

13 August 2025

Mr Peter Nieto

Senior Coroner for the coroner area of Derby and Derbyshire.

Sent via email: [REDACTED]

Our reference: [REDACTED]

Dear Mr Nieto,

Re: Regulation 28 Prevention of Future Deaths Report in respect of Aaron Atkinson

I write in response to your regulation 28 report dated 30 June 2025 regarding the sad death of Aaron Atkinson. I would like to express my sincere condolences to Mr Atkinson's family.

We have reflected on the circumstances surrounding Mr Atkinson's death and the concerns raised in your report. We note your concerns about the clarity and consistency for annual reviews to include ECGs where people are prescribed antipsychotic medication long term.

Following receipt of your report, senior clinical advisors within the patient safety team here at NICE have reviewed the concerns raised, they have outlined the following.

The link included in the report is to the Clinical Knowledge Summaries (CKS) prescribing information on antipsychotics: [bipolar disorder - prescribing information - antipsychotics](#). It is important to note that this is not NICE guidance.

The CKS are developed by an external company called Agilio Software and are designed to summarise the evidence on the treatment of specific health conditions. They use a variety of sources and may include NICE guidance, if there is any that is relevant, but they use many other sources too. We publish them on our website as a source of advice and information for health professionals working in primary care, but as noted above, they do not constitute NICE guidance.

The CKS says (about antipsychotics generally):

Regular monitoring may subsequently be done in primary care on specialist advice or depending on the person's care plan. This may include:

- Electrocardiography (ECG) - after dose changes. Ideally, also annually.
 - Mandatory for haloperidol, pimozide, and sertindole; not required for antipsychotics with no effect, or a low-to-moderate effect on the QT interval and where there are no other risk factors for arrhythmia.

As part of this process, we have shared this report with Agilio Software for their awareness. The publishers of the CKS referred to have outlined that the recommendation on ECGs is taken from the Summary of Product Characteristics (SPC) information for each drug, provided below;

[Orap 4 mg tablets - Summary of Product Characteristics \(SmPC\) - \(emc\) | 6911](#)

[Haloperidol Oral Solution BP 10 mg/5 ml - Summary of Product Characteristics \(SmPC\) - \(emc\) | 4521](#)

[Serdolect 12 Mg Film-Coated Tablets -Summary](#)

For each of these, the advice is 'periodic monitoring'; Agilio have added the concept of 'ideally annually' for these drugs as a pragmatic approach, as the manufacturers do not stipulate what they mean by 'periodic monitoring'.

Agilio will be adding additional wording to clarify that the manufacturer has described risperidone as a medication which does not require further annual follow up ECG monitoring, as this drug is included in the category referred to in the CKS as 'not required for antipsychotics with no effect, or a low-to-moderate effect on the QT interval and where there are no other risk factors for arrhythmia.' Additional information will be added regarding drug interactions and prolongation on the QT interval in particular and the need for additional monitoring for these patients, almost certainly in secondary care.

If further detail is required on the changes to the content of the CKS topic, Agilio Software can be contacted [directly](#).

NICE have also published a clinical guideline on [bipolar disorder: assessment and management \[CG185\]](#) which includes the following relevant recommendations:

1.10.6 Before starting antipsychotic medication, offer the person an electrocardiogram (ECG) if:

- it is specified in the drug's summary of product characteristics (SPC) or
- a physical examination has identified a specific cardiovascular risk (such as hypertension) or
- there is a family history of cardiovascular disease, a history of sudden collapse, or other cardiovascular risk factors such as cardiac arrhythmia or
- the person is being admitted as an inpatient. [2014]

For risperidone, there is no specific requirement for ECG monitoring in the SPC

It says:

QT prolongation has very rarely been reported postmarketing. As with other antipsychotics, caution should be exercised when risperidone is prescribed in patients with known cardiovascular disease, family history of QT prolongation, bradycardia, or electrolyte disturbances (hypokalaemia, hypomagnesaemia), as it may increase the risk of

arrhythmogenic effects, and in concomitant use with medicines known to prolong the QT interval.

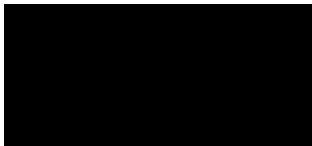
There is no requirement for continued (e.g. annual) ECG monitoring with risperidone in the SPC, NICE guideline or the British National Formulary (BNF). The local guidelines say the following in annual monitoring: *if new medicines or changes to physical health have increased the risk of prolonged QTc arrange ECG.*

The interaction in the BNF on risperidone and methylphenidate (Ritalin) relates to an increased risk of dyskinesia.

In summary, we do not believe there is evidence for justification for annual ECGs for everyone prescribed long term antipsychotics. Prescribing information for risperidone does not include a requirement for continued ECG monitoring, however the publishers of the CKS will make some changes to the prescribing information on this topic to ensure it is clear where ECG monitoring is required.

I hope this response has helped outline our role and the guidance that exists in this topic area. I would like to reiterate my sincere condolences to Mr Atkinson's family.

Yours sincerely,

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Chief Executive