METHADONE AND ECG MONITORING PROTOCOL

Document Reference	Prot532
Version Number	1.1
Author/Lead **Job Title**	Dr Soraya Mayet (Consultant Psychiatrist) Dawn Fawcett (Non Medical Prescribing Lead) East Riding Partnership Addictions Service
Director's sign off **(Name, role and Date)**	Dr Kwame Fofie, Medical Director
Consultation (Date and nature of contact)	East Riding Partnership Clinical Network meeting 7th February 2023 Drug & Therapeutic Group 30th March 2023
Date of Last Changes (This Version)	2 August 2023
Date of Next Review	August 2026
Date approved and name of Approving Group	Director Sign-Off (Dr Kwame Fofie – 2 August 2023)

VALIDITY – Protocols should be accessed via the Trust intranet to ensure the current version is used.

CHANGE RECORD

Version	Date	Change details
1.0	*27 Feb 2020*	*New protocol.*
1.0	*1 Jul 2020*	*Updated to corporate template.*
1.1	*2 Aug 2023*	*Reviewed. Minor changes in grammer. Section 4 - Duties and responsibilities identified. Section 8 - Reporting groups names updated. Approved by director sign-off (Dr Kwame Fofie – 2 August 2023).*

Contents

1. INTRODUCTION

Methadone maintenance pharmacotherapy has been associated with QTc prolongation on the electrocardiogram (ECG). QTc prolongation has a risk of torsade de pointes a rare polymorphic ventricular tachycardia associated with sudden death. It is important to highlight 'the risk of QT prolongation in patients taking methadone, especially at high doses'. It was recommended that there should be 'careful monitoring' for patients on high dose Methadone (>100mg daily) and/or with other QT interval prolongation risk factors including heart or liver disease, electrolyte abnormalities, concomitant treatment with CYP 3A4 inhibitors, or other drugs with the potential to cause QT interval prolongation (MHRA and Commission for Human Medicines 2006, DH 2017).

2. SCOPE

Criteria and Standards MHRA & Commission for Human Medicines 2006

Cases of QT interval prolongation and torsade de pointes have been reported during treatment with Methadone, particularly at high doses (>100 mg/d). Methadone should be administered with caution to patients at risk for development of prolonged QT interval as below:

1. History of cardiac conduction abnormalities;
2. Advanced heart disease or ischaemic heart disease;
3. Liver disease;
4. Family history of sudden death;
5. Electrolyte abnormalities, i.e. hypokalaemia, hypomagnesaemia;
6. Concomitant treatment with drugs that have a potential for QT prolongation;
7. Concomitant treatment with drugs which may cause electrolyte abnormalities;
8. Concomitant treatment with cytochrome P450 CYP3A4 inhibitors.

For patients with recognised risk factors for QT prolongation, or in case of concomitant treatment with drugs that have a potential for QT prolongation, ECG monitoring is recommended prior to Methadone treatment, with a further ECG test at dose stabilisation. ECG monitoring is recommended in patients without recognised risk factors for QT prolongation, before dose titration above 100mg/d and at a suggested seven days after titration.

3. PROTOCOL STATEMENT

As Methadone is prescribed by East Riding Partnership (ERP) Addictions Service, it is important that all patients receiving specialist care are offered an ECG if clinically indicated. Those patients prescribed > 100mg methadone daily should have (as a minimum) an annual ECG undertaken throughout the period of being prescribed 100mgs or over. ECGs can be carried out by the service (ERP) when related to Methadone prescribing.

4. DUTIES & RESPONSIBILITIES

Medical Director
Is responsible for ensuring the protocol is in place and all staff working in the Trust are aware of, comply with and operate within this protocol.

Clinical Leads / Modern Matrons / Service Managers / Team Leaders

- Are responsible for ensuring staff have access to this protocol and other relevant SOPS and polices along with training and support
- Are responsible for ensuring that all areas under their sphere of responsibility have appropriate procedures in place and these are adhered to

Prescribers (including Protocol Lead)
Have responsibility for identifying and ensuring ECG monitoring for those patients who meet the Protocol criteria, or those anticipated to, due to a methadone titration plan going to/beyond 100mg/ml daily.

Key workers
Ensure that services users on their case load, who meet the Protocol criteria, are booked for an ECG screening at least annually and the ECG result is sign-off by a doctor.

Administrators
Have responsibility for scanning/tasking/emailing a copy of the ECG recording to the identified doctor.

5. PROCEDURES

Who needs an ECG?
- Patients prescribed ≥100mg Methadone daily.
- Patients with other QT risk factors including heart or liver disease, electrolyte abnormalities, concomitant treatment with CYP 3A4 inhibitors, or other drugs with the potential to cause QT interval prolongation.
- All keyworkers should contact the GP for an up to date medication summary every three months if the patient records are not accessible via SystmOne. This information should be made available to the doctor or prescriber completing the 3 monthly Prescriber reviews.

Screening
- The patients who are prescribed Methadone ≥ 100mg daily should be identified via the prescription record by the keyworker/nurse/doctor.
- If no ECG recorded within past 12 months, ECG required.
- A screening questionnaire could be used to aid decision making if unclear whether an ECG is required – see Table 2.

How to arrange the ECG?
All patients prescribed ≥ 100 mg Methadone daily are offered an ECG within the Addictions Service. For outreach clinics, the patient may request that the local GP undertakes the ECG and this can be discussed with the GP.

If the patient requests that the GP undertake the ECG (or it is not possible to undertake the ECG at the Addictions Service) a formal referral must be made by letter.

If the patient opts for an ECG at the Addictions Service, the patient should be given the ECG as soon as possible via an appointment system. The planned appointment needs to be recorded in the patient notes.

Who conducts the ECG at the Addictions Service?
Trained Registered nurses (RN) and Band 3/4 Recovery workers/Associate Nurse.

When should the ECG be carried out?
This can be booked at the next available opportunity.

What should happen to the ECG once conducted at the Addictions Service?
Normal sinus rhythm and QT interval within normal range (≤ 470ms for females and ≤ 450ms for males)

- The person undertaking the ECG (RN or Band 3, 4) should assess the ECG recording to evidence the summary being normal sinus rhythm and the QT interval being within normal range, ideally before the patient leaves the premise.
- The ECG can be repeated straight away if an abnormality is detected.
- The ECG and QT interval should be recorded in the patients clinical record and advice sought from either an NMP or doctor for sign off agreement that there is no abnormality. This can be done by face to face discussion provided the NMP/doctor is on site or via Task on S1 after the recording has been scanned into the patient notes.
- If the doctor or NMP is not on site, this can be done via Task on SystmOne to the ERP doctor (ensuring they are not currently absent/on Leave). The recording should be scanned into S1, filed under 'Communication and letters' where the ERP doctor can assess it after accessing the Task.
- The ERP doctor will make an entry in the patient notes confirming the recording outcome, including QT interval and that no further action is required.

Abnormal heart rhythm (summary report) and / or QT interval outside normal range

- The person undertaking the ECG (RN or Band 3, 4) should assess the ECG recording to evidence the summary result and the QT interval – anything other than normal sinus rhythm and QT interval being within range needs to be escalated to a doctor (not NMP), ideally before the patient leaves the premise.
- The ECG can be repeated straight away if an abnormality is detected.
- The ECG and QT interval should be recorded in the patient clinical record and advice sought from the ERP doctor for further action as per policy if an abnormality is evident. This can be done by face to face discussion provided the doctor is on site.
- If the doctor is not on site, they should be contacted by telephone at the relevant Hub and the ECG recording scanned into S1, filed under 'Communication and letters' or emailed direct to the doctor via nhs.net.
- The ERP doctor will provide advice on what action is required next, as per policy instructions e.g. follow the ERP management plan for abnormal QT interval results (Table 1).
- If there is no ERP doctor available, the key worker (or person who undertook the ECG) should contact the On Call doctor for Humber Teaching NHS Foundation Trust (HTFT) via Miranda House switchboard (01482 216624), request the doctor provide their email address, and scan and email the ECG recording to the on call doctor for analysis.
- The HTFT doctor will provide advice on what action is required next, as per policy instruction.
- Following the ECG, the person carrying out the ECG should ensure that the patient's GP is made aware of the abnormalities as they may need to carry out further assessment/repeat ECG/refer to cardiologist for advice.

Table 1: Management plan following ECG

Normal thresholds – no action
≤ 470ms for females and ≤ 450ms for males

		QTc	Action
Borderline Prolonged QTc	Female	≥470ms	Repeat ECG +/- manual QTc Electrolytes requested Assess and modify QT risk factors e.g. cocaine use Regular ECG monitoring until within normal limits
	Male	≥ 450ms	
Prolonged QTc	Males and females	≥500ms	Urgent action required Repeat ECG +/-Manual QTc Discuss with hospital Cardiologist On call Electrolytes if possible Assess and modify QT risk factors Consider reducing Methadone dose with risk–benefit analysis
Very Prolonged QTc	Males and females	≥ 550ms	Very urgent action required As above Consider switch to Buprenorphine or Morphine Sulphate

Table 2: Screening questionnaire for completing an ECG
Is total Methadone Dose ≥ 100mg daily?
Is there a history of cardiac conduction abnormalities?
Is there advanced heart disease or ischaemic heart disease?
Is there liver disease?
Is there a family history of sudden death?
Are there electrolyte abnormalities, i.e. hypokalaemia, hypomagnesaemia?
Is there concomitant treatment with drugs that have a potential for QT-prolongation?
Is there concomitant treatment with drugs which may cause electrolyte abnormalities?
Is there concomitant treatment with cytochrome P450 CYP3A4 inhibitors?
If the answer is yes to any question above, complete an ECG.

6. EQUALITY & DIVERSITY

An Equality and Diversity Impact Assessment has been carried out on this document using the Trust approved EIA.

7. IMPLEMENTATION

All staff are advised to view the latest version on the Trust intranet.

8. MONITORING & AUDIT

- Periodic audits will take place to monitor the percentage up take in ECG monitoring with ERP patients prescribed 100mg methadone or over. This will be at least annually.

- The audit will commonly be undertaken by the Higher Trainee Doctor, supervised by the Consultant Psychiatrist, Dr Soraya Mayet.
- The audit proposal should be discussed with the Clinical Audit Facilitator prior to completing and submitting a Clinical Audit Proposal Form for approval through the relevant Clinical Network before commencement.
- Relevant patients who are currently prescribed at least 100mg Methadone will be identified jointly by administration staff, non-medical prescribers and Dr. Soraya Mayet via SystmOne records.
- Data collection and analysis will be performed by the auditor by looking at each patient's SystmOne clinical record, retrospectively, over the past year.
- ECG compliance will be searched through entering "ECG" as a keyword in the tabbed journal view. Scanned documents and letters will also be searched on S1, for example for evidence of scanned ECGs or Blood results performed by the GP. Prescriber reviews from the past 12 months will be searched to check if an ECG had been performed and if any risk factors for QT prolongation had been referenced.
- The audit will occur at least annually, with a report generated and shared with ERP Clinical Network
- The audit report will be shared with the relevant clinical network for approval and ERP staff members by way of Team Meetings.
- The relevant clinical network may undertake subsequent recommendations and action planning for any or all deficiencies and recommendations, set within reasonable timeframes.
- System or practice changes and lessons learned as a result of the audit will be implemented across the Addictions Service by the Team Leaders and Service Manager. Updates of these will be provided to the relevant clinical network and the clinical audit team via action plan updates.

9. REFERENCES / EVIDENCE / GLOSSARY / DEFINITIONS

- Department of Health (2017) Drug misuse and dependence: UK guidelines on clinical management
- MHRA (2006) Current problems in pharmacovigilance, volume 31. London: Medicines and
- Healthcare products Regulatory Agency

10. RELEVANT HUMBER POLICIES / PROCEDURES / PROTOCOLS / GUIDELINES

- Clinical Audit and Service Evaluation Policy and Procedure N-046
- Consent policy N-052

Appendix 1 - Equality Impact Assessment (EIA)

For strategies, policies, procedures, processes, guidelines, protocols, tenders, services

1. Document or Process or Service Name: **East Riding Partnership**
2. EIA Reviewer: **Dawn Fawcett, NMP Lead**
3. Is it a Policy, Strategy, Procedure, Process, Tender, Service or Other? **Methadone and ECG Monitoring *Protocol***

Main Aims of the Document, Process or Service
Cases of QT interval prolongation and torsade de pointes have been reported during treatment with Methadone, particularly at high doses (>100 mg/d). Those patients prescribed > 100mg methadone daily should have (as a minimum) an annual ECG undertaken throughout the period of being prescribed 100mgs or over.
Please indicate in the table that follows whether the document or process has the potential to impact adversely, intentionally or unwittingly on the equality target groups contained in the pro forma

Equality Target Group	Is the document or process likely to have a potential or actual differential impact with regards to the equality target groups listed?	How have you arrived at the equality impact score?
• Age • Disability • Sex • Marriage/Civil Partnership • Pregnancy/Maternity • Race • Religion/Belief • Sexual Orientation • Gender re-assignment	**Equality Impact Score** Low = Little or No evidence or concern (Green) Medium = some evidence or concern(Amber) High = significant evidence or concern (Red)	• who have you consulted with • what have they said • what information or data have you used • where are the gaps in your analysis • how will your document/process or service promote equality and diversity good practice

Equality Target Group	**Definitions**	Equality Impact Score	Evidence to support Equality Impact Score
Age	Including specific ages and age groups: Older people, Young people, Children, Early years	Low	Accessible 18 years and over. Methadone not licensed for under 18 years (BNF 2023).
Disability	Where the impairment has a substantial and long term adverse effect on the ability of the person to carry out their day to day activities: Sensory, Physical, Learning, Mental Health (and including cancer, HIV, multiple sclerosis)	Low	Accessible for all. With impaired mental capacity, this may need capacity assessment. Needs assessment required to determine if support required for medication administration and accessibility - clinic room (ground floor in all 3 Hubs).
Sex	Men/Male, Women/Female	Low	Accessible for all
Married/Civil Partnership		Low	Accessible for all
Pregnancy/ Maternity		Low	Accessible for all. However, if pregnant, this would need further assessment. Methadone treatment would be off license so informed consent required.
Race	Colour, Nationality, Ethnic/national origins	Low	Accessible for all Language Line used to support those whose first language is not English
Religion or Belief	All Religions Including lack of religion or belief and where belief includes any religious or philosophical belief	Low	Accessible to all No special requirements necessary for Muslim patients during Ramadan
Sexual Orientation	Lesbian, Gay Men, Bisexual	Low	Accessible to all
Gender re-assignment	Where people are proposing to undergo, or have undergone a process (or part of a process) for the purpose of reassigning the person's sex by changing physiological or other attribute of sex	Low	Accessible to all

Summary

Please describe the main points/actions arising from your assessment that supports your decision above			
This protocol has a low equality impact score.			
EIA Reviewer	**Dawn Fawcett**		
Date completed;	**14 April 2023**	Signature	**D Fawcett**