partner spoken to on phone as patient had gone to bed-eye had been well washed many times with water pain relief given stated patient not keen to return to A+E at present but will return if symptoms worsen advised to dispose of ear drops and not to use again- will get script for eye drops from GP</p>	Patient Incidents	Medications/Fluids	Prescribing Processes	Incorrect route	Minor	minor	moderate	possible	medium	

04/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	<p>bank staff nurse on duty 3 south 3-4/4/19 concerns</p> <p>issue 1: Patient [redacted] did not receive critical medicine epilim 200mg/5ml reason on kardex patient refused.</p> <p>issue 2: patient [redacted] Fasting for theatre (IVF prescribed and not erected overnight) Patients enoxaparin 20mg was to be omitted and crossed out on kardex. (staff gave and signed for this)</p> <p>issue 3 [redacted] Patient had an occluded airway, De-saturating, large mucus plug removed from airway this morning. care overnight by SN (NO Tracheostomy suction record completed (that can be found)6 am nebulizer's not given (as per kardex)no documentation about patients airway management.</p>	Enoxaparin		<p>Following am handover I was made aware that [redacted] did not receive critical meds. I spoke with Sn Topsy and was informed that patient was agitated. I discussed other options ie iv/pr meds and whom she had escalated this problem to. No escalation of management of same done overnight.</p> <p>regarding suctioning of [redacted] I have been informed in handover that SN topsy stated no suction required.</p> <p>the other 2 issues have been highlighted to me by SN taking over patients care this am so I have not addressed these with SN Topsy.</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Contraindication due to medical condition	Minor	insignificant	moderate	possible	medium
19/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	<p>Infection control reviewed patients kardex on ward level and there was no signature for Vancomycin 125mg on the 18/4/19 @06:00, 22:00 and 06:00 on the 19/4/19</p>	Vancomycin	Vancomycin	<p>FY1 aware stat doses prescribed Sister in Charge informed</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Administered but drug chart not signed	Insignificant	insignificant	moderate	possible	medium
20/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	<p>Patient missed a dose of Vancomycin on the 20/4/19 @2200hrs</p>	Vancomycin	Vancomycin	<p>Sister in charge informed</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Insignificant	insignificant	moderate	possible	medium
28/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	<p>S/N CC approached me this morning (29/4/19) to say that patient [redacted] did not have her Tegretol 200mg signed for yesterday morning 28/04/2019</p>	Carbamazepine	Tegretol	<p>checked patients kardex, all other medications have been signed for. Checked patients notes to see who was looking after patient 28/4/19 and will speak with S/N involved. No harm came to patient.</p>	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Incorrect frequency of dose (omitted dose)	Insignificant	insignificant	moderate	possible	medium

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11/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	CEAW	On Thursday 11/4/19 I noticed Pt was prescribed enoxaparin 40mg nocte as VTE prophylaxis. Her eGFR was < 30 but there was no weight. I discussed the need to reduce to 20mg nocte if the patient was between 50-100kg with the ward doctor and requested he ensure the review of this medication when the nurse weighed the patient. There was concern that the pt was not steady enough to stand on the scales but the nurse said she would attempt with another nurse. The ward doctor was aware and I documented in the notes that I had requested he review this medication. I return to the ward on Monday 15/4/19 and neither the ward doctor or medical team have reviewed the enoxaparin despite me having documented in the medical notes and on the kardex the need to review this medication. A weight was obtained on the 11/4/19 and documented on the front of the kardex.	Enoxaparin		The pts eGFR has now risen over 30 from 13/4/19. Note made in medical notes to keep eGFR and enox under review. Above discussed with ward doctor.	Patient Incidents	Medication/Bloods/Fluids	Prescribing Processes	Incorrect dose	Minor	insignificant	minor	possible	low
09/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	4 South	When administering morning medications noticed Ramipril 15mg was prescribed. Discussed with patient and discovered Lisinipril was meant to be prescribed. same not administered and doctors made aware to review medications	Ramipril	Lisinopril	Ward sister aware of same. admitting ward made aware of same apparently medication was not prescribed at this time as patient had gone to theatre first on list spoke to fy1 unable to ascertain where drug prescribed /? in theatre or recovery unable to locate prescribing doctor as no bleep number on kardex and signature hard to decipher	Patient Incidents	Medication/Bloods/Fluids	Prescribing Processes	Incorrect medication/fluid	Minor	insignificant	minor	possible	low
24/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	Trauma Ward	Patient was admitted to the trauma ward on 19/4/19, the patient was prescribed tramadol 100mg BD. The patient takes Maxitram SR 100mg BD at home.	Tramadol	Tramadol MR	Pharmacist informed, Maxitram SR 100mg prescribed, nurse in charge informed, patient informed	Patient Incidents	Medication/Bloods/Fluids	Prescribing Processes	Incorrect formulation	Insignificant	insignificant	minor	possible	low
12/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	stat dose of Paracetamol administered and then patient also received regular Paracetamol at 1800hrs with only 2hr20 from stat dose.	Paracetamol		patient and nurse in charge informed	Patient Incidents	Medication/Bloods/Fluids	Administration to Patient	Incorrect frequency of dose (extra dose)	Insignificant	insignificant	minor	possible	low

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23/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	4 South	<p>Patient's potassium on 23/4 low at 3.3. Sando-K prescribed at dose of TT BD. Not written correctly on kardex and two doses missed before mistake noticed. Start date was 23/04/19 but boxed off on kardex from 19/04 PM to 21/4/19.                  (Potassium on 24/4/19 came back at 3.7 and so Sando-K discontinued anyway).                  (Further information: They had put the start date as 23/4 and put lines after the 3 days of treatment on the kardex as normal. However, they hadn't read the dates already written at the top of the kardex columns which started at the 19/4 and so the lines through the boxes on the kardex started from the 22/4 even though treatment should have began on 23/4)</p>	Potassium Chloride		Spoke to FY1. As potassium was back within normal range, they were happy to discontinue the Sando-K anyway.	Patient Incidents	Medication/Biology/Fluids	Prescribing Processes	Incorrect duration of treatment	Minor	minor	minor	possible	low
20/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	CEAW	<p>When we were carrying out medications of patient A we went to check a CD drug, the entry and count of the drug was incorrect (the drug was Plexia 100mg sr.)                  Upon reading back through the entries it was noticeable that there was an entry missing and an entry incorrect which was giving the wrong count of tablets.</p>	tapentadol		bed manger informed- Paula MC Cann Pharmacist informed Claire Murphy	Patient Incidents	Documentation	Controlled drug registers	Ambiguous/incorrect/incomplete	Minor	controlled drugs			
08/04/2019	Acute Services	Surgery and Elective Care	Craigavon Area Hospital	3 South	<p>tapentadol 50mg ordered from pharmacy. 3 tablets in stock in controlled drug cupboard. 10 tablets were ordered and collected from pharmacy. When signing the medication into the controlled drug book it was recorded as 15 tablets received by two registered nurses which brought the total to 18. At handover from day to night staff, drugs were checked and no discrepancies noted. When signing the drug out for a patient it was noticed there was only 13 tablets.</p>	tapentadol	palexia	When noticed, contacted sister in charge of day shift who informed the ward manager. Noticed at this time that only 10 tablets were dispensed from pharmacy therefore this was the reason for the wrong amount of medication recorded in CD book.	Patient Incidents	Documentation	Controlled drug registers	Controlled drug (CD) record keeping error	Insignificant	controlled drugs			

ID	Incident date	Directorate	Division	Site	Loc (Exact)	Description	Drug administered	Correct drug	Action taken	Incident affecting	Incident type tier one	Incident type tier two	Incident type tier three	Consequence	Impact	Likelihood	Severity	Risk rating
Personal information redacted by the USI	25/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	1 East Maternity/Gynaecology	pt rash/urticaria with amoxicillin co-amoxiclav in 2005 and 2009 confirmed with gp. On niecr as allergic to these but s/e not recorded. Pt states she doesn't take penicillin. on allergy status on kardex states patient has had pen allergy but has previously had penicillin?	Amoxicillin		kardex review by dr amoxicillin stopped pt had only 1 dose	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Contraindication due to history of allergy	Insignificant	insignificant	catastrophic	possible	extreme
	25/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	1 East Maternity/Gynaecology	Pt prescribed tazocin allergic to penicillin on kardex not on niecr received one dose of tazocin .Patient doesn't take penicillin as says it causes a rash. Antibiotics changed by dr.	Tazocin		antibiotic changed	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Contraindication due to history of allergy	Insignificant	insignificant	catastrophic	possible	extreme
	10/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	1 East Maternity/Gynaecology	AT THE BEGINNING OF MY AFTERNOON WARD ROUND I WITNESSED THAT THE PATIENTS INSULIN (Lantus), A CRITICAL MEDICATION, HAD NOT BEEN SIGNED AS ADMINISTERED THAT MORNING. I QUESTIONED THIS WITH THE STAFF ON DUTY AS IT HAD BEEN DOCUMENTED IN THE NURSING NOTES THAT IT HAD IN FACT BEEN ADMINISTERED. FOR MY OWN REASSURANCE I CONTACTED THE STAFF NURSE WHO HAD BEEN WORKING THERE AND SHE ADVISED IN FACT IT HAD NOT BEEN GIVEN. I ALSO CONTACTED THE STUDENT NURSE WHO HAD WRITTEN IN THE NOTES AND SHE WAS ABLE TO CONFIRM IT HAD NOT BEEN GIVEN.	Insulins		I SPOKE WITH DOCTOR WHO ADVISED TO GIVE INSULIN AT THIS TIME AS IT IS A CRITICAL MEDICATION	Patient Incidents	Medication/Biologicals/Fluids	Administration to Patient	Failure to administer	Minor	insignificant	moderate	possible	medium
	25/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	1 East Maternity/Gynaecology	pt was to be restarted on 24/04 rivaroxaban 15mg od but started on rivaroxaban 15mg bd patient did not receive bd dose as picked up on ward whilst reviewing on the morning of 25/04 bisoprolol 7.5mg also missing from kardex.	rivaroxaban		kardex amended to od rivaroxaban as per medical team bisoprolol prescribed by medical team	Patient Incidents	Medication/Biologicals/Fluids	Prescribing Process	Incorrect frequency of dose		insignificant	moderate	possible	medium

Personal information released by the USI

05/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	Haematology Clinic	Patient with EBV + LPD/Hodgkins Disease, prescribed Gemcitabine chemotherapy C3D15 for 05/04/19 with HB 63,Plt 46, WBC 2.4, ANC 1.3. Got 2 units RBC on 04/04/19 but no follow up bloods ordered.	Gemcitabine	Gemcitabine	Spoke to prescribing consultant and expressed my concern with the patients blood counts, in particular her PLT count. He was happy to treat as it was only single agent gemcitabine. Having already spoken to the patients nurse who had administered the blood and said she was very sleepy and not in great condition, I requested that he have repeat bloods taken before the treatment was made up. He agreed if that was what I wanted. SN brought patient up for bloods and HB85, PLT 34, ANC 1.37. I contacted the consultant again and he agreed to defer treatment.	Patient Incidents	Medication/Bloods/Fluids	Prescribing Processes	Contraindication due to medical condition	insignificant	moderate	possible	medium
05/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	Antenatal Clinic	medicine fridge has repeatedly been reported on estates and in march was reported on medical equipment repair forum. fridge is reading high and insulin needs stored in same.			re referred on request platform and Ruth McCauley telephoned but not in office. Michelle Portis Aware.	Organizational Incidents	Medication/Bloods/Fluids	Storage Processes (in pharmacy or on unit)	Refrigeration failure	Insignificant	insignificant	minor	possible low
07/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	2 West Maternity Post Natal	Infant in 2West missed dose of gentamicin due to work load of Paeds SHO. Antibiotic was due at 2000 on 7/4 but was not given until night SHO realized it was missed at 0600. Parents of baby have been notified of error and antibiotics was given as soon as error was realized. No harm has come to child but if baby had been more unwell this may have been very important.	Gentamicin	Gentamicin	I have explained to parents the error and informed consultant Dr Hogan.	Patient Incidents	Medication/Bloods/Fluids	Prescribing Processes	Medication not prescribed	Insignificant	insignificant	minor	possible low
18/04/2019	Acute Services	IMWH - Cancer and Clinical Services	Craigavon Area Hospital	1 East Maternity/Gynaecology	Patient on gynae ward had been in recovery ward for a number of days 15-17/04 then gynae from the night 17/04 written up for longtec 5-10mg bd in regular section by anaesthetist. Doses given in both wards, gynae ward stated dose but not recovery. Also jentadueto prescribed which pharmacy do not stock contains two separate meds which should be prescribed separately if patient does not have their own pods.this had been given in recovery even though patient did not have their own supply but once in gynae rewritten as separate meds.	Oxycodone		Rewrote Kardex with set dose of longtec not a range , spoke to gynae sister and recovery sister. Anaesthetist not on site at present will contact when on site.	Patient Incidents	Medication/Bloods/Fluids	Prescribing Processes	Incorrect dose	insignificant	minor	possible low	

ID	Incident date	Directorate	Division	Site	Loc (Exact)	Description	Drug administered	Correct drug	Action taken	Incident affecting	Incident type tier one	Incident type tier two	Incident type tier three	Consequence	Impact	Likelihood	Severity	Risk rating
Personal information redacted by the USI	03/04/2019	Acute Services	Pharmacy	Daisy Hill Hospital	Pharmacy Dispensary	AC@HT Rx for several items was presented to Pharmacy for dispensing. All items dispensed except the Enoxaparin inj. Missed at labelling, dispensing & final check. Discovered the following day by AC@HT pharmacist.	Enoxaparin	Enoxaparin	Continued need for Enoxaparin confirmed with Dr (only 3 days rather than original 5) by AC@HT pharmacist. These were dispensed using the original Rx.	Patient Incidents	Medications/Fluids	Preparation/Formulation Processes	Omitted Ingredient	Minor	insignificant	major	unlikely	high
	08/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Pharmacy Aseptic Unit	when dispensing prednisolone tablets at oral chemo scripts in pharmacy cah I discovered there was 25mg tablets in a 5mg pack	Prednisolone		took the 25mg tablets out and check bn and expiry date and put them into correct pack from shelf. I alerted eh rest of the technician team and my line manager	Patient Incidents	Medications/Fluids	Dispensing Processes	Incorrect dose	insignificant	moderate	possible	medium	
	30/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Bronte Ward	A supply of clozapine 25mg, for a named patient, was found in the non stock drawer on Bronte. inside the skilnet labeled Clozapine 25mg was a strip containing 12 clozapine 25 mg and 2 strips containing a total of 13 clozapine 100mg. (this patient is still an in patient on bronte ward they have not left . The reason we have labelled stock is that he transferred from Rosebrook ( Their clozapine is named patient and labelled and supply made in line with bloods- due to them not having a pharmacist ) to Bronte ward. In bronte ward we keep stock of 25mg and 100mg tablets. As the box in question was stored in the non stock and not currently in use we have no way of knowing what patient may have been affected ( there have been 4 patients on clozapine during that time) and if they were affected or if the 100mg were stuffed into the 25mg box since being put back into non stock. )	Clozapine	Clozapine	The skilnet was removed from the non stock drawer, the pharmacist was informed and a Datix was filled in. A staff nurse was also informed. The pharmacist checked the blood results from the patient that was named on the skilnet to see if any harm had come to the patient in question.	Patient Incidents	Medications/Fluids	Storage Processes (in pharmacy or on unit)	Incorrect storage environment	insignificant	moderate	possible	medium	
	05/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Pharmacy Aseptic Unit	Lenalidomide 25mg OD day 1-21 prescribed, calculation using Cockcroft and Gault determined patient's renal function to be 46.6ml/min. As per chart when renal function <50ml/min 10mg OD is recommended.	lenalidomide	lenalidomide	I contacted prescriber Returned chart Dose and electronic prescription authorisation form (ePaf) amended Lenalidomide 10mg OD dispensed Mandeville contacted to make patient aware when relative came to collect medication that dose was changed.	Patient Incidents	Medications/Fluids	Prescribing Processes	Incorrect dose	insignificant	moderate	possible	medium	

16/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Pharmacy Dispensary	Final checking ACAH prescription. Daptomycin had no fridge labels on containers or in tray. ACAH team contacted dispensary to check if prescription had been refrigerated prior to transport to South Tyrone. Advised that it hadn't.	Daptomycin		ACAH contacted MI to seek advice if could still be used which it could.	Patient Incidents	Medication/Biologicals/Fluids	Storage Processes (in pharmacy or unit)	Medication stored at wrong temperature	Minor	insignificant	minor	possible	low
24/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Pharmacy Dispensary	New ongoing script sent to pharmacy to be dispensed, dosing times had changed and I made a note of original time on script ward, I contacted the ward to verify time change but I forgot to remove one of the times and as a result patient received Quetiapine M/R TID instead of BD. When script was being prepared on 01/05/2019 checker noticed difference between script and kardex and asked me to clarify. I realised my error and contacted Bluestone pharmacist for advice. She spoke to patient's Consultant who had seen her this week and said patient was ok but to reduce back to twice a day. No harm came to patient	Quetiapine	Quetiapine	Patient's Consultant made aware of error	Patient Incidents	Medication/Biologicals/Fluids	Dispensing Processes	Incorrect frequency		insignificant	minor	possible	low
26/04/2019	Acute Services	Pharmacy	Daisy Hill Hospital	Pharmacy Dispensary	A prescription for Bisoprolol was labelled with the correct strength (1.25mg) but Bisoprolol 2.5mg was dispensed. The same person had both labelled and dispensed the item.	Bisoprolol	Bisoprolol	This was detected at the final check. The member of staff was informed and the correct strength dispensed.	Patient Incidents	Medication/Biologicals/Fluids	Dispensing Processes	Incorrect dose	Minor	insignificant	minor	possible	low
03/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Pharmacy Aseptic Unit	the wrong drug strength was dispensed. Ondansetron 8mg dispensed instead of ondansetron 4mg tablets.	Ondansetron	Ondansetron	prescription was taken back and the correct strength was dispensed.	Patient Incidents	Medication/Biologicals/Fluids	Dispensing Processes	Incorrect dose		insignificant	insignificant	possible	low
08/04/2019	Acute Services	Pharmacy	Craigavon Area Hospital	Pharmacy Dispensary	Patient brought POD into hospital (ward 2 south stroke) of Captopril 12.5mg (along with other meds). Captopril POD was issued by community pharmacy on 22/3/19 but the contents expired 31/3/19.	Captopril		Spoke to the patient and explained to him as well as contacting the community pharmacy and highlighting this to them. Also informed the ward Pharmacist.	Patient Incidents	Medication/Biologicals/Fluids	Dispensing Processes	Expired product	Insignificant	community pharmacy			

**Southern Health & Social Care Trust****Summary of All Staff with Acute Directorate by Division including % of Staff trained as at 31st March 2019**

Prepared by/HR Contact: Andrea Sergeant/Louise Rainey

Date: 30/5/2019

**Notes**

Pure Bank Staff have been separated from main figures.

Key: % Trained	
0% - 59%	
60% - 79%	
80% - 100%	

Information Governance					
Directorate	Division	Not Trained	Trained	Head Count	% Trained
Acute Services	ATICS & Surgery & Elective Division	182	773	955	81%
	Director's Office	1	1	2	50%
	Functional Support Services Division	244	766	1010	76%
	IM&WH and Cancer & Clinical Services Division	174	856	1030	83%
	Medicine & Unscheduled Care Division	276	724	1000	72%
	Pharmacy Division	49	146	195	75%
<b>Acute Services Total</b>		<b>926</b>	<b>3266</b>	<b>4192</b>	<b>78%</b>

Safeguarding					
Directorate	Division	Not Trained	Trained	Head Count	% Trained
Acute Services	ATICS & Surgery & Elective Division	246	709	955	74%
	Director's Office		2	2	100%
	Functional Support Services Division	192	818	1010	81%
	IM&WH and Cancer & Clinical Services Division	183	847	1030	82%
	Medicine & Unscheduled Care Division	285	715	1000	72%
	Pharmacy Division	4	191	195	98%
<b>Acute Services Total</b>		<b>910</b>	<b>3282</b>	<b>4192</b>	<b>78%</b>

Manual Handling					
Directorate	Division	Not Trained	Trained	Head Count	% Trained
Acute Services	ATICS & Surgery & Elective Division	354	601	955	63%
	Director's Office		2	2	100%
	Functional Support Services Division	429	581	1010	58%
	IM&WH and Cancer & Clinical Services Division	333	697	1030	68%
	Medicine & Unscheduled Care Division	444	556	1000	56%
	Pharmacy Division	25	170	195	87%
<b>Acute Services Total</b>		<b>1585</b>	<b>2607</b>	<b>4192</b>	<b>62%</b>

Fire Safety					
Directorate	Division	Not Trained	Trained	Head Count	% Trained
Acute Services	ATICS & Surgery & Elective Division	484	471	955	49%
	Director's Office	1	1	2	50%
	Functional Support Services Division	394	616	1010	61%
	IM&WH and Cancer & Clinical Services Division	331	699	1030	68%
	Medicine & Unscheduled Care Division	491	509	1000	51%
	Pharmacy Division	50	145	195	74%
<b>Acute Services Total</b>		<b>1751</b>	<b>2441</b>	<b>4192</b>	<b>58%</b>

**Infection Prevention & Control**

Directorate	Division	Not Trained	Trained	Head Count	% Trained
Acute Services	ATICS & Surgery & Elective Division	459	496	955	52%
	Director's Office	1	1	2	50%
	Functional Support Services Division	303	622	925	67%
	IM&WH and Cancer & Clinical Services Division	302	728	1030	71%
	Medicine & Unscheduled Care Division	560	440	1000	44%
	Pharmacy Division	48	147	195	75%
<b>Acute Services Total</b>		<b>1673</b>	<b>2434</b>	<b>4107</b>	<b>59%</b>

**Equality e-learning**

Directorate	Division	Not Trained	Trained	Head Count	% Trained
Acute Services	ATICS & Surgery & Elective Division	852	103	955	11%
	Director's Office	2		2	0%
	Functional Support Services Division	860	150	1010	15%
	IM&WH and Cancer & Clinical Services Division	835	195	1030	19%
	Medicine & Unscheduled Care Division	917	83	1000	8%
	Pharmacy Division	153	42	195	22%
<b>Acute Services Total</b>		<b>3619</b>	<b>573</b>	<b>4192</b>	<b>14%</b>

**Corporate Induction**

Directorate	Division	Not Trained	Trained	Head Count	% Trained
Acute Services	ATICS & Surgery & Elective Division	47	18	65	28%
	Functional Support Services Division	68	13	81	16%
	IM&WH and Cancer & Clinical Services Division	35	19	54	35%
	Medicine & Unscheduled Care Division	76	16	92	17%
	Pharmacy Division	11	4	15	27%
<b>Acute Services Total</b>		<b>237</b>	<b>70</b>	<b>307</b>	<b>23%</b>

**Departmental Induction**

Directorate	Division	Not Trained	Trained	Head Count	% Trained
Acute Services	ATICS & Surgery & Elective Division	65		65	0%
	Functional Support Services Division	79	2	81	2%
	IM&WH and Cancer & Clinical Services Division	51	3	54	6%
	Medicine & Unscheduled Care Division	88	4	92	4%
	Pharmacy Division	15		15	0%
<b>Acute Services Total</b>		<b>298</b>	<b>9</b>	<b>307</b>	<b>3%</b>

**MAPA CH3, Level 3 & Level 4**

Directorate	Division	Not Trained	Trained	Head Count	% Trained
Acute Services	ATICS & Surgery & Elective Division	450	13	463	3%
	Functional Support Services Division	16	30	46	65%
	Medicine & Unscheduled Care Division	545	121	666	18%
<b>Acute Services Total</b>		<b>1011</b>	<b>164</b>	<b>1175</b>	<b>14%</b>

**Food Safety**

Directorate	Division	Not Trained	Trained	Head Count	% Trained
Acute Services	ATICS & Surgery & Elective Division	112	371	483	77%
	Functional Support Services Division	174	201	375	54%
	IM&WH and Cancer & Clinical Services Division	77	239	316	76%

	Medicine & Unscheduled Care Division	200	501	701	71%
<b>Acute Services Total</b>		<b>563</b>	<b>1312</b>	<b>1875</b>	<b>70%</b>

This report has been compiled and is intended for use only by the official recipient.

Due to the delay in receipt of, and occasional delays in processing and verification of, some New Start, Transfer/Amendment and Termination forms, the information contained in this report may not be completely up-to-date. In order to minimise this it is essential that New Start, Amendment/Transfer and Termination forms are completed and forwarded to the relevant department in a timely manner.

For staff on pay protection, the grade and pay scale information indicates the band that the person is currently protected on, not the actual post they are working in.

If you believe the information in this report does not accurately reflect the current position, please contact the Education, Learning and Development Department.

Please remember your responsibilities under data protection legislation, for example ensure personal information is kept secure (for example not left in view of unauthorised staff or visitors), is only used for the purpose intended, and is not shared with anyone who should not have access to it. Also, once personal information has been used for its intended purpose it should be appropriately destroyed, or kept in a secure location if it is required for future use.

## MUSC GOVERNANCE MEETING

Date: Friday 28 June 2019  
 Time: 2pm – 4pm  
 Venue: Meeting Room 1, Admin Floor, CAH with videolink to  
 Tutorial Room, DHH

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## AGENDA

<p><b>1.0</b></p>	<p>Welcome          Dr P Murphy, Dr Una Bradley, Mrs Anne McVey, Mrs Kay Carroll, Miss Catriona McGoldrick, Mrs Caroline Beattie, Mrs Patricia Loughan, Mrs Patricia Kingsnorth          Mrs Flo Fegan, Mrs Mary Haughey.</p> <p>Apologies:</p>
<p><b>2.0</b></p>	<p>Standards and Guidelines</p> <p><b>Caroline provided an overview of works in progress and to be undertaken.</b></p> <p><b>Valporate working group – 23 reps on the group. Dr McKnight lead, shared with PHA. Need to review MHR guidance. BSO legal requirements around prescribing needs to be reviewed.</b></p> <p><b>Autonomic dysreflexia – meeting held with lead nurses – draft guidance issued. Need for clarity around which staff need to be trained. Agreed coordinators will be trained. Recognised difficulty in maintaining skills. Catriona to take forward to Wendy McQuillan</b></p> <p><b>Appropriate use of saturation probes – ensure correct positioning of probes.</b></p> <p><b>Need to develop “End of use guidance” – requires consistency trustwide – date arranged for end of October. Melanie for sign off.</b></p> <p><b>Action plans for positive assurance has been shared.</b></p> <p><b>Management of life threatening bleeds.</b></p> <p><b>Hyperkalemia – Dr Sharpe leading on this. Needs primary care work.</b></p> <p><b>LVad – action plan completed. Will be put on resuscitation committee agenda, to be included in resuscitation policy.</b></p>

**Quarterly e proforma discussed at all heads of services meeting. 14 tabled for Tuesdays meeting. New policies – medical photography of services users – SOP linked for staff.**

**Head injury – working group – going to policy scrutiny in October. Post falls protocol needs to be completed before head injury policy can be signed off. The post falls meeting is 8<sup>th</sup> July. TILS training to be rolled out. Steering group will need to agree sign off of post falls protocol.**

**Line Labelling – integrated into nursing file maker tool. 97 patients audited only 1 non- compliance. 99% compliance for first audit.**



20190628\_Agenda -  
MUSC Divisional Meet

### 3.0

Minutes of previous meeting

**Absonding patient's policy should be adhered to. The southern trust policy is different from the regional guidance. We would need to adhere to the regional guidelines. There are additional elements in the Trust.**

- Review of previous minutes discussed for action points.
- Anne Mc Vey to liaise with Ronan Carroll re NICE NG 39 – Major trauma – assessment and initial management and NICE NG 40 – Major trauma service delivery. Re: spinal injuries and management of same.
- 
- Kay Carroll to update at next meeting re NICE CG 161 - The assessment and prevention of falls in older people. Need to liaise with Anita Carroll on how she would like this to be taken forward in Esther's absence. Paula Fearon has been seconded to assist with the implementation of falls pathway
- Louise Devlin advised Biologics to be put on risk register.- more IBD nurses, new suite for biologics.
- 
- Dr Moan advised telemetry has been on the risk register for years and stated that risk registers become irrelevant if nothing is being done about them.
- More telemetry available increased from 6 to 8 machines. Discussion took place about mobile telemetry machines which will be discussed outside of meeting. There is the availability for cardiologist to review ECGs via app off site.
- 



Minutes  
31082018.docx

<p><b>4.0</b></p>	<p>Complaints</p> <p><b>Complaints responses discussed at length, agreed to ensure that the response is only answering the complaint and remove extraneous information. Keep the terminology for general public. There is a need to complaints response to be shared with lead / HOS or consultant involved. Will be piloted in medicine – send to AD first before final draft. No response should be sent before being shared with senior staff involved.</b></p> <div style="text-align: center;">  <p>Current Complaints 24.06.19.xlsx</p> </div>
<p><b>5.0</b></p>	<p>Clinical Incidents</p> <div style="text-align: center;">  <p>Incident Review Position as at 18.06.1</p> </div> <p><b>The Liverpool hospital investigation was discussed in relation to management of clinical incidents. There is a need to generate a trigger list to ensure the appropriate incidents are being reported and investigated promptly. Suggest new registrars to work on trigger list.</b></p>
<p><b>6.0</b></p>	<p>SAI's /New/ongoing</p> <div style="text-align: center;">  <p>SAI update as at 25.06.19.xlsx</p> </div> <p><b>The review of governance structure is taking place as commissioned by the medical director- will this include operational clinicians, AMD and ADs? PK to check with Medical Director. The review of governance structure should include the clinicians/ ADs/ HOS for input.</b></p>
<p><b>7.0</b></p>	<p>Implementation of Learning from SAIs</p> <div style="text-align: center;">  <p>MUSC ED Summary and Recommendation</p> </div> <p><b>Summary of learning discussed. Ensure recommendations are appropriate, discussions re professional chairs. Shared learning needs to be shared with all M+M. Patricia K has agreed to forward reports to Sandra McLoughlin and Raymond Haffey to present to M+M leads. The minutes will then be shared with the governance team for closing the loop.</b></p>
<p><b>8.0</b></p>	<p>Risk Register, Directorate, Divisional and Corporate</p>

	 Directorate RR July19.xlsx  MUC Div.HOS.Team RR July19.xlsx <b>Risk registers discussed re: ward environment.</b> <b>Vivienne will come to a HOS meeting to update all the risk registers. Same to be set up.</b>
<b>9.0</b>	<b>A.O.B</b> <b>Anne- patients with tracheostomies are all cared for in 3 South. Is this the appropriate place to care for these patients? Needs to be some agreement, previous agreement for trachea patients, a meeting took place in November 2017 which agreed patients to go to 3 South. This is causing some resource issues for 3 South. Not suitable to go to DHH. They should go to a base ward, with input from the head and neck specialist nurses - need for agreement with directors and AMD/ CD/AD.</b>
	<b>Date and Time of Next Meeting:</b> Friday 30 August 2019 at 2pm Meeting Room 1, Admin Floor, CAH with videolink to Board Room, DHH

# MUSC DIVISIONAL GOVERNANCE MEETING

Date: Friday 28<sup>th</sup> June 2019  
 Time: 2pm (for review of Standards and Guidelines)  
 Venue: Meeting Room, Admin Floor, CAH

<p><b>1.0</b></p>	<p><b>Standards &amp; Guidelines Activity Report – new regionally endorsed guidance</b>  <i>(1<sup>st</sup> April 2019 – 31<sup>st</sup> May 2019)</i></p>	 20190501Standards and Guidelines Month   20190613 Standards and Guidelines Month
<p><b>2.0</b></p>	<p><b>Outstanding Change Leads:</b></p> <p><b>NICE NG 99</b> – Brain Tumours Primary and Brain Metastases in Adults</p> <p><b>NICE NG 115</b> – Chronic Obstructive Airways Disease</p> <p>Following 1:1 meeting with Mrs Kay Carroll on 24/06/2019 it was agreed that Dr John would take the lead on this guideline implementation with support from the wider MDT. To now be progressed.</p>	
<p><b>3.0</b></p>	<p><b>Key Priorities:</b></p> <p><b>Patient Safety Alerts</b></p> <ul style="list-style-type: none"> <li>➤ HSC (SQSD) 19/17 - <i>Resources to Support the Safety of Girls and Women Who Are Being Treated With Valproate</i> – regional PHA/HSCB meeting with SHSCT representation being held on 21 May 2019 (CCL – Dr Karen McKnight)</li> <li>➤ PL/2018/026 - Circular HSS (MD)19/18 - <i>Resources to support safer bowel care for patients at risk of Autonomic Dysreflexia</i></li> <li>➤ PL-2019-031 - Circular HSS HSC (SQSD) 38/18 - <i>Risk of harm from inappropriate placement of pulse oximeter probes</i> (CCL: Acute Equipment Steering Group) – response to the HSCB was due 18<sup>th</sup> June 2019</li> </ul>	 NEW Pan College guidance and the new   Patient_Safety_Alert_-_safer_care_for_px   Patient_Safety_Alert_-_Placement_of_oxi
<p><b>4.0</b></p>	<p><b>Submissions by Acute Services to Corporate Governance office for onward submission to the HSCB (from 1<sup>st</sup> April 2019 – 21<sup>st</sup> June 2019):</b></p> <ul style="list-style-type: none"> <li>➤ Positive Assurance May report to the HSCB  <i>(NICE guidelines / Technology Appraisals)</i></li> </ul>	 20190605_APPROVE D - NICE Positive Assi

- Safer Temporary Identification Criteria for Unknown or Unidentified
- Management of life threatening Bleeds
- Resources to support safe and timely management of hyperkalaemia

**Regional Learning Letters:**

- SQR-SAI-2019-049 (AS) Specific Cardiac Arrest Protocol for Patients fitting with Left Ventricular Assist Devices LVAD

  
20190605\_APPROVE  
D-SHSCT Response-S

  
20190513 -  
APPROVED - Acute A

  
20190508\_APPROVE  
D - Action Plan - Man

  
20190619\_APPROVE  
D SHSCT Action Plan

**5.0**

- **Quarterly E proforma report – NICE Guidelines Assurance position (April 2019)**
- **NICE Guideline E proformas submitted to HSCB (1 April 2019 to 31 May 2019)**

NICE CG 94 Unstable Angina (CCL: Dr M Moore)

  
20190510\_APPROVE  
D SHSCT Acute Sectic

NICE CG 137 Epilepsy (CCL: Cross Directorate working group led by Dr McKnight)

  
20190416  
APPROVED - SHSCT E

NICE CG 165 Hepatitis B (Chronic) (CCL: Dr Philip Murphy)

  
20190403\_APPROVE  
D - Section E NICE CC

NICE CG 186 Multiple Sclerosis (CCL: Dr Jamie Campbell)

  
20190403\_APPROVE  
D Section E NICE CG

NICE NG 3 Diabetes in Pregnancy ((CCL: Dr McConnell / Louise Devlin working with IMWH colleagues)

  
20190403\_APPROVE  
D Section E NICE NG



20190426\_MASTER  
Acute Services E prof

NICE NG 14 Melanoma (CCL: Dr A O'Hagan)



NICE NG 49 NAFLD (CCL: Dr Philip Murphy)



NICE NG 50 Cirrhosis in the over 16's (CCL: Dr Philip Murphy)



NICE NG 100 Rheumatoid Arthritis (CCL: Dr Maiden)



➤ **E proformas pending approval at Acute S&G forum (02/07/2019)**

- NICE CG 152 Crohn's Disease (CCL: Dr Bhat, Dr Murdock, Louise Devlin)
- NICE CG 162 Rehabilitation following stroke - Dr McCaffrey, Kathleen McGoldrick, Catherine Sheeran, Cathie McIlroy)
- NICE CG 166 Ulcerative Colitis (CCL: Dr Bhat, Dr Murdock, Louise Devlin)
- NICE CG 163 Idiopathic Pulmonary Fibrosis (Dr L Polley)
- NICE NG 56 Multi-morbidity (Dr McCaffrey)
- NICE NG 65 Spondyloarthritis (CCL: Dr Maiden)

<p><b>6.0</b></p>	<p><b>New Policy/Guidelines/Protocols</b></p> <p>Medical photography guideline - <a href="#">Medical Photography of Services Users</a></p>	 CG0605 Photography-of-Serv
<p><b>7.0</b></p>	<p><b>Update on Progress</b></p> <ul style="list-style-type: none"> <li>• NICE CG 176 - Head Injury Initial Diagnosis and Management</li> <li>• Regional Line Labelling Policy / RQIA audit tool</li> </ul>	 Trustwide May 19.pdf
<p><b>8.0</b></p>	<p><b>Any Other Business</b></p>	
<p><b>9.0</b></p>	<p><b>Date of next meeting:</b>                  Friday 25<sup>th</sup> October 2019 at 2pm</p>	

## **Acute Services Directorate SMT Governance Meeting**

### **Standards & Guidelines Monthly Activity Report**

#### **Key Discussion Points at Acute S&G Forum**

**7th May 2019 , Meeting Room, Admin Floor**

*Report Author: Mrs Caroline Beattie  
Standards & Guidelines Manager – Acute Services*

*Date of submission: 03/05/2019*



### New Regionally Endorsed S&G received from 01/04/2019 to 31/04/2019

<u>Title of Correspondence</u>	<u>Date of Issue from External Agency</u>	<u>Reference</u>	<u>Guidance Type</u>	<u>NICE Assurance 3 month</u>	<u>Full Implementation Date for S&amp;G</u>	<u>Date Received by Acute Directorate</u>	<u>Date Reviewed by Acute S&amp;G Group</u>	<u>Applicable to Acute Y/N?</u>	<u>Acute Clinical Change Lead</u>	<u>Acute Directorate Compliance Rating</u>	<u>Acute Risk Rating</u>
<a href="#">Caesarean Section</a>	18/04/2019	CG 132	NICE Clinical Guideline Update	n/a	n/a		Tabled for 07/05/2019	Yes	To be confirmed	To be confirmed	To be confirmed
<a href="#">Medication Errors in Children</a>	15/04/2019	n/a	HSCB Letter	n/a	n/a		Tabled for 07/05/2019	Yes	To be confirmed	To be confirmed	To be confirmed
<a href="#">Outcome of Review of Pre-School Childhood Vaccination Delivery Model in Northern Ireland</a>	15/04/2019	HSS(MD) 5/2019	CMO Letter	n/a	n/a		Tabled for 07/05/2019	No	Not applicable to Acute Services	N/A	N/A
<a href="#">Pembrolizumab for treating relapsed or refractory classical Hodgkin lymphoma</a>	09/04/2019	TA 540	NICE Technology Appraisal	09/04/2019	09/01/2020	<u>12/04/2019</u>	16/04/2019	Yes	Dr Kathryn Boyd (Acute)	To be confirmed	LOW

**Responses Submitted to External Agencies by Acute Services****SUBMITTED March 2019*****SAFETY AND QUALITY REMINDERS OF BEST PRACTICE***

<u>Title of Correspondence</u>	<u>Date of Issue from External Agency</u>	<u>Reference</u>	<u>Guidance Type</u>	<u>Full Implementation Date for S&amp;G</u>	<u>Date Reviewed by Acute S&amp;G Group</u>	<u>Applicable to Acute Y/N?</u>	<u>Acute Clinical Change Lead</u>	<u>Action Plan/BAT Review/Trigger date for review of outstanding actions</u>	<u>Acute Directorate Compliance Rating</u>	<u>Acute Risk Rating</u>
<a href="#">NI Flowchart for Management of Suspected ST Elevation MI or Acute Posterior NI in a Hospital Setting</a>	30/01/2019	SQR/SAI/2019/048 (AS)	Safety and Quality Reminder of Best Practice Guidance	01/03/2019	05/02/2019	Yes	Dr Mlodzianowski & Kay Carroll	30/06/2019	PC [I]	LOW
<a href="#">Misdiagnosis of Diabetic Ketoacidosis in Children</a>	16/01/2019	SQR-SAI-2019-045 (AS/MCH)	Safety and Quality Reminder of Best Practice Guidance	07/03/2019	05/02/2019	Yes	Mary Burke & Dr Eleanor McCormick	Not applicable	C	Medium

***OVERDUE FOR SUBMISSION***

<u>Title of Correspondence</u>	<u>Date of Issue from External Agency</u>	<u>Reference</u>	<u>Guidance Type</u>	<u>Full Implementation Date for S&amp;G</u>	<u>Date Reviewed by Acute S&amp;G Group</u>	<u>Applicable to Acute Y/N?</u>	<u>Acute Clinical Change Lead</u>	<u>Action Plan/BAT Review/Trigger date for review of outstanding actions</u>	<u>Acute Directorate Compliance Rating</u>	<u>Acute Risk Rating</u>
<a href="#">Resources to support safer bowel care for patients at risk of autonomic dysreflexia</a>	12/09/2018	PL/2018/026 HSS (MD)19/18	Patient Safety Alert	20/02/2019	18/09/2018	Yes	Short life working group	The assurance response is tabled for approval at the Acute S&G forum scheduled for 07/05/2019	PC [I]	LOW

**DUE FOR SUBMISSION TO EXTERNAL AGENCY**  
**(deadline dates 01/05/2019 to 30/07/2019)**

<u>Title of Correspondence</u>	<u>Date of Issue from External Agency</u>	<u>Reference</u>	<u>Guidance Type</u>	<u>NICE Assurance 3 month</u>	<u>Full Implementation Date for S&amp;G</u>	<u>Date Reviewed by Acute S&amp;G Group</u>	<u>Applicable to Acute Y/N?</u>	<u>Acute Clinical Change Lead</u>	<u>Acute Directorate Compliance Rating</u>	<u>Acute Risk Rating</u>
<a href="#">Obinutuzumab for untreated advanced follicular lymphoma.</a>	01/08/2018	TA 513	NICE Technology Appraisal	01/11/2018	01/05/2019	07/08/2018	Yes	Fiona Reddick	C	LOW
<a href="#">Tivozanib for treating advanced renal cell carcinoma.</a>	01/08/2018	TA 512	NICE Technology Appraisal	01/11/2018	01/05/2019	07/08/2018	Yes	Fiona Reddick	C	LOW
<a href="#">Resources to support safe and timely management of hyperkalaemia</a>	12/09/2018	PL/2018/027 HSS (MD)23/18	HSCB/PHA Letter	n/a	08/05/2019	18/09/2018	Yes	Dr Peter Sharpe	PC [I]	LOW
<a href="#">Heavy menstrual bleeding: assessment and management (updates &amp; replaces CG44) Updated received 08/11/18</a>	08/05/2018	NG 88	NICE Clinical Guideline	08/08/2018	08/05/2019	15/05/2018	Yes	Dr E Boggs	PC [I&E]	LOW
<a href="#">Wrong Selection of Plates Used for Fixation of Fractures</a>	04/03/2019	HSC (SQSD) 4/19	Patient Safety Alert	n/a	10/05/2019	19/03/2019	Yes	Mr McKeown and Helena Murray	C	LOW
<a href="#">Brodalumab for treating moderate to severe plaque psoriasis.</a>	10/08/2018	TA 511	NICE Technology Appraisal	10/11/2018	10/05/2019	21/08/2018	Yes	Dr Art O'Hagan	C	LOW
<a href="#">Pirfenidone for treating idiopathic pulmonary fibrosis (review of TA282).</a>	10/08/2018	TA 504	NICE Technology Appraisal	10/11/2018	10/05/2019	21/08/2018	Yes	Liam Polley	C	LOW
<a href="#">Management of life threatening Bleeds</a>	12/12/2018	HSS (SQSD) 33/2018	Patient Safety Alert	n/a	13/05/2019	08/01/2019	Yes	Dr Morgan	TBC	Medium
<a href="#">Venous thromboembolism in over 16s reducing the risk of hospital acquired deep vein thrombosis or pulmonary embolism (updates and replaces CG 92) - Update received 25/10/18 recommendations 1.8.13 to 1.8.17</a>	31/05/2018	HSC (SQSD) (NICE NG 89) 13/18	NICE Clinical Guideline	31/08/2018	31/05/2019	05/06/2018	Yes	Trust Thrombosis Committee Dr Boyd (Acute)	TBC	LOW
<a href="#">Safer Temporary Identification Criteria for Unknown or Unidentified</a>	30/01/2019	PL/2019/032	Safety and Quality Reminder of Best Practice Guidance	n/a	05/06/2019	05/02/2019	Yes	Mary Burke/Dr Gareth Hampton/ Dr Hilda Nicholl	TBC	LOW
<a href="#">Lyme disease (Updated 18/10/18 the information in table 2 relating to treatments)</a>	08/06/2018	NG 95	NICE Clinical Guideline	08/09/2018	08/06/2019	19/06/2018	Yes	Dr Sarah Hedderwick	TBC	LOW
<a href="#">Tocilizumab for treating giant cell arteritis</a>	11/09/2018	TA 518	NICE Technology Appraisal	11/12/2018	11/06/2019	18/09/2018	Yes	Dr Nicola Maiden	C	LOW
<a href="#">Physical activity and the environment</a>	12/06/2018	NG 90	NICE Public Health Guideline	12/09/2018	12/06/2019	19/06/2018	Yes	For Dissemination	N/A	LOW
<a href="#">Risk of Harm From Inappropriate Placement of Pulse Oximeter Probes</a>	30/01/2019	PL/2019/031 (SQSD 38/18)	Safety and Quality Reminder of Best Practice Guidance	n/a	18/06/2019	05/02/2019	Yes	Orlagh Murphy	PC [I]	LOW
<a href="#">Autologous chondrocyte implantation using chondrosphere for treating symptomatic articular cartilage defects of the knee</a>	24/09/2018	TA 508	NICE Technology Appraisal	24/12/2018	24/06/2019	02/10/2018	Yes	Mr Paul Magill / Mr Gavin McLean	PC [E]	LOW
<a href="#">Development of Diabetic Keto-Acidosis DKA as an In-Patient Further Update</a>	07/02/2019	SQR-SAI-2018-035 (AS & MCH)	Safety and Quality Reminder of Best Practice Guidance	n/a	03/07/2019	19/02/2019	Yes	Mrs Mary Burke & Dr E McCormick (Acute)	PC [I&E]	Medium
<a href="#">Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma</a>	03/10/2018	TA 524	NICE Technology Appraisal	03/01/2019	03/07/2019	16/10/2018	Yes	Dr Kathryn Boyd	C	LOW
<a href="#">Guselkumab for treating moderate to severe plaque psoriasis</a>	03/10/2018	TA 521	NICE Technology Appraisal	03/01/2019	03/07/2019	16/10/2018	Yes	Dr A O'Hagan	TBC	LOW

## **Acute Services Directorate SMT Governance Meeting**

### **Standards & Guidelines Monthly Activity Report**

#### **Key Discussion Points at Acute S&G Forum**

**18th June 2019 , Meeting Room, Admin Floor**

*Report Author: Mrs Caroline Beattie  
Standards & Guidelines Manager – Acute Services*

*Date of submission: 18/06/2019*



### New Regionally Endorsed S&G received from 01/05/2019 to 31/05/2019

<u>Title of Correspondence</u>	<u>Date of Issue from External Agency</u>	<u>Reference</u>	<u>Guidance Type</u>	<u>NICE Assurance 3 month</u>	<u>Full Implementation Date for S&amp;G</u>	<u>Date Received by Acute Directorate</u>	<u>Date Reviewed by Acute S&amp;G Group</u>	<u>Applicable to Acute Y/N?</u>	<u>Acute Clinical Change Lead</u>	<u>Acute Directorate Compliance Rating</u>	<u>Acute Risk Rating</u>
<a href="#">Specialist Neonatal Respiratory Care for Babies Born Preterm</a>	31/05/2019	HSC (SQSD) (NICE NG124) 14/19	NICE Clinical Guideline	31/08/2019	31/05/2020	Pending	Pending	Pending	Pending	Pending	Pending
<a href="#">Therapeutic hypothermia for acute ischaemic stroke - DO NOT USE</a>	30/05/2019	HSC (SQSD) (NICE IPG647) 13/19	NICE Interventional Procedures	n/a	n/a	Pending	Pending	Pending	Pending	Pending	Pending
<a href="#">Shingles Vaccination Programme - Eligibility Criteria for 2019-2020</a>	29/05/2019	HSS(MD)10/2019	CMO Letter	n/a	n/a	Pending	Pending	Pending	Pending	Pending	Pending
<a href="#">Assessment and Management of Babies Who Are Accidentally Dropped in Hospital</a>	24/05/2019	HSC (SQSD) 11/19	Patient Safety Alert	n/a	n/a	Pending	Pending	Pending	Pending	Pending	Pending

**Responses Submitted to External Agencies by Acute Services****SUBMITTED April 2019*****SAFETY AND QUALITY REMINDERS OF BEST PRACTICE***

<b>Title of Correspondence</b>	<b>Date of Issue from External Agency</b>	<b>Reference</b>	<b>Guidance Type</b>	<b>Full Implementation Date for S&amp;G</b>	<b>Date Reviewed by Acute S&amp;G Group</b>	<b>Applicable to Acute Y/N?</b>	<b>Acute Clinical Change Lead</b>	<b>Action Plan/BAT Review/Trigger date for review of outstanding actions</b>	<b>Acute Directorate Compliance Rating</b>	<b>Acute Risk Rating</b>
<a href="#">Mismatched Incompatible components in elective orthopaedic joint replacement surgery</a>	06/02/2019	SQR/SAI/2019/046	Safety and Quality Reminder of Best Practice Guidance	22/03/2019	19/02/2019	Yes	Dr McKeown		C	LOW

***NICE Clinical Guidelines***

<b>Title of Correspondence</b>	<b>Date of Issue from External Agency</b>	<b>Reference</b>	<b>Guidance Type</b>	<b>Full Implementation Date for S&amp;G</b>	<b>Date Reviewed by Acute S&amp;G Group</b>	<b>Applicable to Acute Y/N?</b>	<b>Acute Clinical Change Lead</b>	<b>Action Plan/BAT Review/Trigger date for review of outstanding actions</b>	<b>Acute Directorate Compliance Rating</b>	<b>Acute Risk Rating</b>
<a href="#">Rheumatoid arthritis in adults management updates and replaces CG79</a>	04/09/2018	HSC (SQSD) (NICE NG100) 26/18	NICE Clinical Guideline	04/09/2019	18/09/2018	Yes	Dr Nicola Maiden	31/03/2020	PC [I&E]	LOW
<a href="#">Non-Alcoholic Fatty Liver Disease (NAFLD): Assessment and Management</a>	23/08/2016	NG 49	NICE Clinical Guideline	23/08/2017	N/A - Pre establishment of Acute S&G Group	Yes	Dr M Gibbons (Acute Services)	31/03/2020	PC [I&E]	LOW
<a href="#">Cirrhosis in over 16s: Assessment and Management</a>	23/08/2016	NG 50	NICE Clinical Guideline	23/08/2017	N/A - Pre establishment of Acute S&G Group	Yes	Dr M Gibbons (Acute Services)	31/03/2020	PC [I&E]	LOW
<a href="#">Diabetes in Pregnancy: Management of Diabetes and its Complications from Preconception to the Postnatal Period - This guideline updates and replaces NICE guideline CG63</a>	15/05/2015	NG 3	NICE Clinical Guideline	15/05/2016	N/A - Pre establishment of Acute S&G Group	Yes	Dr Sidhu/Sahid/McConnell/Bradley/Joanne McGlade plus AD IMWH	Ongoing Review	PC [I&E]	LOW
<a href="#">Multiple Sclerosis: Management in Primary and Secondary care</a>	28/11/2014	CG 186	NICE Clinical Guideline	28/11/2015	N/A - Pre establishment of Acute S&G Group	Yes	Dr Jamie Campbell	31/03/2020	PC [I&E]	LOW
<a href="#">Hepatitis B (Chronic): Diagnosis and Management of Chronic Hepatitis B in Children, Young People and Adults (Updated 20/10/17)</a>	02/12/2013	CG 165	NICE Clinical Guideline	31/03/2015	Pre-Establishment of Acute S&G Forum	Yes	Dr Mike Gibbons	31/03/2020	PC [I&E]	LOW
<a href="#">Epilepsy Update received 24/04/18</a>	07/08/2012	CG 137	NICE Clinical Guideline	07/11/2012	N/A - Pre establishment of Acute S&G Group	Yes	Epilepsy Working Group (Chair Dr K McKnight - Acute)	BAT currently being scoped	PC [I&E]	LOW

***HSCB Email***

<u>Title of Correspondence</u>	<u>Date of Issue from External Agency</u>	<u>Reference</u>	<u>Guidance Type</u>	<u>Full Implementation Date for S&amp;G</u>	<u>Date Reviewed by Acute S&amp;G Group</u>	<u>Applicable to Acute Y/N?</u>	<u>Acute Clinical Change Lead</u>	<u>Action Plan/BAT Review/Trigger date for review of outstanding actions</u>	<u>Acute Directorate Compliance Rating</u>	<u>Acute Risk Rating</u>
<a href="#">Pause In Vaginal Mesh Surgery Restriction of Use and High Vigilance Scrutiny Requirements</a>	08/04/2019	PL/2018/025	HSCB E-Mail	29/04/2019	16/04/2019	Yes	Wendy Clarke & Dr Boggs (Acute)		PC [I&E]	MEDIUM

<u>Title of Correspondence</u>	<u>Date of Issue from External Agency</u>	<u>Reference</u>	<u>Guidance Type</u>	<u>Full Implementation Date for S&amp;G</u>	<u>Date Reviewed by Acute S&amp;G Group</u>	<u>Applicable to Acute Y/N?</u>	<u>Acute Clinical Change Lead</u>	<u>Action Plan/BAT Review/Trigger date for review of outstanding actions</u>	<u>Acute Directorate Compliance Rating</u>	<u>Acute Risk Rating</u>
<a href="#">Resources to support safer bowel care for patients at risk of autonomic dysreflexia</a>	12/09/2018	PL/2018/026 HSS (MD)19/18	Patient Safety Alert	20/02/2019	18/09/2018	Yes	Ronan Carroll & Anne McVey	30/09/2019	PC [I]	LOW

**DUE FOR SUBMISSION TO EXTERNAL AGENCY**  
**(deadline dates 01/06/2019 to 31/08/2019)**

3 Month Assurance										
Title of Correspondence	Date of Issue from External Agency	Reference	Guidance Type	NICE Assurance 3 month	Full Implementation Date for S&G	Date Reviewed by Acute S&G Group	Applicable to Acute Y/N?	Acute Clinical Change Lead	Acute Directorate Compliance Rating	Acute Risk Rating
<a href="#">Specialist Neonatal Respiratory Care for Babies Born Preterm</a>	31/05/2019	HSC (SQSD) (NICE NG124) 14/19	NICE Clinical Guideline	31/08/2019	31/05/2020	To be reviewed at the Acute S&G Forum on the 18/06/2019				
<a href="#">Lenvatinib for Untreated Advanced Hepatocellular Carcinoma</a>	24/05/2019	TA 551	NICE Technology Appraisal	23/08/2019	24/02/2020	To be reviewed at the Acute S&G Forum on the 18/06/2019				
<a href="#">Lung Cancer Diagnosis and Management (Updates and Replace CG121)</a>	23/05/2019	NG 122	NICE Clinical Guideline	23/08/2019	23/05/2020	To be reviewed at the Acute S&G Forum on the 18/06/2019				
<a href="#">Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged up to 25 years</a>	03/05/2019	TA 554	NICE Technology Appraisal	03/08/2019	03/02/2020	21/05/2019	Yes	Dr Kathryn Boyd	To be confirmed	LOW
<a href="#">Women With Existing Medical Conditions or Obstetric Complications And Their Babies</a>	30/04/2019	NG 121	NICE Clinical Guideline	30/07/2019	30/04/2020	07/05/2019	Yes	Dr Meeta Kamath & Dr Aoife Currie	To be confirmed	LOW
<a href="#">Crizotinib for treating ROS1-positive advanced non-small-cell lung cancer</a>	08/04/2019	TA 529	NICE Technology Appraisal	08/07/2019	08/01/2020	16/04/2019	Yes	Fiona Reddick (Acute)	To be confirmed	LOW
<a href="#">Tofacitinib for moderately to severely active ulcerative colitis</a>	01/04/2019	TA 547	NICE Technology Appraisal	01/07/2019	01/01/2020	16/04/2019	Yes	Dr Bhat (Acute)	To be confirmed	LOW
<a href="#">Daratumumab monotherapy for treating relapsed and refractory multiple myeloma</a>	28/03/2019	TA 510	NICE Technology Appraisal	28/06/2019	28/12/2019	02/04/2019	Yes	Dr Kathryn Boyd	To be confirmed	LOW
<a href="#">Ixazomib with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma</a>	27/03/2019	TA 505	NICE Technology Appraisal	27/06/2019	27/12/2019	02/04/2019	Yes	Dr Kathryn Boyd	To be confirmed	LOW
<a href="#">Cerebral Palsy in Adults</a>	12/03/2019	NG 119	NICE Clinical Guideline	12/06/2019	12/03/2020	19/03/2019	Yes	Dr Forbes	To be confirmed	LOW
<a href="#">Renal and Ureteric Stones Assessment and Management</a>	04/03/2019	SQSD 07/19 (NG 118)	NICE Clinical Guideline	04/06/2019	04/03/2020	19/03/2019	Yes	Mr Young and Mr Tyson (Acute)	To be confirmed	LOW
Full Implementation										
Title of Correspondence	Date of Issue from External Agency	Reference	Guidance Type	NICE Assurance 3 month	Full Implementation Date for S&G	Date Reviewed by Acute S&G Group	Applicable to Acute Y/N?	Acute Clinical Change Lead	Acute Directorate Compliance Rating	Acute Risk Rating
<a href="#">Proposed Changes In The Prescribing and Supply of Drugs for the Treatment of Tuberculosis</a>	03/06/2019	n/a	HSCB Letter	n/a	28/06/2019	To be reviewed at the Acute S&G Forum on the 18/06/2019				
<a href="#">Specific Cardiac Arrest Protocol for Patients fitting with Left Ventricular Assist Devices LVAD</a>	08/05/2019	SQR-SAI-2019-049 (AS)	Safety and Quality Reminder of Best Practice Guidance	n/a	26/06/2019	21/05/2019	Yes	For Dissemination	For Dissemination	N/A
<a href="#">Wrong Selection of Orthopaedic Fracture Fixation Plates</a>	07/05/2019	HSC (SQSD) 4/19	Patient Safety Alert	n/a	05/06/2019	21/05/2019	Yes	Ronan Carroll & Helena Murray	C	LOW
<a href="#">Safer Temporary Identification Criteria for Unknown or Unidentified</a>	30/01/2019	PL/2019/032	Patient Safety Alert	n/a	05/06/2019	05/02/2019	Yes	Mary Burke/Dr Gareth Hampton/ Dr Hilda Nicholl	PC [I&E]	LOW

<a href="#">Hearing loss in adults assessment and management</a>	20/08/2018	HSC (SQSD) (NICE NG98) 22/18	NICE Clinical Guideline	20/11/2018	20/08/2019	04/09/2018	Yes	Avril Watson	To be confirmed	LOW
<a href="#">Dementia assessment management and support for people living with dementia and their carers</a>	17/08/2018	HSC (SQSD) (NICE NG97) 21/18	NICE Clinical Guideline	17/11/2018	17/08/2019	21/08/2018	Yes	MHLD Led	To be confirmed	LOW
<a href="#">Lyme disease (Updated 18/10/18 the information in table 2 relating to treatments)</a>	08/06/2018	NG 95	NICE Clinical Guideline	08/09/2018	08/06/2019	19/06/2018	Yes	Dr Sara Henderwick	To be confirmed	LOW
<a href="#">Tocilizumab for treating giant cell arteritis</a>	11/09/2018	TA 518	NICE Technology Appraisal	11/12/2018	11/06/2019	18/09/2018	Yes	Dr Maiden	C	LOW
<a href="#">Physical activity and the environment</a>	12/06/2018	NG 90	NICE Public Health Guideline	12/09/2018	12/06/2019	19/06/2018	Yes	For Dissemination	For information only (NICE Public Health guidance)	N/A
<a href="#">Risk of Harm From Inappropriate Placement of Pulse Oximeter Probes</a>	30/01/2019	PL/2019/031 (SQSD 38/18)	Patient Safety Alert	n/a	18/06/2019	05/02/2019	Yes	Orlagh Murphy	PC [I]	LOW
<a href="#">Autologous chondrocyte implantation using chondrosphere for treating symptomatic articular cartilage defects of the knee</a>	24/09/2018	TA 508	NICE Technology Appraisal	24/12/2018	24/06/2019	02/10/2018	Yes	Paul Magill / Gavin McLean	PC [E]	LOW
<a href="#">Development of Diabetic Keto-Acidosis DKA as an In-Patient Further Update</a>	07/02/2019	SQR-SAI-2018-035 (AS & MCH)	Safety and Quality Reminder of Best Practice Guidance	n/a	03/07/2019	19/02/2019	Yes	Mrs Mary Burke & Dr E McCormick (Acute)	PC [I&E]	Medium
<a href="#">Brentuximab vedotin for treating CD30-positive Hodgkin lymphoma</a>	03/10/2018	TA 524	NICE Technology Appraisal	03/01/2019	03/07/2019	16/10/2018	Yes	Dr Kathryn Boyd	C	LOW
<a href="#">Guselkumab for treating moderate to severe plaque psoriasis</a>	03/10/2018	TA 521	NICE Technology Appraisal	03/01/2019	03/07/2019	16/10/2018	Yes	Dr A O'Hagan	C	LOW

**Witczak, Maria**

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**From:** Beattie, Caroline  
**Sent:** 08 April 2019 12:36  
**To:** Adams, Dr Beverley; Beattie, Caroline; Campbell, Clarke; Clarke, Wendy; Cluett, Adrian; Coulter, Aaron; Cunningham, Marietta; Devlin, Louise; Donnelly, Mary; Funston, Lesley Ann; McBirney, Orla; McCooe, Clare; McCracken, Jean; McCullagh, Rose; McGlade, Joanne; McKnight, Karen; McMahan, Dr; McQuillan, Wendy; Minay, Joanne; O'Neill, Edel; Redpath, Jillian; Reid, Trudy; Robinson, Alison; Subramanian, Arun; Wylie, Sandra  
**Cc:** OKane, Maria; Boyce, Tracey; McVey, Anne Personal Information redacted by the USI; Murphy, Philip Personal Information redacted by the USI; Black, Tony; McNally, ClaireA; Magennis, Marita; Reid, Trudy; Kane, Megan  
**Subject:** \*\*NEW Pan College guidance and the new ARAF form - Sodium valproate  
**Attachments:** 270319\_Trust CEXs letter re Valproate and Women of Childbearing Potentia....pdf; RCGP-pan-college-valproate-march-2019.pdf  
**Importance:** High

Dear All

On behalf of Dr McKnight, I am advising you of the new Pan-College Guidance on valproate use in women and girls - this was published on 29 March 2019 and I have attached a pdf version for your ease of reference.

The link to this is also outlined below:

<https://www.rcgp.org.uk/about-us/news/2019/march/thirteen-uk-healthcare-bodies-launch-pragmatic-guidance-on-valproate-use.aspx>

Experts from 13 national bodies, including seven Royal Colleges, have joined forces to launch new practical guidance to support doctors and other health professionals around valproate use in women and girls in their reproductive years.

The 'pan-College' advice is based on 2018 regulations issued by the Medicines and Healthcare Products Regulatory Authority (MHRA) around the prescribing and dispensing of valproate - but it also looks at the more challenging issues that clinicians across primary and specialist care might encounter in daily practice. These include transition from paediatric to adulthood services, competence to consent to treatment, and confidentiality. The new Annual Risk Acknowledgement Form (ARAF) was published on 28 March 2019. The MHRA plans to provide a summary of the available guidance and the new ARAF form in this month's Drug Safety Update newsletter.

Given the challenges that we outlined at our Trust working group meeting on 15th January 2019, these have been fed back to the PHA by Dr McKnight on 29th January 2019. Subsequent to this meeting there are now plans on facilitate a regional meeting on 21 May 2019 to discuss these issues further and this new guidance document will be timely.

I will keep you updated on progress

Many thanks

Regards  
Caroline

Standards & Guidelines Manager | Acute Services Clinical and Social Care Governance Team The Maples | Craigavon Area Hospital | 68 Lurgan Road | Portadown BT63 5QQ

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12-22 Linenhall Street  
Belfast  
BT2 8BS

**By email**

To: Trust Chief Executives

W: [www.publichealth.hscni.net](http://www.publichealth.hscni.net)

T: Personal Information redacted by the USI

27 March 2019

Dear Colleague,

**Valproate and Women of Childbearing Potential**

I refer to my letter of 12<sup>th</sup> February 2018 in respect of the Trust's response to the actions in circular **HSC (SQSD) 19/17**. Shortly afterwards the guidance on the use of valproate in women of childbearing potential changed to become more restrictive following a review across the EU. Valproate is now contraindicated in women of childbearing potential unless they meet conditions of a Pregnancy Prevention Programme and the CMO and CPO issued **HSS (MD) 8/2018** in response to this change.

Work will already be underway within each Trust as per the DOH letter however discussions with clinical and Trust colleagues have reflected the complexity of the issues involved, and a regional group would help support further implementation.

The first meeting of this group has been set for the **morning of Tuesday 21<sup>st</sup> May 2019** to allow sufficient notice for clinical colleagues.

This issue affects multiple specialties including paediatrics, neurology, psychiatry, learning disability and obstetrics and will therefore require a consistent and co-ordinated approach to be taken across multiple directorates in your Trust. A number of Trusts have established an internal group on this issue and you may like to consider this for your Trust if it has not already been established.

Given the range of specialties involved it is not possible to have each specialty represented per Trust. Therefore suggested representation from across the Trusts is included in the table overleaf. A Director nominee has been requested since more than one service area will be affected; however you may

wish to nominate another member of senior management as relevant to your organisation.

I would be grateful if you could please nominate relevant representatives from your Trust as per the table overleaf to become members of this group.

Please send the details of your nominees by **Wednesday 10<sup>th</sup> April 2019** to

Personal information redacted by the USI

If you have any queries in respect of this please contact Catherine Coyle, Consultant in Public Health Personal information redacted by the USI.

Yours sincerely

Personal information redacted by the USI

**DR ADRIAN MAIRS**  
**Acting Director of Public Health**

Cc Trust Medical Directors  
Trust Heads of Pharmacy  
Catherine Coyle  
Matthew Dolan  
Damien Bennett  
Alan Marsden  
Rachel Edwards

**Proposed Membership – Regional Valproate Group**

**Trusts**

BHSCT	NHSCT	SEHSCT	SHSCT	WHSCT
Trust lead director governance	Trust lead director governance	Trust lead director governance	Trust lead director governance	Trust lead director governance
Neurologist (epilepsy sub-specialist)	Psychiatrist	Neurologist	Learning disability consultant	Paediatric learning disability consultant
Paediatric neurology	Paediatrician with interest in epilepsy	Epilepsy nurse specialist	Obstetrician	Learning disability nurse specialist
Obstetrician (interest in epilepsy)				
Psychiatrist				

**Proposed Non-Trust Members**

Role	Organisation
Community Pharmacist	CPNI
Pharmacy	HSCB
GP Medical Adviser	HSCB
Commissioning	HSCB
PMSI	HSCB
PHA consultant	PHA
GP representative	NIGPC
GP representative	RCGP
Family Planning Representative	TBC
Medicines governance pharmacist	From regional medicines governance pharmacists group

# **Guidance Document on Valproate Use in Women and Girls of Childbearing Years**

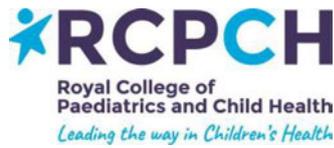
**Judy Shakespeare FRCGP<sup>1</sup>, Sanjay M Sisodiya FRCP<sup>2</sup>**

<sup>1</sup> On behalf of the Royal College of General Practitioners  
and <sup>2</sup>Association of British Neurologists and  
Royal College of Physicians

**Version 1, 29<sup>th</sup> March 2019**

**Endorsements**

The following organisations have endorsed this document:



## Contents

Endorsements.....	2
Foreword.....	5
Executive Summary.....	6
List of Abbreviations .....	7
Introduction .....	8
1. Girls with epilepsy .....	9
1.1 Females under 10 years .....	9
1.2 Females aged 10-12 years.....	10
1.3 Females aged 13-15 years.....	10
1.4 Females aged 16 years and over .....	10
2. Girls with bipolar disorder.....	10
3. Competence to consent to treatment and confidentiality in young women .....	11
4. Transition of care from paediatric services or CAMHS to adult services .....	11
5. Women of childbearing potential .....	12
5.1 Contraception for the PPP .....	12
5.2 Contraceptive choice in young women.....	14
5.3 Contraception choice in older women .....	14
5.4 Emergency contraception .....	14
5.5 Adverse effects of contraception .....	15
5.6 Discontinuation or exchanging of valproate .....	15
5.7 Women choosing to remain on valproate, but without a PPP.....	15
5.8 Intellectual Disability (ID).....	16
5.8.1 With lack of mental capacity.....	17
5.8.2 With mental capacity.....	17
5.9 Women who fail to attend their specialist appointment.....	17
5.10 Prescribing responsibility: consider shared care .....	18
5.11 Particular situations that may arise .....	18
5.11.1 Status epilepticus.....	18
5.11.2 Women on valproate who are detained in prison .....	18
5.11.3 Women detained under the Mental Health Act (MHA).....	18
5.12 Pharmacies and valproate dispensation.....	19
6. Women not at risk of pregnancy for other reasons .....	19
7. Pregnancy in women on valproate .....	19
8. Other issues .....	20
8.1 Which healthcare professionals can be considered as specialists?.....	20
8.2 Epilepsy Specialist Nurses (ESN) and specialist midwives.....	21
8.3 GPs with an extended role in epilepsy (GPWERS).....	21
8.4 Adoption and surrogacy.....	21

9. Babies born to women who have taken valproate during pregnancy ..... 22  
Concluding remarks..... 22  
Patient Support Networks..... 23  
Contributors ..... 24  
Acknowledgements..... 24  
References ..... 25

**Foreword**

Medicine changes all the time based on new research, evidence and learnings, and as such the way we do things as healthcare professionals is constantly evolving. When best practice changes, in the interests of delivering the safest possible care for our patients, the way it is communicated across the profession is essential – and that we all take it on board.

Use of sodium valproate in pregnancy is associated with a 40% risk of persistent neurodevelopmental disorders and a 10% risk of physical birth defects. In April 2018, I wrote to all healthcare professionals in England advising them of new regulations from the Medical and Healthcare products Regulatory Agency that valproate should not be prescribed to women of childbearing potential unless they meet the conditions of a Pregnancy Prevention Programme.

This is, of course, important for healthcare professionals to know – but it is also important for them to know how to implement this change and work differently.

I am very pleased that the Medical Royal Colleges have come together to produce this important and helpful guidance, so that doctors and other healthcare professionals across primary and secondary care are on the same page regarding the use of sodium valproate - including around instances where its use is still appropriate.

I hope this new guidance will provide clarity for doctors, and ultimately, improve patient care.



**Professor Dame Sally Davies**  
Chief Medical Officer for England

## **Executive Summary**

Valproate (Epilim, Depakote, Convulex, Episenta, Epival, Kentlim, Orlept, Syonell, Valpal) is associated with a significant risk of birth defects and developmental disorders in children born to women who take valproate during pregnancy. Strengthened regulations governing its use have recently been put in place, and received extensive publicity. The pregnancy prevention programme, PPP, is a key element of the new regulations.

Valproate is licensed for use only in the treatment of epilepsy and bipolar disorder. For some women with these conditions, it may be the only drug that controls their condition. In any woman, abrupt cessation of valproate is dangerous and should not be undertaken. For most women of child-bearing potential with bipolar disorder there are other drugs that have been shown to be at least as effective. The implementation of the new regulations is central to reducing the significant harms associated with valproate use. In daily practice, challenging situations may arise when valproate use is being considered, reviewed or discontinued. Clinicians are required to act in the best interests of each individual patient. This document is intended to provide practical information and guidance, and sources of further support, for clinicians involved with valproate: it gathers data, where available, on best practice and summarises consensus opinion from seventeen national bodies across the UK.

The areas covered for girls are: epilepsy; bipolar disorder; competence to consent to treatment, confidentiality in young women and transition from paediatric to adulthood care. In women of childbearing potential, we discuss: contraception for the PPP across the age range and its risks, discontinuation or exchanging of valproate, women remaining on valproate without a PPP, intellectual disability, failure to carry out annual specialist review, prescribing responsibility, special situations such as status epilepticus, women detained in prison or under the Mental Health Act. In addition, we consider: valproate dispensing; women not at risk of pregnancy; healthcare when pregnancy does occur on valproate; competencies across specialties and roles; adoption and surrogacy; peri-menopausal women and babies born following in utero valproate exposure.

The licensed indications for valproate are serious, sometimes life-threatening, conditions. Valproate may be an effective therapy, but the significant risks associated with its use require clinicians to observe the regulations. However, the circumstances of each individual patient are unique and require bespoke management. This guidance cannot cover every scenario and will require updating as regulations, circumstances and knowledge evolve, and clinicians should pay attention to new information as it is made available.

### **Disclaimer**

**This guidance should not override the clinical discretion of the prescriber to act in the best interest of their patient and in accordance with their professional duties and within the limits of their expertise**

**List of Abbreviations**

(A)RAF, (Annual) Risk Acknowledgement Form  
CAMHS, Child and Adolescent Mental Health Services  
CHC, Combined Hormonal Contraception  
Cu-ICD, Copper Intrauterine Device  
DMPA, Depot Medroxyprogesterone Acetate  
ESN, Epilepsy Specialist Nurses  
FACS, Fetal Anticonvulsant Syndrome  
FSRH, Faculty of Sexual & Reproductive Healthcare  
GMC, General Medical Council  
GPs, General Practitioners  
GPwERS, GPs with an extended role in epilepsy  
HCPs, Healthcare Professionals  
ICD, International Classification of Diseases  
ID, Intellectual Disability  
IMP, Progestogen-only Implant  
IUC, Intrauterine Contraception  
LARC, Long Acting Reversible Contraceptive  
LNG-IUS, Levonorgestrel Intrauterine System  
MHA, Mental Health Act  
MHRA, Medicines and Healthcare products Regulatory Agency  
NICE, National Institute for Health and Care Excellence  
POP, Progesterone-only Pill  
PPP, Pregnancy Prevention Programme  
PREVENT, Pregnancy Prevention Programme  
QOF, Qualities and Outcomes Framework  
RCOG, Royal College of Obstetrics and Gynaecology  
RCPsych, Royal College of Psychiatrists  
RPS, Royal Pharmaceutical Society  
SRH, Sexual and Reproductive Health  
SUDEP, Sudden Unexpected Death in Epilepsy  
UKMEC, UK Medical Eligibility Criteria for Contraceptive Use

## **Introduction**

New regulations were issued by the Medicines and Healthcare products Regulatory Agency (MHRA) regarding the use of valproate in girls and women of childbearing potential in March 2018 (1). These regulations have been extensively publicised, with periodic updates, and require action by all involved in the recommendation, prescription and dispensing of valproate. Issues around the use of valproate are also part of the Independent Medicines and Medical Devices Safety Review chaired by Baroness Cumberlege (2).

Historically, valproate was used extensively in this population. Although recent practice has changed, difficulties with implementation of the regulations were foreseen and have emerged in practice. Valproate is an effective drug for certain types of **epilepsy** (3), and epilepsy is a serious neurological condition that carries risks, including of premature mortality. The drug is widely used for the licenced indication of **bipolar disorder**, but there is evidence that there are other treatments with equal or superior efficacy (4). In addition, other treatments present much lower potential risks to fetal development (5). In other mental disorders where valproate is unlicensed there is either no or very limited evidence of efficacy (4). The National Institute for Health and Care Excellence (NICE) recommends that it is not offered to girls and women with mental disorders who are pregnant or have childbearing potential (6).

Women of childbearing potential, whatever their underlying diagnosis, should therefore not be prescribed valproate unless there are exceptional circumstances. During pregnancy, the MHRA regulations also state that valproate should not be prescribed unless a girl or woman suffers from a type of epilepsy that is not responding to other treatments.

In response to these complexities and the serious consequences of valproate use in women during pregnancy, this cross-speciality consensus document has been produced as a practical guide to management, including for particular situations that may present difficulties. There may be separate, additional, risks that are specialty- and disease-specific (e.g. the independent risk of inheritance of the condition for which the mother is prescribed valproate), but such risks will have been present irrespective of valproate use, and are not considered here. The document is based on evidence where available. In many areas there is no evidence base and here the document is based on cross-specialty expert opinion. Additional research is needed in many of these areas. This document seeks to provide support and guidance for the individual healthcare professional facing challenging situations, but it cannot cover every possible clinical scenario.

The MHRA is a regulatory body covering the whole of the UK. The current MHRA regulations (1) state that valproate must no longer be used in any woman or girl able to have children unless she has a pregnancy prevention programme (PPP), also known as PREVENT, in place. The PPP involves:

- Assessing the patient's potential for becoming pregnant
- Explaining the known risks to an unborn child exposed to valproate (30-40% for poor neurodevelopmental outcomes and 10% for major congenital malformations)
- Conducting pregnancy tests before and during treatment as appropriate (<https://www.gov.uk/drug-safety-update/medicines-with-teratogenic-potential-what-is-effective-contraception-and-how-often-is-pregnancy-testing-needed>)

- Explaining the need for highly effective contraception
- Annual (or more frequent) specialist review of treatment
- Specialists using an annual risk acknowledgement form (ARAF) to confirm provision and understanding of the requirements:  
<https://www.medicines.org.uk/emc/rmm/1207/Document>

Materials for healthcare professionals (HCPs) and patients are available to support discussions at <https://www.gov.uk/guidance/valproate-use-by-women-and-girls> (1). From April 2019, General Practitioners (GPs) will be encouraged to undertake patient safety quality improvement activities through the Qualities and Outcomes Framework (QOF), including for valproate (7). Changing skills within the NHS mean that many pharmacists, nurses, and midwives are now also Independent Prescribers and the Royal Pharmaceutical Society (RPS) has produced a practical guide for these professionals (8).

The MHRA are currently leading discussions on the creation of a registry of women and girls of childbearing age who are taking valproate. It will be important that such a registry also includes individuals who have stopped valproate as a result of the new regulations, in order to track all significant outcomes related to the changes.

Individual clinicians are required to act in the best interests of each individual patient (9, 10). Each woman or girl of childbearing potential is an individual and, wherever possible, should be fully involved in the choices she makes about her health and fertility (11). The regulations could lead to some situations where the best interests of the patient may not appear to be served. In this situation, clinical judgement should be exercised. When faced with difficult individual circumstances, clinicians should consider making use of additional resources, such as best interest meetings, peer review, consultation with multidisciplinary teams, advice from Trust or Health Board medicines committees or Clinical Director, and speciality support groups. The General Medical Council (GMC) also provides information, for example on prescribing unlicensed drugs (12). Some of the points raised by implementation of the new regulations are complex ethical issues, which we do not attempt to answer in this document. We take a pragmatic approach, considering issues through life stages.

## **1. Girls with epilepsy**

Our consensus is that the current guidance requires clarity with regard to the age and developmental stage of girls/young people as it is not appropriate for all children/young people in the paediatric population. In order to provide a framework for clinical management, the prescribing needs of children/young people should be considered by age and learning ability (13).

The prescribing needs of girls with intellectual disability (ID) are specifically considered further under section 5 of this document.

### **1.1 Females under 10 years**

The current regulations do not advise against the use of valproate in this age group. Girls with epilepsy under the age of 10 years will be managed by specialist services and will be under regular review and must be seen in specialist services at least annually. The choice

of antiepileptic drug in this age group should follow national guidance (13). There is existing information for parents/carers of girls and girls in this age group about the risks of valproate therapy, and that it is not a desirable treatment when they reach adolescence due to the associated risks (14). Information for older girls and their parents is also available (15, 16). This should be discussed and documented in the ARAF on an annual basis. The PPP is not required in this age group.

If a girl less than 10 years has already gone through the menarche (and paediatricians should always ask), they should be managed as for the 10-12 years age category.

### **1.2 Females aged 10-12 years**

Unless there are pressing clinical needs, no female patient aged over 10 years should be commenced on treatment with valproate, if there is potential for future pregnancy. Existing patients should undergo formal evaluation to see if the valproate can be discontinued or substituted with an alternative therapy. Existing patients must remain under specialist care and be seen at least annually. Additionally, the prescriber must ensure that:

- The parents/caregivers of female children and girls understand the need to contact the specialist once the female child using valproate experiences menarche.
- The parents/caregivers and girls who have experienced menarche are provided with the valproate guidance and managed as girls aged 13-15 years (1).
- The ARAF should be completed by the specialist and the responsible person documenting that they are aware of the risks of teratogenicity, but no PPP intervention is required.

### **1.3 Females aged 13-15 years**

Females in this age group who have potential for future pregnancy should only be prescribed valproate if other treatments are ineffective. They must be kept under at least annual review by specialists.

The young woman herself is the most important person in the discussion about the importance of avoiding pregnancy during use of valproate. Therefore, the person that needs to be informed (in language that she can understand and with age-appropriate written/digital information) is the young woman. Discussing the contents of the ARAF could be very sensitive if the parents or carers are present (see Section 3 below). If there are "*compelling reasons to indicate that there is no risk of pregnancy*" (1), information about pregnancy risk should be given, but the full PPP may not be required.

In girls who are known to be, or are likely to become, sexually active in the near future the full PPP should be implemented as for an adult woman. MHRA are currently developing an ARAF more appropriate to this age group which will soon be available on the MHRA website.

### **1.4 Females aged 16 years and over**

These young women should be managed as adult women in line with PPP. Females over 16 with ID should be managed as outlined in section 5.

## **2. Girls with bipolar disorder**

Bipolar disorder is a condition that can be highly disruptive to the development of young people and frequently requires treatment with medication. As in adults, valproate should rarely be used in girls who could get pregnant: for example, when the illness is very severe and there is no effective alternative option. A girl receiving treatment with valproate should be under the close supervision of a specialist Child and Adolescent Mental Health Service (CAMHS).

### **3. Competence to consent to treatment and confidentiality in young women**

Many young women do not wish to discuss their sex lives with their parents or carers. The median age for first heterosexual sexual experience is 14 years (17). Those under age 13 are not considered competent legally to consent to sexual activity (18-20). If a girl under 16 years has mental capacity, her competence to consent to treatment needs to be assessed (21). This applies to valproate as well as contraception. However, having the capacity to consent to sexual activity may be different from the capacity to consent to a high risk treatment, such as valproate. Competence to consent to treatment is demonstrated (22) if she can:

- understand the treatment, its purpose and nature, and why it is being proposed
- understand its benefits, risks and alternatives
- understand in broader terms what the consequences of the treatment will be
- retain the information for long enough to use it and weigh it up in order to arrive at a decision

In young women who are assessed as being competent to consent to sexual activity, the conversation about sexual activity and contraception should take place without the parents and respect the principles of confidentiality (23). These discussions should take place in paediatric services and CAMHS, with onward referral to primary care or sexual health services for contraceptive provision if required. A subsequent discussion in the presence of the parents/carers can *also* take place (but must respect confidentiality) and discussion between the girl and her parents/carers should be actively encouraged.

We consider that if competence has been demonstrated, then after discussion regarding the risks associated with use of valproate in pregnancy and in line with GMC guidance, it follows that contraceptive advice, provision of contraception and signing of the valproate ARAF is entirely appropriate for young women aged 13-15; parental consent would *not* be required, but should be encouraged.

Where ID is also present, there will be additional issues to consider (see below, main section 5).

### **4. Transition of care from paediatric services or CAMHS to adult services**

The transition of girls from paediatric epilepsy care or CAMHS to adult care is a time requiring particular care across the spectrum of health conditions. Anecdotal evidence suggests this is when a girl can fall between the gaps and local services should have clear policies about when the transition happens. It is essential to proactively ensure continuity

of care, including for use of valproate and the PPP, at a time when behavioural and compliance issues may be particularly acute, whilst conversely seizure or mood control on valproate may be good. Vigilant, seamless prescribing support is imperative in this cohort of young women due to lifestyle issues, increased risk of sudden unexpected death in epilepsy (SUDEP), potential interactions with contraception, balancing future risk of teratogenicity versus seizure control, and associated cognitive, hormonal, and psychiatric adverse effects of alternative antiepileptic drugs prescribed instead of valproate. For girls with moderate to severe ID, this transition process can be protracted as they often attend specialist schools until the age of 19 years or later.

All young people with **epilepsy**, with or without significant ID, should ideally participate in a transition process from the age of 12 years to specifically address the needs of this age group and plan for handover to adult services. This is essential for young women who remain on valproate treatment. In girls with **mental illness** the transition to adult services will normally occur around 18 years.

## 5. Women of childbearing potential

The MHRA regulations apply to both **epilepsy** and **bipolar disorder** and state:

*"In girls and women of childbearing potential (a pre-menopausal female who is capable of becoming pregnant) valproate must be initiated and supervised by a specialist experienced in the management of epilepsy or bipolar disorder. Valproate should not be used in girls and women of childbearing potential unless other treatments are ineffective or not tolerated. Valproate may be initiated in girls and women of childbearing potential only if the conditions of PREVENT – the valproate pregnancy prevention programme (PPP) are fulfilled."*

*"This includes women who are not currently sexually active unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy. Individual circumstances should be evaluated in each case, involving the patient in the discussion, to guarantee her engagement, discuss therapeutic options and ensure her understanding of the risks and the measures needed to minimise the risks."*

The regulations do not refer to specific age ranges.

### 5.1 Contraception for the PPP

When discussing the PPP, the information voluntarily provided by women and girls about their contraceptive choices should generally be taken in good faith to be accurate.

Prior to provision of contraception, appropriate valid consent must be obtained by the provider. For consent to be valid, the woman must (24):

- Have the mental capacity to make the decision
- Have enough information and opportunity for discussion prior to making a decision
- Be free from duress

Valid consent is obtained by the woman being informed of the nature and purpose of any proposed treatment and the likely outcome(s)—including any significant possible adverse outcomes and the likely result of not proceeding with the proposed treatment—so that she

can make an informed decision. Women must be treated as individuals and their wishes respected at all times (24).

Women of reproductive age who are using valproate are advised to use highly effective contraception to avoid pregnancy. Women should be made aware that no method of contraception is 100% effective (25).

Methods of contraception which are considered '*highly effective*' (1) include the long-acting reversible contraceptive (LARC) methods: copper intrauterine device (Cu-IUD), levonorgestrel 13.5mg/19.5mg/52mg intrauterine system and progestogen-only implant (IMP), as well as male and female sterilisation (with male sterilisation, the possibility of a new partner needs to be kept in mind). These methods all have a failure rate of less than 1% with typical use (Table 1) (26). Women using the progestogen-only implant should avoid use of any medication that induces hepatic enzyme activity as this could reduce contraceptive effectiveness (27).

**Table 1: Percentage of women experiencing an unintended pregnancy within the first year of use with typical use and perfect use** (modified from Trussell et al. (26))

Method	Typical use (%)	Perfect use (%)
No method	85	85
Fertility awareness-based methods	24	0.4–5
Female diaphragm	12	6
Male condom	18	2
Combined hormonal contraception (CHC) including combined contraceptive pill, transdermal patch and vaginal ring	9	0.3
Progestogen-only pill (POP)	9	0.3
Progestogen-only injectable depot medroxyprogesterone acetate (DMPA)	6	0.2
<b>Copper intrauterine device (Cu-IUD)</b>	<b>0.8</b>	<b>0.6</b>
<b>Levonorgestrel 13.5mg/19.5mg/52mg intrauterine system (LNG- IUS)</b>	<b>0.2</b>	<b>0.2</b>
<b>Progestogen-only implant (IMP)</b>	<b>0.05</b>	<b>0.05</b>
Female sterilisation	0.5	0.5
Vasectomy	0.15	0.1

The estimated typical use failure rate of combined hormonal contraception (CHC; the combined contraceptive pill, transdermal patch and vaginal ring) and progesterone-only pill (POP) is 9%; for the progestogen-only injectable intramuscular and subcutaneous depot medroxyprogesterone acetate (DMPA) it is 6%. Given the importance of avoiding pregnancy during use of known teratogenic drugs, the Faculty of Sexual & Reproductive Healthcare (FSRH) recommends that during use of valproate, women using CHC, POP or DMPA should be advised to use additional contraceptive precautions (e.g. condoms) (25).

It is important to note that ethinylestradiol (present in most combined contraceptive pills, the combined transdermal patch and the combined vaginal ring) may modestly reduce valproate levels (27). The contraceptive effectiveness of CHC, POP and IMP is not reduced by valproate, but may be reduced by use of other medications that induce liver enzymes; intrauterine contraception (IUC) (28) and the DMPA are not affected (29).

### **5.2 Contraceptive choice in young women**

Young age alone does not limit contraceptive choice. From menarche, the benefits of use of all effective reversible methods of contraception generally outweigh potential risks (22, 30). Young age and nulliparity do not contraindicate use of IUC (28). Despite concerns about achieving peak bone mineral density, use of DMPA by women under age 18 is acceptable if other methods have been discussed and considered unsuitable or unacceptable (22, 30). The UK Medical Eligibility Criteria for Contraceptive Use (UKMEC 2016) should be used to assist clinicians in determining which contraceptive methods can be used safely in young people with particular medical conditions/characteristics (30).

### **5.3 Contraception choice in older women**

Women aged 50 and over should be advised to avoid CHC due to associated cardiovascular and breast cancer risk (31). DMPA is generally avoided for women over 50 and for women over 40 with additional risk factors for osteoporosis (of which long term valproate use is one) because of concern regarding bone health. The Cu-IUD, LNG-IUS, IMP (and POP plus condoms) can all be used for contraception by a woman using valproate until age 55 years. The UKMEC 2016 should be used to determine safety of contraceptive use by women with other medical conditions (30).

In general, contraception is required until age 55 unless a clinical diagnosis of menopause is made before this time; spontaneous conception after age 55 is exceptionally rare. FSRH guidelines recommend that, *"women should be informed that although a natural decline in fertility occurs with age and spontaneous pregnancy is rare after age 50, effective contraception is required until menopause to prevent an unintended pregnancy"* (31).

Menopause can be diagnosed in a woman aged over 50 after one year of amenorrhoea (this applies only if the woman is not using hormonal contraception) (31). If a woman aged over 50 is very keen to stop contraception and has a follicle stimulating hormone level >30iU/L, she may consider stopping contraception a year later. However, this would not absolutely exclude future ovulation and risk of pregnancy, as hormone levels fluctuate widely in the peri-menopause. Post-menopausal women do not need to be referred for specialist advice for the PPP; however, it would be helpful to document their status on the ARAF.

### **5.4 Emergency contraception**

If a woman or girl is not compliant with the PPP, she should also be advised to seek emergency contraception, if appropriate, to prevent a pregnancy. If a woman using valproate has had unprotected intercourse, if all recent unprotected intercourse was within the last 5 days or she is within 5 days of the earliest likely date of ovulation, she should be offered a Cu-IUD, the most effective method of emergency contraception. If a Cu-IUD is not suitable or acceptable, she should be offered oral emergency contraception with effective contraception "quick started" immediately after levonorgestrel oral emergency contraception or 5 days after ulipristal acetate oral emergency contraception (32).

### 5.5 Adverse effects of contraception

When prescribing any medicine, the potential risks as well as the intended benefits of the medication(s) in question need to be considered. In this instance, the potential benefits of valproate, as well as the potential harms to the patient and to any future offspring, are well described. However, it is also important to consider that the contraception required as part of the PPP may also have potential adverse effects associated with its use e.g. irregular bleeding. The risk/benefit assessment and potential adverse effect profile is therefore more complex than for most other medications and may require coordinated specialist input. By consensus, most neurologists and psychiatrists responsible for recommending valproate use lack the knowledge, experience and communications skills about contraception needed for this aspect of the discussion. Healthcare professionals must recognise and work within the limits of their competence: appropriate referral is essential for implementation of the PPP. In some areas of the UK there are limitations in services for contraception provision. Each specialist clinic should foster relations with their local sexual and reproductive health (SRH) services so that there are special access pathways for these patients, who may be less able than other women to access SRH services directly without help from healthcare professionals.

### 5.6 Discontinuation or exchanging of valproate

Any fully informed discussion about the use of valproate must also present the risks of withdrawing or exchanging valproate for another agent.

In the context of **epilepsy**, the discussion will include the limited information available on the comparative effectiveness of different antiepileptic drugs in particular types of epilepsy (3, 33); additional data will be emerging from further comparative trials (e.g. SANAD2). Discussions should include the risk of unintended consequences of not taking valproate when this might be the best therapeutic option – such as the risks of loss of seizure control on its withdrawal (34, 35), or lack of control when its use may not even have been considered (36). The potential accompanying increased risk of SUDEP with lack of seizure control needs consideration. The proportion of maternal deaths related to epilepsy is estimated at between 4-7%; SUDEP is an important contributor to these deaths (37). Whilst overall maternal deaths fell over the 30 year period from 1979-2008, the proportion attributed to epilepsy has risen (38). Clinical experience also shows that in a proportion of individuals who recommence an antiepileptic drug that has been withdrawn, the previous degree of seizure control cannot be regained (39). Women who are in the process of gradually switching from valproate to alternative treatments should be counselled to continue using effective contraception, if they wish to avoid unintended pregnancy. Valproate has a mood-stabilising effect, and, separately, unintended consequences on mood need to be explained, as these can affect quality of life and seizure control.

In the context of **bipolar disorder**, if a non-pregnant woman wishes to withdraw her valproate she should be referred for specialist assessment. Under specialist care, valproate should be tapered down gradually (4).

### 5.7 Women choosing to remain on valproate, but without a PPP

This is a very contentious issue. Prescription and use of valproate in a woman of childbearing potential without a PPP would be outside its licence. The General Medical Council prescribing guideline outlines the roles and responsibilities of the prescriber (typically the GP) under these circumstances (12).

There will be women who wish to remain on valproate but do not want to comply with a PPP. This document does not take a position on such use, but seeks to provide guidance for healthcare professionals faced with this situation. Examples of these circumstances include: in the context of epilepsy, with its attendant risk of SUDEP and other impacts on quality of life (such as for driving privileges) (40), concern about the risks of changing to a different antiepileptic drug with either proven lack of, or unknown, efficacy in the individual patient. Patients may not consent to a PPP for personal, medical, religious or cultural reasons. In addition, there may be women who wish to avoid bleeding problems or side effects associated with some hormonal methods. The GMC consent process (currently under consultation) (41), states that:

*You **should** do your best to make sure that such patients have considered the available options and reached their own decision (clause 42).*

*You **must** respect a patient's decision to refuse an investigation or treatment, even if you think their decision is wrong or irrational (clause 43).*

It is essential that the discussion is fully documented, so that it is clear how it has been made, and following best practice all parties involved should be included in correspondence. Even if a woman is non-compliant with a PPP, it is unsafe to withhold the prescription of valproate.

In this situation the requirement for decisions to be fully informed must be followed. Patient support groups for families affected by in utero valproate exposure can offer information on the undesirable outcomes that can follow such exposure and relevant information and links are provided at the end of the document. Whilst the risks may be known, the actual outcomes may not be within the direct experience of healthcare professionals discussing valproate usage with women and girls of childbearing potential. A second professional opinion (e.g. another neurologist, psychiatrist, fetal medicine specialist, clinical geneticist) may be helpful for women choosing to remain on valproate without a PPP, though the reality of service provision issues need to be recognised. The discussion and decision need to be fully documented, revisited at least annually, with a mechanism for rapid review in case of changes, including pregnancy.

Important issues concerning the right to autonomy and societal values are beyond the scope of this document.

### **5.8 Intellectual Disability (ID)**

The prevalence of epilepsy is high in patients with ID: they constitute nearly 25% of the total population with epilepsy and 60% of the total population with treatment-resistant epilepsy (42). General considerations about capacity must always be borne in mind, including the possibility that capacity may fluctuate and should be considered with regard to the issue in hand (43).

Apart from epilepsy and bipolar disorder, valproate is sometimes prescribed to people with ID for the management of challenging behaviours: these include acts of aggression towards people or property, self-neglect, and self-harm and occur in 5–15% of people with ID (44). Scientific support for the efficacy of valproate in this area is very limited (45) and the most commonly prescribed drugs for challenging behaviour are antipsychotics. In clinical practice, valproate is also sometimes used in people with ID to manage mood

instability and fluctuations of arousal in the absence of a psychiatric diagnosis, but again the evidence base here is very limited.

Because of the lack of supporting evidence and valproate's unlicensed status for these problems, alternative management strategies should be pursued in girls and women with ID and childbearing potential. Discussions of the research evidence and detailed management guidance can be found in NICE (44) and RCPsych reports (4, 42, 45)

#### 5.8.1 With lack of mental capacity

There are women of childbearing potential in whom lack of mental capacity means that discussion with the woman herself cannot take place and in whom consent to sexual activity would be unlikely to be given, or impossible. This will include most girls and women with some specific epilepsy syndromes, such as Dravet Syndrome or Lennox-Gastaut Syndrome, for which valproate is the recommended first-line treatment (13). Valproate is typically also the first-line treatment for many other severe epilepsies ('developmental and epileptic encephalopathies') which are typically associated with ID.

The following statement from the MHRA guide needs consideration: "*For children or for patients without the capacity to make an informed decision, provide the information and advice on highly effective methods of contraception and on the use of valproate during pregnancy to their parents/caregiver/responsible person and make sure they clearly understand the content.*" For women in this category, we recommend discussion with the family and the care providers to evaluate whether sexual activity is likely to occur or not. If it is agreed that there is no risk of pregnancy, the ARAF should be completed on at least one occasion. The discussion should be clearly documented in medical records and relevant correspondence, and the position should be reviewed at least annually in case of changes in circumstances. It is important to recognise that these discussions in themselves are difficult and can cause psychological distress for any party involved.

#### 5.8.2 With mental capacity

Girls and women with mild ID and mental capacity should be involved in the discussion wherever possible. Careful evaluation will be required in this setting: the PPP and ARAF will be necessary if there is judged to be childbearing potential. Capacity needs to be considered in each individual situation e.g. consent to have sex is not the same as consenting to use contraception. Women with ID have the right to be sexually active if this is consensual, but healthcare professionals also need to be alert to the possibility of sexual abuse.

Involvement and use of best interest meetings, adult safeguarding, Mental Health Capacity Advocacy, Court of Protection, community ID services, hospital leads for people with ID, and others involved in supporting the individual woman may be required, in order to balance working in their best interests, sexual human rights and least invasive therapy. Many of these issues are discussed in a useful paper (46).

### **5.9 Women who fail to attend their specialist appointment**

Some women who are on valproate and have childbearing potential may miss their appointment for specialist assessment and may be at risk of a valproate-affected pregnancy. In this situation, the specialist needs to follow up, by re-inviting the woman, attempting a telephone discussion and by contacting the GP. Good communication

between service providers and the patient is clearly very important: the letter from the specialist needs to explicitly identify the risks of a valproate-affected pregnancy and to request the GP to proactively contact the woman to discuss. The onus and responsibility then lies with the prescriber to decide how to manage this situation, which would involve prescribing outside the licence. Taking advice and scrupulous documentation are clearly very important, but the GP needs to carefully consider the risks of failing to prescribe.

### **5.10 Prescribing responsibility: consider shared care**

Most specialist services will request the GP to issue valproate prescriptions for their patients. As far as the GMC is concerned, the prescriber takes the responsibility and must be competent to do so (12). Not all GPs can be expected to accept this responsibility if they feel this involves them practising beyond their level of competence. Shared care is another way for the responsibility of prescribing to be distributed between specialist and GP. However, the doctor who signs a prescription will still be responsible, even in shared care (47).

In addition, all parties, including the patient, must be willing to accept this arrangement. Shared responsibility, education, communication and support in getting rapid advice may reassure the GP and it is our consensus view that all those involved consider moving towards this as the usual way in which valproate prescribing should be arranged.

### **5.11 Particular situations that may arise**

#### 5.11.1 Status epilepticus

Although NICE protocols for the management of this acute medical emergency do not include valproate, its intravenous formulation (and those of other antiepileptic drugs) is not uncommonly used for status epilepticus (48). Best interest considerations will apply in the acute setting. Whilst an urgent pregnancy test is not always part of protocols for treatment of status, it would be prudent for this to be included, and should be undertaken if valproate is to be used, but should not delay treatment of this life-threatening emergency. Antiepileptic drugs introduced for seizure control in status may or may not be continued on recovery, and discussion will need to include following the usual PPP if valproate continuation is being considered.

#### 5.11.2 Women on valproate who are detained in prison

There may be additional confounding factors, such as mental illness or substance abuse. Healthcare services in prison are commissioned separately by NHS England (49). However, medical management still needs to follow MHRA regulations, and women should have access to specialist epilepsy, mental health and contraceptive services, including access to valproate if its use is considered best: the principles of care remain unchanged.

#### 5.11.3 Women detained under the Mental Health Act (MHA)

An acute and severe episode of mania is the most likely clinical scenario where reproductive safety issues of valproate could arise in a girl or woman detained under the MHA. Valproate should only be considered in patients who have had an insufficient treatment response to other medications and for whom there are good reasons not to use electroconvulsive therapy (ECT). Sexual disinhibition and impaired judgement are common in acutely ill manic patients, so that a girl or woman with childbearing potential is at an elevated risk of unintended pregnancy. It would be unlikely that she has the mental capacity to consent to sexual activity, so that it becomes the responsibility of the clinical team to prevent her from having intercourse and to put appropriate measures in place.

Her mental capacity needs to be assessed repeatedly to permit discussions with the patient or carer according to the PPP as soon as her mental state has sufficiently improved.

Once the patient's mood has stabilized it may be possible to cautiously rationalise medication ideally withdrawing valproate and replacing it with an alternative drug if necessary. It is essential that plans for treatment, need for contraception and proactive follow up are discussed with the community mental health team to whom the patient's care is transferred on discharge from hospital. It is the responsibility of the mental health team to communicate actions clearly with the GP and agree which professional is responsible for ensuring that they are followed up. Clinical experience shows that transition between services can be a time when a patient 'falls through the gap'.

In a pregnant woman with a mental disorder detained under the Mental Health Act, valproate should not be initiated, and other drug treatments or ECT should be used (4, 50).

### **5.12 Pharmacies and valproate dispensation**

Pharmacists have been advised that they need, on presentation of a prescription for valproate, to discuss the warnings about its use with the patient, and through doing so should be able to determine if there is a PPP in place or not. If not, the patient should be referred back to their GP, but the prescription should still be dispensed. The pharmacy pathway is available from the RPS (51). Dispensing GPs need to ensure that their pharmacy technicians are aware of this guidance.

## **6. Women not at risk of pregnancy for other reasons**

There will be women who are not at risk of pregnancy for health-related, physical or personal reasons. Examples include women who have had a hysterectomy or tubal ligation, a woman in a long term monogamous relationship with a vasectomised male partner, women in same sex relationships not planning pregnancy or a transgender woman who does not have a uterus. The reason for no contraception being needed in such cases can be documented on the ARAF and wherever appropriate reviewed annually. In addition, it is recommended that such information is documented in the patient records and relevant clinical correspondence. If the reason for not being at risk of pregnancy is permanent, annual specialist review from the perspective of the regulations per se should not be necessary, but may be indicated for the underlying condition. There may be other compelling reasons that will need to be considered on an individual basis, such as religious convictions.

If the reason for not being at risk of pregnancy is not considered permanent, the woman needs to be fully aware of the high likelihood of serious harm to the child if she should conceive, and attend for annual specialist review and completion of the ARAF, in line with the PPP. For women detained under the MHA, see above.

## **7. Pregnancy in women on valproate**

Despite the change in the prescribing regulations for valproate, some women will still become pregnant whilst taking valproate. Whatever their diagnosis, they should be

referred for an urgent appointment with an appropriate specialist and advised to continue their medication until seen, because of the high risks of stopping abruptly.

There will be some women who understand the issues, and after consideration, decide that continuing valproate during a pregnancy is a better option for them than the consequences of stopping valproate.

In the **context of a pregnancy in a woman with epilepsy**, detailed discussion will be necessary between the woman, her obstetrician and neurologist, especially to attempt to minimise risk (52).

Valproate is contraindicated in bipolar disorder in pregnancy. In the **context of a pregnancy in a girl or woman with bipolar disorder** a referral for an urgent appointment with a psychiatrist and obstetrician should be made. She should be advised to continue the medication until seen because she would be at a high risk of rapid deterioration if valproate is abruptly stopped. To avoid this, valproate should be tapered down gradually (4). All treatment options to reduce the risk of recurrence and optimize the woman's mental health in pregnancy should be offered and discussed with her. Services should work with the woman to develop a comprehensive care plan for the perinatal period that is appropriate for her individual needs. It is important that the community or specialist mental health midwife works closely with the team and that the obstetrician, GP and all other involved agencies know about the care plan. This is particularly important around the time of delivery and the early postnatal period when the woman is most likely to relapse. Perinatal mental health services can also provide assessment, consultation and management advice for pregnant girls whilst their main care remains with services for child and adolescent mental health and intellectual disabilities.

The woman may decide that she wishes to consider termination of the pregnancy, and in such cases she would meet the relevant criteria under [Section 1.1.d of the Abortion Act 1967](#) ("that there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped").

If the woman decides to continue with the pregnancy, this should be managed as described in Royal College of Obstetrics and Gynaecology (RCOG) guidelines (53). Women should receive timely and non-judgmental support and advice throughout their pregnancy, and be encouraged to engage with their obstetric and specialist care. There is a risk that if the woman perceives the care as judgemental she may disengage from all care.

## **8. Other issues**

### **8.1 Which healthcare professionals can be considered as specialists?**

The latest guide for HCPs (54) from the MHRA notes:

*"Specialist prescriber is defined as a consultant psychiatrist or a consultant neurologist who regularly manages bipolar disorder or complex epilepsy".*

However, there is an expectation that some functions to support the PPP may be carried out by other healthcare professionals as part of a consultant-led team.

**8.2 Epilepsy Specialist Nurses (ESN) and specialist midwives**

Epilepsy specialist nurses (and specialist midwives during planning for pregnancy, pregnancy and post-natally) are in an excellent position to support girls and women with epilepsy taking valproate. For the purposes of this guidance, they should be regarded as specialists and are integral to the process. There would be different levels of responsibility depending on whether the nurse held an independent prescribing qualification or not.

Epilepsy specialist nurses with an independent prescribing qualification will be able to see women and girls taking valproate, advise on an appropriate alternative drug, or on appropriate contraception in line with the PPP, and complete the ARAF. They would also be in a position to initiate valproate for women who satisfy the terms of the PPP and for whom alternative treatment is unsuitable. This decision should be taken as part of a multidisciplinary team, involving a consultant neurologist.

Epilepsy specialist nurses who do not hold an independent prescribing qualification will have local governance arrangements, whereby recommendations they make would be ratified by a consultant neurologist. This would be the same process used by nurses without a prescribing qualification when changing medication for other reasons. Following a decision from the multidisciplinary team, which would include a consultant neurologist, an epilepsy specialist nurse without a prescribing qualification would be able to provide ongoing management and support for a woman continuing to take valproate, and complete the annual PPP risk assessment. Nurses without an independent prescribing qualification would not be able to recommend the initiation of valproate without referral to a consultant neurologist.

**8.3 GPs with an extended role in epilepsy (GPwERs)**

GPwERs exist in some areas of the country (e.g. Bradford) and have the necessary skills to undertake the specialist role described by the MHRA. They are in a particularly good position to provide long-term continuity of care, to see women closer to home and to advise women about appropriate contraception. The competencies required have been described (55). They can initiate valproate for women who satisfy the terms of the PPP and for whom alternative treatment is unsuitable. It would be good practice for this decision to be taken as part of a multidisciplinary team, involving a consultant neurologist. In Bradford, where the service is commissioned, GPwERs are ideally placed to deal with the vast majority of this work, with the support of local neurologists.

**8.4 Adoption and surrogacy**

Women on valproate may need support and encouragement to approach adoption. However, uncontrolled seizures may in some circumstances be considered a safeguarding risk and as a result adoption may be declined. Another option may be surrogacy. Surrogacy is legal in the UK and a pathway was published in February 2018 (56). Currently, it is only available privately, and would be financially prohibitive for many women. It is unknown if surrogacy protects from all risks: it is not known if there is a potential risk through an ovum exposed to valproate before ovarian retrieval in the in vitro fertilisation process. However, women in these difficult circumstances need support and exploring the option of surrogacy on the NHS for appropriate women on valproate should be considered by NICE for cost-effectiveness.

## 9. Babies born to women who have taken valproate during pregnancy

At the moment there is no standard follow up pathway for babies born to mothers who have taken valproate during pregnancy. If no abnormalities are obvious at birth the baby is usually discharged with instructions to be referred back if problems develop. However neurodevelopmental issues may be subtle and overlooked by generalist healthcare professionals. Moreover, some neurodevelopmental issues, especially if mild, cannot be diagnosed until much later in childhood, at which point maternal medication history in pregnancy may either not be available or not considered. In addition, fetal valproate syndrome is not recognised yet by the International Classification of Diseases (ICD); the closest classification is fetal anticonvulsant syndrome (FACS). Families may be reluctant or less able to seek help. All harm to these babies can be documented on a [Yellow Card](#) and they should be referred to the Valproate Register when it is operational.

There are some simple steps that could be taken. Midwives could notify the GP and Health Visitor on discharge from hospital that the baby has been exposed to valproate (or other antiepileptic drugs) in utero. This should be coded on medical records and entered into the baby's "Red Book". The best way for standardised coding across settings will need to be defined. Health visitors should be competent to monitor for FACS during child development checks, so that they are able to identify and refer early. In order to fulfil this role, they need access to training and resources.

It is our consensus view that specialist routine follow up of all babies at risk of FACS should be recommended, so that health, education and social care services can optimise the care of these children and help their families. The details of how this should happen and how it will be funded need to be developed. The Valproate Register could be a means of facilitating this. The UK Epilepsy and Pregnancy Register, which has provided important evidence on valproate risks, should also be considered.

### Concluding remarks

Valproate use is now under strict regulation. Complicated situations can arise that require careful thought and may need referral for specialist management. We recognise that not all scenarios are covered in this document, and that regulations and associated guidance may change over the coming period of time. Most importantly, clinicians must pay close attention to each particular girl or woman's circumstances, and always act in their best interests.

**Patient Support Networks**

<a href="#">Bipolar UK</a>	0333 323 3880
<a href="#">Epilepsy Action</a>	0808 800 5050
<a href="#">Epilepsy Society</a>	0149 460 1400
<a href="#">FACSaware</a>	0116 220 0486
<a href="#">Meds and Birth Defects</a>	0208 386 9271
<a href="#">Mind</a>	0300 123 3393
<a href="#">OACS</a>	0790 420 0364
<a href="#">SUDEP Action</a>	0123 577 2850
<a href="#">UK Epilepsy and Pregnancy Register</a>	0800 389 1248

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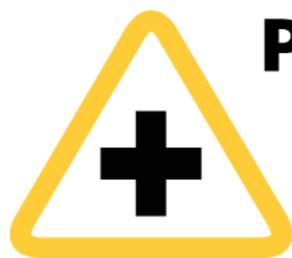
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# Patient Safety Alert

## Resources to support safer bowel care for patients at risk of autonomic dysreflexia

25 July 2018

Alert reference number: NHS/PSA/RE/2018/005

### Resource Alert

Patients with spinal cord injury or neurological conditions may have neurogenic bowel dysfunction, which often means they depend on routine interventional bowel care, including the digital (manual) removal of faeces (DRF).

Some of these patients, especially those with spinal cord injury above T6, are particularly susceptible to the potentially life-threatening condition autonomic dysreflexia, which is characterised by a rapid rise in blood pressure, risking cerebral haemorrhage and death. A small number of patients who have had a severe stroke or who have severe forms of Parkinson's Disease, multiple sclerosis, cerebral palsy, or spina bifida may also be susceptible to autonomic dysreflexia.

Autonomic dysreflexia can be caused by non-adherence to a patient's usual bowel routine or during or following interventional bowel care. For all of these patients, bowel care is vital for their health and dignity.

Patients have made NHS Improvement aware of difficulties ensuring their regular bowel care is provided when they come into hospital or mental health units, or access other NHS care such as community care. For example, one patient said:

"Despite explaining my situation, I had to wait eight days for an enema. I'd had shoulder surgery so couldn't do it myself. Had the beginnings of autonomic dysreflexia."

A search of the National Reporting and Learning System (NRLS) over a four-and-a-half-year period identified 61 reports of significant delays in providing DRF or an appropriate alternative, including three cases of autonomic dysreflexia. Reports came from acute hospitals, community services and care homes.

The key issues appeared to be a lack of staff with the training and experience to perform DRF (particularly as opportunities to learn and practice are limited outside of spinal injuries units and community teams who regularly undertake this procedure), or an inability to identify staff with the appropriate training.

The search also indicated:

- unclear local policies stating who could perform DRF, including the patient's carers or healthcare professionals from another provider
- lack of knowledge of relevant clinical guidance
- uncertainty over requirement for and provision of training
- uncertainty over using alternative methods of bowel management
- a mistaken belief that this type of care constitutes assault.

Despite a previous Patient Safety Alert,<sup>1</sup> national clinical guidance,<sup>2,3</sup> profession-specific guidance<sup>4,5,6,7</sup> and patient resources,<sup>8</sup> issues persist that cause patients distress and can put them at risk of severe harm or death. Providers have indicated that additional resources to develop and maintain staff skills in this area would be helpful. This alert provides links to a [range of resources](#)<sup>9</sup> to support safer bowel care for patients at risk of autonomic dysreflexia, and highlights the publication of [NHS England's Excellence in continence care guidance 2018](#)<sup>10</sup> which addresses how providers can overcome implementation challenges.

## Actions

**Who:** All providers of NHS-funded inpatient and community healthcare\*

**When:** To begin as soon as possible and be completed by 25 January 2019

- 1 Identify an appropriate clinical leader to co-ordinate implementation of this alert.
- 2 Using the resources referred to in this alert, review your local clinical policy and guidance relating to bowel assessment and management.
- 3 Review your local education and training provision for interventional bowel management, and develop an action plan to ensure patients have adequate and timely access to staff who are appropriately trained to carry out these procedures, including in the evening and at weekends.
- 4 Share your reviewed local guidance, advice on how to identify staff who can provide DRF, and the key messages in this alert with medical, nursing and other relevant clinical staff.

\*GPs would not be expected to lead on policy/training actions but should be aware of the need to act quickly, and appropriately escalate care for affected patients.

## Sharing resources and examples of work

If you are aware of any resources or examples of work developed in relation to this alert that you think would be useful to others, please share them with us by emailing [patientsafety.enquiries@nhs.net](mailto:patientsafety.enquiries@nhs.net)

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Alert reference number: NHS/PSA/RE/2018/005

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Resource Alert

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### NRLS search dates and terms

The NRLS was searched for incidents occurring on or after 13 May 2013 if reported by 19 May 2016, and this search was updated for incidents occurring on or after 13 May 2013 if reported between 19 May 2016 and 1 December 2017, using the search terms [%stool% or %faeces% or %bowel%] AND [%manual% or %digital%] AND [%remov% or %evac%]. This combined search yielded 61 relevant reports describing difficulties providing appropriate bowel care, including three incidents where autonomic dysreflexia had occurred.

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10. NHS England (updated 2018) Excellence in continence care framework <https://www.england.nhs.uk/publication/excellence-in-continence-care/>

### Resources

- The resources to support the implementation of this Alert are available on the NHS Improvement website <https://improvement.nhs.uk/resources/resources-to-support-safer-bowel-care-for-patients-at-risk-of-autonomic-dysreflexia>

### Stakeholder engagement

- Royal College of Nursing Continence Forum
- NHS England Excellence in Continence Care Committee
- The Spinal Injuries Association
- National Patient Safety Response Advisory Panel (for a list of members and organisations represented on the panel, see [improvement.nhs.uk/resources/patient-safety-alerts/](https://improvement.nhs.uk/resources/patient-safety-alerts/))

### Advice for Central Alerting System officers and risk managers

This alert is particularly relevant to all healthcare services where patients with existing spinal cord injury may need care for other conditions, and is likely to include community nursing services and mental health inpatient units, as well as acute hospitals for adults and children, and care homes.

This alert requires central co-ordination of a revision to local policies and training, so should not be widely circulated until these have been developed.

If you are unsure who to direct this alert to, your local continence nurse specialist will be able to signpost the medical, nursing and allied health professional staff and educational leads who will coordinate local implementation of this alert.



# Patient Safety Alert

## *Risk of harm from inappropriate placement of pulse oximeter probes*

18 December 2018

Alert reference number: NHS/PSA/W/2018/009

Warning Alert

Measurement of oxygen saturation, using a pulse oximeter probe, is routinely undertaken as part of patients' vital signs during diagnosis and ongoing monitoring. Oxygen saturation readings are a key component of the National Early Warning Score (NEWS2).<sup>1</sup>

Oximeter probes can be single or multiple use and are designed to attach to specific parts of the body. Adult oximeter probes can be attached to either a finger or an ear, but are not interchangeable between these sites, whilst probes for babies and children need to be selected according to the patient's weight.

If an oximeter probe intended for the finger is attached to the ear (or vice versa), or a probe intended for an adult is attached to a baby or a child (or vice versa), it can produce a reading up to 50% lower or 30% higher than the real value.<sup>2,3,4</sup> The clinical implication of an inaccurately high reading, especially as part of NEWS2, is that staff may be falsely reassured about a patient's condition, when in reality the patient is deteriorating, or may make an inappropriate intervention when in fact a patient is stable or improving.

The national patient safety team was made aware that this issue may be under-recognised. To gain further information, we carried out a survey of clinical staff and observed clinical practice. Key issues identified were:

- a substantial proportion of staff do not know that finger probes can give misleading results if attached to ears
- a quarter said they do not have access to probes specifically for the ear, even though in almost all clinical settings some patients will need these
- once probes are removed from their packaging there is no easily visible prompt to remind the user where to attach the probe
- staff may not be aware of other factors that can affect the accuracy of the reading.

Although no reports were found in the National Reporting and Learning System (NRLS) relating to this issue, the scale of these gaps in knowledge and equipment suggests the potential for severe patient harm is high.

The local actions required by this alert will help reduce the risk of incorrect probe selection and placement. To reinforce and embed these local changes, NHS Improvement and the Medicines and Healthcare products Regulatory Agency (MHRA) are asking manufacturers to review device labelling and provide prompts for correct attachment. NHS Improvement have also asked the Clinical and Products Assurance (CAPA) arm of NHS Supply Chain (NHSSC) to review the oximeter probe descriptions in its catalogue.

### Actions

**Who:** All organisations providing NHS funded-care where oxygen saturation probes are used as part of routine or emergency monitoring of patients

**When:** To commence immediately and actions completed by 18 June 2019

- 1 Identify a clinical leader to bring together people with responsibilities for medical device training and education, clinical skills assessment, NEWS2 implementation and procurement of pulse oximeters.
- 2 Develop an action plan to reduce the risk of inappropriate placement of pulse oximetry probes. This should:
  - arrange for ongoing access to adult finger and ear probes in all clinical areas where oximetry is used (including for the range required for babies and children where appropriate)
  - provide point-of-use reminders on why it is vital to use the correct probe for fingers and for ears, and for babies and children
  - provide point-of-use reminders on other factors that may interfere with the accuracy of the reading.
- 3 Once your organisation's action plan for managing these risks has been agreed, communicate the key messages in this alert and the plan to relevant clinical staff, clinical education/training staff, and patients or their carers who self-monitor oxygen saturation levels.