



Quick reference guide and links to contents:

- o Prescribing decision support algorithm
- O What is the QT interval, how to measure it & adjust for heart rate
- o Reference ranges for prolonged QTc interval (men QTc >440 msec, women QTc >470 msec) & age-related differences (children/older adults)
- o Patient and drug-specific risk factors for Torsade de Pointes to enable completion of following risk assessment when initiating new medication:
 - Does the patient have any risk factors for QT prolongation?
 - Is the new medication associated with a risk of QT prolongation?
 - Are there any potential drug interactions that could increase the risk of QT prolongation?
 - Is the medication essential? Are there any alternatives?
- o When to conduct an ECG, what to do if ECG identifies abnormal QTc interval & when to refer to cardiology

Patient-specific risk factors (see page 4)

- Electrolyte disorders
- Drugs/conditions which may impact on electrolytes
- Kidney or liver disease
- Age ≥ 65 years
- Female gender
- Baseline QTc interval >480 msec
- Personal history/congenital or family history of long QT syndrome
- Cardiac risk factors
- Untreated thyroid disease
- Unexplained syncope/presyncope
- Family history of sudden cardiac death or syncope
- Prescribed a drug that may affect elimination of the psychotropic drug, e.g. affecting cytochromes or drug transporters required for elimination
- Drug toxicity, e.g. due to patient's metaboliser status, drug interaction or accidental or intentional overdose
- Prescribed another drug with potential to prolong QTc interval
- Methadone dose ≥100 mg/day

Psychoti	ropic Drugs with poter	ntial effects on QTc interval (see table	e 2 for more detail)	
Only in overdose	r effect or average increase msec	Moderate effect Average increase of 10-20 msec at therapeutic doses	High effect Significant average increase at therapeutic doses usually >20 msec	
Amitriptyline Aripiprazole Asenapine Buprenorphine Bupropion Clozapine Duloxetine Fluoxetine Flupentixol Fluphenazine Galantamine Lithium	Loxapine Memantine Mirtazapine Olanzapine Paliperidone Perphenazine Prochlorperazine Promethazine Risperidone Sulpiride Trazodone Venlafaxine	Amisulpride Chlorpromazine Citalopram Clomipramine Escitalopram Haloperidol Imipramine Levomepromazine Methadone (esp. doses >100mg) Nortriptyline Quetiapine Trimipramine	Any IV antipsychotic Pimozide Sertindole Thioridazine Any drug or combination of drugs used in doses exceeding recommended maximum (HDAT)	
		ential to prolong QTc interval (not exh	,	
Anti-arrhythmics		mide, Dronedarone, Flecainide, Procair		
Antibiotics	Azithromycin, Ciprofloxacin, Clarithromycin, Erythromycin (IV), Levofloxacin, Moxifloxacin			
Anti-emetics	Droperidol, Ondansetron			
Anti-fungals	Fluconazole, Ketocona	zole, Pentamidine		
Others	Anagrelide, Chloroquir	ne, Cilostazol, Domperidone, Mizolastin	e, Quinine, Vandetanib	

More information on QT-prolongation potential of drugs & interactions: www.crediblemeds.org; BNF; Manufacturer SPC's www.medicines.org.uk

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Prescribing decision support algorithm – prescribing drugs with potential to prolong QTc interval

Need for new psychotropic drug identified

Evaluate patient TdP risk (including risk factors related to current medication) and correct any modifiable risk factors e.g., electrolyte imbalance

LOW RISK PATIENT & no concurrent QT prolonging medication

HIGH RISK PATIENT &/or Concurrent QT prolonging medication (Seek alternative drugs for patients with congenital long QT syndrome)

Check risk stratification of preferred psychotropic drug (Table 2 or other resource e.g., Crediblemeds) Check risk stratification of preferred psychotropic drug & for any potential contraindicated combinations (Table 2 or other resource e.g., Crediblemeds)

LOW / MODERATE RISK DRUG

 Usual follow up, no additional monitoring necessary unless specified by manufacturer or symptomatic

HIGH RISK DRUG

- Baseline ECG
- Early follow up & ECG 1-3 weeks after dose change
- Check for any new symptoms/concerns on ECG
- Repeat ECG once drug at steady state.
- Ongoing monitoring not recommended if asymptomatic, unless required by manufacturer

LOW RISK DRUG

If concurrent QT prolonging drug: Baseline ECG recommended; repeat once new drug at steady

state.

 Otherwise: usual follow up, no additional monitoring necessary unless specified by manufacturer or symptomatic

MODERATE RISK DRUG

- Baseline ECG
 - Early follow up & ECG 1-3 weeks after dose change
- Check for any new symptoms/concerns on ECG
- Repeat ECG once new drug at steady state.
- Ongoing monitoring not recommended if asymptomatic, unless required by manufacturer (e.g., es/citalopram 6monthly)

HIGH RISK DRUG

Avoid in patients with existing QTc prolongation

 Baseline ECG & cardiology input recommended prior to prescribing

Only if cardiology & analysis of risk/benefits supports prescribing:

- Early follow up & ECG 1-3 weeks after dose change
- Check for any new symptoms/concerns on ECG
- Repeat ECG once new drug at steady state, then regular ECG monitoring

ACTION:

- All patients who present with palpitations, light headedness, or dizziness while prescribed a medication with the potential to prolong the QTc interval should be offered an ECG regardless of other risk factors. Cardiology follow up should be sought where appropriate (e.g., history suggestive of arrhythmia, prior cardiac event).
- Additional ECG monitoring should be considered with any dose increase or the addition of a new risk factor e.g., drug interaction, concomitant use of another potential QTc-prolonging drug, etc.
- If ECG identifies abnormal QTc <500 msec, consider reducing dose/switching to alternative lower risk drug, address any non-pharmacological modifiable risk factors, repeat ECG in 1-2 weeks and consider referral to cardiology (Immediate referral if associated with unexplained CV symptoms or unable to alter current potential QTc-prolonging drug).
- If ECG identifies marked QTc interval prolongation (>500 msec), or a sudden increase of QTc interval (>60 msec from baseline), refer to cardiology urgently, stop the suspected causative agent and switch to lower risk alternative, address any non-pharmacological modifiable risk factors and repeat ECG in 1-2 weeks or sooner. If syncope/presyncope are also present, this an emergency which requires immediate referral for continuous ECG monitoring.



Background

Many drug therapies are associated with prolongation of the QT interval. This is an independent risk factor for developing Torsades de Pointes (TdP), a potentially lifethreatening cardiac arrhythmia, and sudden cardiac-related death.

Most case reports of TdP associated with psychotropic drugs include additional risk factors such as:

- Patient-specific factors e.g., advanced age, female sex, hypokalaemia, hypomagnesaemia, bradycardia, and/or heart disease.
- Factors increasing drug exposure e.g., drug overdose or impaired drug elimination due to a drug interaction.

And/or:

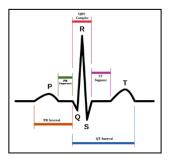
Concomitant administration of another drug known to prolong the QT interval.

It is therefore important to consider drug-related and individual patient factors prior to prescribing any new psychotropic drugs.

QT prolongation might worsen weeks, months, or years after treatment is started because of changes like the addition of potentially interacting drugs or the appearance of new medical conditions that cause electrolyte imbalances (particularly hypokalaemia and/or hypomagnesaemia), otherwise affect the QT interval, or increase the plasma concentrations of psychoactive drugs.

The QT interval

The QT interval measures the time between the start of ventricular depolarisation and the end of ventricular repolarisation, represented on an ECG by the beginning of the Q wave to the end of the T wave. There is variation in QT intervals between ECG leads, lead II is usually the basis of most reference ranges.



To minimise inconsistencies, it is best to measure the tangent of the descending T wave to baseline in leads II or V5. The tangent of the downslope of the T wave is taken to the baseline of the ECG and the QT interval measured in seconds between the Q wave and point where the tangent hits the baseline. It is important to use seconds as the measurement rather than milliseconds in the calculation if using a calculator or the QTc value will be incorrect. An average of 3–5 beats should be measured.

QT interval varies dependent on the length of the cardiac cycle and is usually corrected (QTc) for heart rate, several formulas can be used for this, most commonly Bazett's formula is used (QTc=QT/\\RR; QT interval in seconds, RR cardiac cycle in seconds), other correction formulae such as Frederica, Hodges or Framingham may be used. Correction of QT interval for heart rate is controversial and inexact. The reliability of the standard QTc decreases at higher heart rates.

The major limitation of Bazett's formula is that it overestimates QTc interval at any heart rate much higher than 60 beats per minute (bpm) and underestimates QTc interval at rates lower than 60 bpm. It is therefore recommended to use the Frederica formula if heart rate < 60bpm or >100bpm.

Definitions for QT prolongation vary in the literature, but for **men QTc >440 msec** and for **women QTc >470 msec** are commonly used. The risk of TdP increases with increasing QTc, for every 10 msec increase, there is a ~5-7% increase in the risk of arrhythmic events.

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When QTc is greater than 500 msec for both men and women and/or an increase of >60 msec from baseline, risks are higher, and urgent action is required.

Stress/anxiety can affect an ECG & it may be necessary to manage the patient's anxiety and repeat the ECG if affected.

Age-related differences in QTc values

Children and Young People

Some literature sources state that there is an absence of gender difference until early adolescence and suggest a normal QTc (Bazett's formula) of <440 msec age 1-15 years, with QTc values >460 msec considered prolonged in this age group. At age 16 and over, they suggest that adult reference ranges (see above) should be used.

Other literature sources suggest that in young people aged between 13 and 16, gender does influence QT interval, in some studies longer QTc intervals were observed in girls over 14 years old compared with boys. It is thought that this is due to QT shortening after puberty in boys rather than QT lengthening in girls.

Heart rate and the effect of heart rate on the performance of QT correction factors is more variable in the paediatric age range, it is therefore suggested that the threshold for seeking specialist cardiology advice may be lower in paediatric patients than in adult patients.

Older adults (over 65 years old)

It should be noted that the predisposition to prolonged QT interval in women diminishes with increasing age, it has been suggested that cardiac ion channel activity is altered by sex hormones, which in turn affects the QT interval. Differences in cut-off points between men and women are therefore not as relevant among older people.

TdP Risk Factors

Before prescribing a new psychotropic drug for a patient, prescribers should take into consideration patient-specific risk factors and the risk-rating of the proposed drug, these must then be balanced against the benefits of treatment with the proposed drug. (See algorithm)

Prescribers should also consider whether there are any alternative solutions that could reduce the risk of QT prolongation without compromising overall safety and efficacy.

The following approach to risk-assessment is recommended:

- 1. Does the **patient** have any risk factors for QT prolongation?
- 2. Is the **new medication** associated with a risk of QT prolongation?
- 3. Are there any **potential drug interactions** that could increase the risk of QT prolongation?
- 4. Is the medication **essential**? Are there any alternatives?

Electrolyte imbalances may need correcting prior to prescribing a new drug with potential to prolong the QTc-interval and patients should be warned to avoid other QTc prolonging medications (prescribed and those available to buy over the counter e.g., diphenhydramine).

Combinations of risk factors have been shown to correlate with subsequent prolongation of the QTc interval in at-risk patients and potential cumulative effects must be seriously considered.

For a low TdP risk patient – choose the drug with best psychiatric benefit/risk ratio for their condition, for a patient with higher TdP risk e.g., multiple risk factors, evaluate the cardiac risk and psychiatric efficacy of available agents prior to selecting a drug to prescribe (See table 2). Higher risk drugs should be avoided in patients with existing QTc prolongation.

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For patients with an elevated risk of TdP, the decision to commence a QT-prolonging drug should be made collaboratively with the patient, and the potential impact should be clearly communicated. Patients should be educated on the common symptoms of cardiac arrhythmias—such as dizziness, palpitations and syncope—and advised on when to seek medical attention. Choice and medication offer a handy fact sheet "Prolonged QT interval from medicines" to support these discussions. The discussion, information provision and decision to initiate treatment (or not) should be recorded in the electronic patient record.

Patient-specific risk factors

(A comprehensive list of potential patient-specific risk factors is available at www.crediblemeds.org; the risk factors with the most significant impact are highlighted in bold)

Most clinical cases of drug-induced QT prolongation occur in the presence of at least one of these risk factors, and >70% occur in the presence of two or more.

- Electrolyte disorders hypokalaemia, hypomagnesaemia, hypocalcaemia, risk increases with lower levels. (Hypokalaemia-related QTc prolongation is commonly observed in acute psychotic admissions)
- Drugs or conditions which may impact on electrolytes e.g., diuretics, dietary supplements, severe acute illness, gastroenteritis, endocrinopathies, eating disorders (purging behaviours and dietary restriction), starvation, binge drinking in alcohol use disorder, extreme physical exertion, fasting behaviours,
- Kidney or liver disease (**risk increases with increased severity**) also consider impact on metabolism of other drugs/risk of increased adverse effects
- Age ≥ 65 years
- Female sex
- Baseline QTc interval >480 msec
- Personal history/congenital or family history of long QT syndrome
- Cardiac risk factors such as heart failure, left ventricular hypertrophy, bradycardia (heart rate <60), IHD, myocarditis, MI
- Untreated thyroid disease more common with hypothyroidism
- Unexplained syncope/presyncope
- Family history of sudden cardiac death or syncope
- Prescribed a drug that may affect elimination of psychotropic drug e.g., affecting cytochromes or drug transporters required for elimination
- Drug toxicity e.g., due to patient's metaboliser status, drug interaction or accidental or intentional overdose
- Prescribed another drug with potential to prolong QTc interval
- Methadone dose ≥100 mg/day

Drug-specific risk factors

Information on the potential of an individual drug to prolong the QTc interval is available from various sources which may offer slightly different risk stratification/risk categories. Data are often inconclusive about arrhythmic risk for drugs that increase the QTc interval by <20 msec; drugs associated with a change in baseline QTc of >20 msec are of greatest concern and are generally categorised as higher risk regardless of source used.

Reliable sources for information on QT prolongation include:

- Crediblemeds website (https://www.crediblemeds.org/) or download mobile phone app (US-based resource, doesn't include all UK licensed drugs)
- Maudsley Prescribing and Physical Health guidelines

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- Psychotropic Drug Directory
- Stockley's Drug Interactions (UK resource, subscription only, access via Pharmacy)
- Manufacturer Summary of Product Characteristics (UK resource, search by drug, www.medicines.org.uk)

Some of the more common non-psychotropic drugs that can cause QT-prolongation are listed in table 1; table 2 lists the potential impact of psychotropic drugs on the QTc interval.

In the UK, the MHRA has issued safety alerts regarding the QT prolonging potential of specific drugs including es/citalopram, domperidone, ondansetron and quinine. There are some psychotropic drugs where the manufacturer specifically contra-indicates use with other drugs with potential to prolong the QT-interval.

For example, the manufacturer of citalopram contra-indicates its use with other medicinal products that are known to prolong the QT-interval e.g., Class IA and III antiarrhythmics, antipsychotics (e.g., phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g., sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine).

Another example is that the manufacturer of chlorpromazine, specifically contra-indicates its use with es/citalopram.

Prior to prescribing a new medication, <u>all</u> current physical health and psychotropic medication should be checked against a reliable source for their QT-prolongation potential.

It is important to recognise that the extent and the associated risk of developing QT prolongation when combining drugs with QT-prolonging effects are still unknown, but such combinations do not necessarily have an additive effect and a pragmatic approach should be taken which considers both patient and drug specific risk factors.

Whilst it is not recommended as standard practice, it is recognised that on occasion, combinations that are contra-indicated by the manufacturer, may be considered clinically appropriate after exhausting all other potential options (e.g., citalopram + antipsychotic; haloperidol for RT when other QT-prolonging drugs are being taken regularly).

In these circumstances, prescribing such a combination would be outside of the product licence and appropriate steps should be taken to identify and manage potential risks prior to prescribing. The patient should be informed of the planned off-label prescribing, (there are <u>choice and medication leaflets</u> available to support these discussions), their consent should be obtained and documented.

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Table 1 - Non-psychotropic Medication known to prolong QTc-interval (this list is not exhaustive)

Drug Group	Drugs	
	Amiodarone	Procainamide
A nti arrhythmiae	Disopyramide	Quinidine
Anti-arrhythmics	Dronedarone	Sotalol
	Flecainide	
	Azithromycin	Erythromycin (IV)
Antibiotics	Ciprofloxacin	Levofloxacin
	Clarithromycin	Moxifloxacin
Anti amatica	Droperidol	
Anti-emetics	Ondansetron	
	Fluconazole	
Anti-fungals	Ketoconazole	
	Pentamidine	
	Anagrelide	Mizolastine
Others	Chloroquine	Quinine
Others	Cilostazol	Vandetanib
	Domperidone	

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Table 2 Psychotropic Medication – by potential impact on QTc-interval

			Impact on QTc Interval					
		Unknown	No known effe (At therapeutic dose/in		Only in overdose o	effect or average increase msec	Average increase of 10-20 msec at therapeutic doses	High effect Significant average increase at therapeutic doses usually >20 msec
) / Drugs	Antipsychotics	Pipotiazine Trifluoperazine Zuclopenthixol	Brexpiprazole Cariprazine Lurasidone		Aripiprazole Asenapine Clozapine Flupentixol Fluphenazine Loxapine	Olanzapine Paliperidone Perphenazine Prochlorperazine Risperidone Sulpiride	Amisulpride Chlorpromazine Haloperidol Levomepromazine Quetiapine	Any IV antipsychotic Pimozide Sertindole Thioridazine Any drug or combination of drugs used in doses exceeding recommended maximum (HDAT)
Drug Group	Anti- depressant s		Paroxetine ¹ Fluvoxamine ¹ Sertraline ¹		Fluoxetine ¹ Venlafaxine Bupropion Duloxetine	Mirtazapine Amitriptyline ² Trazodone	Citalopram ⁴ Escitalopram ⁴ Clomipramine ² Trimipramine ² Nortriptyline ² Imipramine ²	
	Others		Atomoxetine Value Lis/dexamfetamine La Guanfacine Be Clonidine Ga	arbamazepine alproate amotrigine enzodiazepines abapentin regabalin	Buprenorphine Lithium³ Promethazine Memantine Galantamine		Methadone especially doses >100mg	

- 1. Cytochrome P450 inhibitor, may prolong QTc interval if prescribed in combination with another QTc prolonging drug
- 2. Risk is increased at doses ≥100mg/day amitriptyline equivalent
- 3. Some sources suggest that lithium may produce a greater increase in QTc interval during initiation (average 19 msec), with high serum levels or with concurrent electrolyte imbalances.
- 4. Risk is increased at doses above licensed maximum: citalopram 40mg/day (20mg/day age ≥ 65 years); escitalopram 20mg/day (10mg/day age ≥ 65 years). 6 monthly ECG monitoring recommended for patients prescribed doses > licensed maximum.

Drugs where an ECG is recommended by manufacturer in certain circumstances (see when to obtain ECG for details) are listed in italics.

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When to obtain an ECG

Due to the wide variety of physiologic and pharmacologic factors that can influence the QTc interval; it is recommended that QTc interval measurement should be no more than one month prior to the prescribing decision point, and no substantial changes in medications, electrolytes, or cardiovascular status (e.g., an episode of heart failure or an acute MI) should have occurred after the measurement. If there is uncertainty regarding the patient's status, an ECG should be considered. Most patients will have no symptoms, even if their QT interval is prolonged.

Clinicians should consult Trust guidelines surrounding the baseline and ongoing ECG monitoring for specific medications e.g., <u>Trust psychotropic drug monitoring guidance</u>, the following is a summary of when an ECG is recommended:

- If a physical examination has identified a specific cardiovascular risk (such as hypertension or irregular pulse).
- If admitted as an in-patient.
- If there is a family history of cardiovascular disease, a history of sudden collapse, or other cardiovascular risk factors such as cardiac arrhythmia.
- If a pre-treatment ECG is recommended by the manufacturer e.g.,
 - o Es/citalopram, fluoxetine, clomipramine in patients with stable cardiac disease
 - o Imipramine monitoring of cardiac function recommended in elderly patients
 - Antipsychotics such as chlorpromazine, haloperidol, levomepromazine, pimozide, sertindole and thioridazine.
 - o Lithium in patients with cardiovascular disease/risk factors.
 - o ADHD medication in patients with potential cardiovascular risk factors
 - Methadone
 - ECG monitoring is recommended prior to methadone treatment, with a further ECG at dose stabilisation in patients with recognised risk factors of QT prolongation, or in case of concomitant treatment with drugs that have a potential for QT prolongation.
 - ECG monitoring is recommended in patients without recognised risk factors for QT prolongation, before dose titration above 100 mg/day, and at seven days after titration.
- If patient is already taking certain medicines which are known to cause ECG abnormalities (e.g., erythromycin, fluconazole, domperidone, anti-arrhythmics)
- If the patient is on high dose antipsychotic therapy (HDAT)
- If the patient has factors which may predispose to arrhythmias (see patient-specific factors) including e.g.,
 - Electrolyte abnormalities hypokalaemia, hypocalcaemia, hypomagnesaemia.
 - Systemic disease liver disease, renal disease, hypothyroidism.
- The date any ECG is completed and any relevant findings including QTc interval should be documented in the appropriate section of the patient's electronic record as well as filing the ECG within their paper notes.

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- Where a baseline ECG is recommended above, this should be repeated at least annually unless otherwise specified.
- Additional ECG monitoring should be considered with any dose increase or the addition of a risk factor e.g., drug interaction, concomitant use of a QTc-prolonging drug, etc.
- All patients who present with palpitations, light headedness, or dizziness whilst
 prescribed a medication with the potential to prolong the QTc interval should be offered
 an ECG regardless of other risk factors. Cardiology follow up should be sought where
 appropriate (e.g., history suggestive of arrythmia, prior cardiac event).
- If ECG identifies abnormal QTc <500 msec, consider reducing dose or switching to alternative lower risk drug, address any non-pharmacological modifiable risk factors, repeat ECG in 1-2 weeks and consider referral to cardiology (Immediate referral if associated with unexplained CV symptoms or unable to alter current potential QTcprolonging drug).
- If ECG identifies marked QTc interval prolongation (>500 msec), or a sudden increase of QTc interval (>60 msec from baseline), refer to cardiology urgently, stop the suspected causative agent, and switch to lower risk alternative, address any non-pharmacological modifiable risk factors, repeat ECG in 1-2 weeks or sooner. If syncope/presyncope are also present, this an emergency which requires immediate referral for continuous ECG monitoring.

When to consult cardiology

Routine cardiology consultation is not indicated when prescribing QTc interval prolonging medications to a patient without cardiac risk factors; however, many higher risk clinical scenarios are best approached with cardiology input.

In patients with known heart disease and one or more risk factors for drug induced TdP, the clinician may consider consulting with the existing cardiologist when starting a medication with liability. In higher risk scenarios including co-administration of high-risk medications (e.g., amiodarone and parenteral haloperidol), marked QTc interval prolongation (>500 msec), or a sudden increase of QTc interval (>60 msec from baseline), referral to cardiology is appropriate.

Patients on a known offending drug who experience cardiac symptoms such as syncope, dizziness, and palpitations should immediately be referred to cardiology.

For specialist cardiology advice contact your local on-call cardiologist. It is recommended that you have the following information collated prior to seeking advice and are able to share a copy of the relevant ECG(s) with the cardiologist:

- 1. What medications have been prescribed for the patient's mental health condition?
- 2. What other medications is the patient taking (comprehensive list)?
- 3. Has the patient experienced any faintness, near collapse or collapse episodes?
- 4. Is the patient known to have any cardiac history / conditions?
- 5. What was the patient's heart rate and QTc (rate corrected QT-interval from the automatic report at the top of the tracing) before starting therapy?
- 6. What is the patient's latest heart rate and QTc measurement?
- 7. Biochemistry results (within last two weeks): sodium, potassium, urea, creatinine, eGFR [+ magnesium level if potassium (< 3.5mm/L]; FBC results
- 8. Do you have alternative medication options open to you if the current regime needs to be changed because of excessive prolongation in the QT-interval?

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