

Notes From Nottingham and Nottinghamshire ICS NatPSA Sodium Valproate Stakeholders Meeting

Wednesday 13th December 2023

9.00-10.30 am via MS Teams

Present:

NHS Nottingham & Nottinghamshire ICB

Nottingham University Hospitals

Nottinghamshire Healthcare Trust

Sherwood Forest Hospitals Trust

General Practice

Primary Integrated Community Services

No.	Item	Action
1.	Welcome, Introductions & Apologies ICB welcomed everyone to the meeting and a full round of introductions took place.	
2.	Overview of Nat PSA – ICB Quality Assurance and Governance process ICB explained that this meeting was being held following receipt of an MHRA National Patient Safety Alert regarding Valproate: organisations to prepare for the new regulatory measures for oversight of prescribing valproate to new patients and existing female patients. The MHRA is asking organisations to put a plan in place to implement new regulatory measures for valproate following a comprehensive review of safety data and liaison with various clinicians and organisations. There is now known significant risk to serious harm to a baby after exposure to valproate in pregnancy, and these measures aim to ensure valproate is only used if other treatments are ineffective or not tolerated, and that any use of valproate in women of childbearing potential who cannot be treated with other medicines is in accordance with the PPP. The regulatory change in January 2024 for valproate medicines means that:- - Valproate must not be started in new patients younger than 55 years unless 2 specialists independently consider and document that there is no other effective/tolerated treatment, or there are compelling reasons that the reproductive risks do not apply. - At the patients next specialist review, women of childbearing age should be reviewed using a revised valproate Risk Acknowledgment Form (RAF) which will include the need for a second specialist signature if the patient is to continue with valproate. ICB advised that by 31 st January 2024 this group will need to co-ordinate the implementation of the new regulatory measures. The need to update local guidance and protocols relating to the prescribing of valproate to reflect the new regulatory position including the roles and responsibilities of clinicians and provider organisations along with the recording of compliance with the risk forms is required.	

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	The group needs to produce an action and improvement plan that is communicated with all relevant staff to ensure smooth implementation of the new regulatory measures and allow continuous improvement in the care of patients. The group will need the right remit and delegation to carry out this work. The ICB are to implement co-ordination of the alert. The group will have until the end of January 2024 to pull together an action and improvement plan. ICB reported that much work has already taken place in Nottinghamshire around valproate. In terms of the governance process this group will include relevant stakeholders and our medicines safety leads, and clinician links are all in place. The group will feed into the ICS Medicines Optimisation Programme Board and the ICB Quality & People Committee. The action plan will contain the 5 main sections of the alert.	
3.	Sodium Valproate – Nottinghamshire picture ICB presented some slides which were shown at an MSO Network Group meeting in September 2023 which XXXXX, Patient Safety Specialist and Clinical Improvement, Lead Medicines Safety Improvement Programme at NHSE attended. September data showed that approximately 3,220 patients in Nottinghamshire were prescribed valproate of which 2,020 patients were male and 1,200 were female. The average patient age is 50 with the youngest being 1 year old and the oldest being 103 years. 78% of the patients have an epilepsy diagnosis, 6% a bi-polar diagnosis and 0.9% a bi-polar and epilepsy diagnosis. Nottinghamshire Healthcare Trust (NHT) stated that getting appropriate specialist engagement in the process may be a challenge and he agreed to talk to key opinion leaders. Another challenge is locating some patients and getting them to attend reviews. Nottinghamshire Healthcare Trust advised that an audit carried out in October 2022 showed 25 patients of childbearing age taking valproate but did not take compliant PPP, and unfortunately that figure has risen to 23 patients. NHT stated a template may be needed for medics, nursing staff and pharmacists for when a patient is not compliant with PPP. Perhaps a Trust wide register covering adult mental health and community services would also be beneficial. Forensics can also be a problem, as low secure forensic patients do eventually go out into the community and access primary care.	
4.	Draft Action and Improvement Plan The main areas that need to feed into the action plan are:- • Communication and planning • Guidance section • Commissioning work • Reviewing local audit results • Commissioning and determining local pathways • Planning for identification of clinical resource ICB spoke of needing to keep a track of what and when we send out communications. All primary and secondary care documents will need updating.	

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	NHT like to stagger the communications that they send out. Clinical leadership from medical and nursing colleagues will be important. Communications for patients will need to be addressed sensibly and with understanding, with perhaps help from a PPI working group. It was suggested that maybe a 'comms cell' would be of use. It was noted that a national communication had not been mentioned, and that that level of work may take a while to be ratified. NHT reported that many third sector charitable organisations are likely to be talking to their members about the alert and may be developing their own information and resources. ICB stated that evidence will be needed to show work on updates to paperwork, protocols etc.	
5.	Organisational Feedback, Considerations and Actions NUH – advised that a meeting at NUH was taking place on 13th December 2023 to determine what work is needed following receipt of the alert. Paediatricians, pain and neurology have been invited to attend. ICB asked for any outcomes following the meeting on 13th December 2023 to be advised to this group. SFHT – stated that SFHT follow an NUH/SFHT model and would look into how patients are covered. ICB spoke of the potential to do collaborative communications for NUH/SFHT. ICB asked if the group felt that the right people were in this meeting to have the discussions needed, and do we have the right clinical leadership ? Do we think input from obstetricians may be of help, which SFH agreed to look into. A range of different specialists need to be linked in. ICB spoke of stakeholder mapping and asked all organisations to ensure they have the relevant people engaging. NHT agreed to send a named lead to ICB in contraceptive services for her to link in with. PICS advised that primary care do not always see a copy of the patients risk assessment form. Data is only as good as coding. We need to find a way to interact with patients who do not attend regular reviews and suggested that community pharmacists be included in communications as they see patients when dispensing. DBH – reported that he had not been sighted on any work around valproate, but it maybe be being addressed in South Yorkshire. ICB spoke of needing to understand the South Yorkshire element. From a neurology perspective any Bassetlaw patients are seen in South Yorkshire, and NHT cover MH services in Bassetlaw. ICB spoke of the potential reclassification of sodium valproate to Amber 1 for all patients, and Red would cause a stir within the Trust. A possible alert around valproate and male patients may come out in early 2024, and there may be a need to look at commissioning and workforce if this additional work does come through. Men can father children when they're over 55 years of age, and 2% of the	

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	male population do father children aged over 55 years, so they will need valproate information. ICB stated in terms of local guidance nationally some education materials will become available for us to integrate into local guidance. The new national forms are being updated which we will also need to integrate into local policies and procedures. ICB reported that part of this work is for us to plan for double signatures. The second specialist signatory could include:- • Consultant adults or paediatric neurologists • Consultant psychiatrists • Speciality and associate specialist doctors in psychiatry and neurology • Specialist doctors in psychiatry • Paediatrician with special interest in epilepsy • Paediatrician who regularly manages complex epilepsy or bipolar disorder • Epilepsy nurse consultant • Specialist nurses in relevant disciplines NHT has recently looked at some RAF forms, and they were not very good. Some of the forms were incomplete. RAF forms are currently being addressed to make improvements.	
6.	Agreement of Next Steps ICB advised that the next meeting of the group was arranged for 24th January 2024. If any organisations need any help or support from the ICB team this can be offered – ICB are more than happy to help. The Nottinghamshire MSO Network meeting in January 2024 will have Valproate on its meeting agenda. ICB reminded the group of the following:- • Feedback from all stakeholder groups required • Look at engaging relevant clinicians • ICB will share spreadsheets, but be aware that the regional team may also send items out • Communications – possible ‘comms cell’. What communications do we need in place for clinicians, primary care and patients • NUH feedback • What do primary care and PCN need ? What work can be completed in primary care • Bassetlaw update required – link in with South Yorkshire ICB advised that the ICB is planning to send out communication to PCNs and GPs advising on conversations around Valproate. ICB highlighted that locating paperwork for patients can be a problem, where is it kept ? It was agreed for a further stakeholder group meeting to be arranged for the second week in January 2024 and then a final meeting already arranged for 24th January 2024. ICB thanked everyone for their time and attending this meeting.	

No.	Item	Action
	Date of next meetings: Wednesday 10 th January 2024 – 11am – 12 noon Wednesday 24 th January 2024 – 9am - 10.50am	