

ARTICLE

# Analysis of Orders for QTc-Prolonging Medication for Intensive and Cardiac Care Unit Patients with Pre-existing QTc Prolongation (QTIPPP Study)

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## ABSTRACT

**Background:** A prolonged QTc interval on electrocardiography is often used as a surrogate marker for ventricular arrhythmia. Medications that can prolong the QTc interval may increase the risk of cardiac complications, although the exact incidence is unknown. It is reasonable to assume that administration of QTc-prolonging medications to patients with pre-existing QTc prolongation will further increase the risk of cardiac consequences. This study was designed to examine the frequency of prescription of QTc-prolonging medications in such patients and to explore the potential for clinical pharmacists to minimize the associated risks.

**Objectives:** The primary objective was to identify the number of patients with pre-existing prolonged QTc interval for whom QTc-prolonging medications were prescribed, from among all patients with orders for QTc-prolonging medications. The secondary objectives were to determine patterns of intervention by clinical pharmacists in these cases and to document any further QTc prolongation and occurrence of cardiac events.

**Methods:** A prospective, observational, quality assessment study was conducted over 4.5 months. Adult patients admitted to beds with cardiac monitoring by telemetry for whom one or more QTc-prolonging medications were ordered were eligible for inclusion. Patients were included if the QTc interval was longer than 450 ms on the most recent 12-lead electrocardiogram before the QTc-prolonging medication was ordered. These patients were followed to identify outcomes of interest after administration of QTc-prolonging medication.

**Results:** Overall, a QTc-prolonging medication was prescribed for 207 patients. Of these, 53 patients (26%) had pre-existing prolongation of the QTc interval. Clinical pharmacists made recommendations related to 28 medication orders; of these, 16 (57%) were accepted by the physician. Fifty-one (96%) of the 53 patients received at least one dose of QTc-prolonging medication and were monitored daily for complications. Nine (18%) of the 51 patients who underwent daily monitoring experienced at least one cardiac event.

**Conclusions:** A substantial proportion (26%) of patients for whom QTc-prolonging medications were prescribed had pre-existing prolongation of the QTc interval. Clinical pharmacists may have a role in reducing the risk of subsequent complications.

## RÉSUMÉ

**Contexte :** Le L'allongement de l'intervalle QTc à l'électrocardiogramme est souvent utilisé comme critère de substitution d'arythmie ventriculaire. Les médicaments pouvant allonger l'intervalle QTc peuvent accroître le risque de complications cardiaques, bien que l'incidence exacte demeure inconnue. On peut raisonnablement prétendre que l'administration de médicaments allongeant l'intervalle QTc chez des patients présentant un allongement préexistant de l'intervalle QTc augmentera le risque de complications cardiaques. Cette étude a été conçue pour examiner la fréquence de prescription de médicaments allongeant l'intervalle QTc chez de tels patients et la possibilité pour les pharmaciens cliniciens de réduire au minimum les risques associés à cette situation.

**Objectifs :** Le principal objectif était de déterminer le nombre de patients présentant un allongement préexistant de l'intervalle QTc à qui l'on a prescrit des médicaments allongeant cet intervalle sur l'ensemble des patients à qui l'on a prescrit des médicaments allongeant l'intervalle QTc. Les objectifs secondaires étaient de déterminer les habitudes d'intervention par les pharmaciens cliniciens dans ces cas et de constater tout allongement supplémentaire de l'intervalle QTc et la survenue d'événements cardiaques.

**Méthodes :** Une étude d'évaluation qualitative, prospective et observationnelle a été menée sur une période de quatre mois. Les patients adultes hospitalisés avec surveillance cardiaque par télémétrie au chevet et à qui l'on prescrivait au moins un médicament allongeant l'intervalle QTc étaient admissibles à l'étude. Les patients étaient admis si l'intervalle QTc objectif sur le plus récent ECG à 12 dérivations excédait 450 ms avant la prescription de médicaments allongeant l'intervalle QTc. Ces patients ont été suivis afin de déterminer les résultats d'intérêt après l'administration de tels médicaments.

**Résultats :** Dans l'ensemble, on a prescrit un médicament allongeant l'intervalle QTc à 207 patients. De ceux-ci, 53 (26 %) présentaient un allongement préexistant de l'intervalle QTc. Les pharmaciens cliniciens ont formulé des recommandations liées à 28 des prescriptions de ces médicaments; de ces recommandations, 16 (57 %) ont été acceptées par le médecin. De plus, 51 (96 %) des 53 patients ont reçu au moins une dose de médicament allongeant l'intervalle QTc et ont fait l'objet d'une surveillance quotidienne des complications. Neuf (18 %) de ces 51 patients ont présenté au moins un événement cardiaque.

**Key words:** QTc interval, torsade de pointes, pre-existing prolongation, pharmacist practice

**Conclusions :** Une proportion considérable (26 %) des patients à qui l'on a prescrit un médicament allongeant l'intervalle QTc présentait un allongement préexistant de cet intervalle, ce qui porte à croire que les pharmaciens cliniciens pourraient avoir un rôle à jouer dans la réduction du risque de complications subséquentes.

**Mots clés :** intervalle QTc, torsade de pointes, allongement préexistant de l'intervalle QTc, pratique du pharmacien

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## INTRODUCTION

The QT interval on an electrocardiogram (ECG) represents depolarization and repolarization of the cardiac ventricular cells. This interval is measured from the beginning of the QRS complex to the end of the T wave.<sup>1,2</sup> It varies inversely with heart rate and is therefore corrected by formulas that take this variation into account; the corrected interval is designated "QTc".<sup>1</sup> Because of its dynamic nature, the QTc interval is highly individualized.<sup>1,2</sup> The cause of prolongation may be multifactorial but is generally congenital (e.g., long QT syndrome) or acquired (e.g., induced by medications).<sup>3,5</sup> A prolonged QTc interval on ECG is often used as a surrogate marker for ventricular types of arrhythmias, such as torsade de pointes.<sup>3</sup> Although usually self-terminating, torsade de pointes can lead to catastrophic events, potentially causing cardiac arrest and sudden death.<sup>6</sup> As such, several medications have had warnings issued or have been withdrawn from the market because of their pro-arrhythmic potential.<sup>3,5</sup>

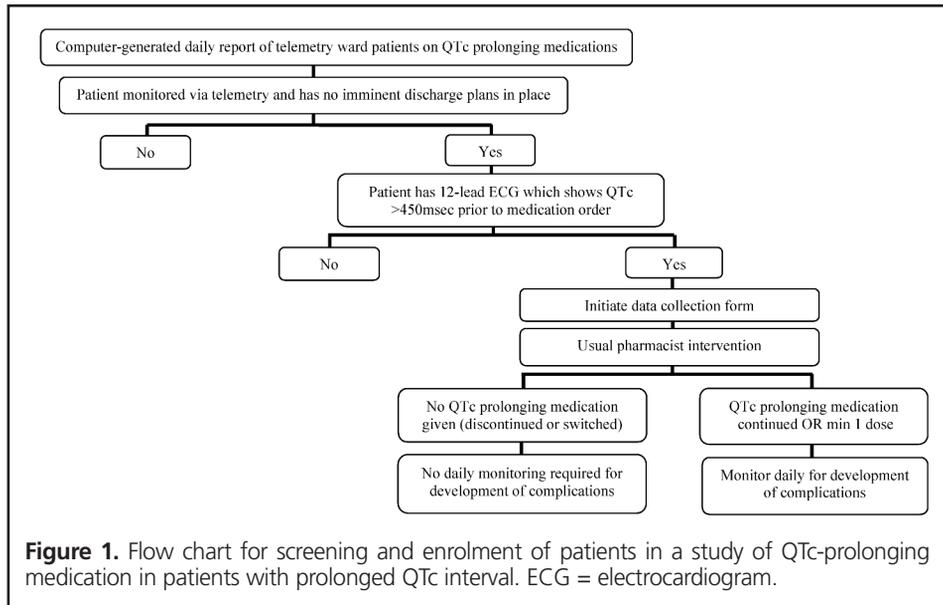
The incidence of QTc prolongation progressing to ventricular arrhythmias is largely unknown, and the relationship is not linear.<sup>1,3,4</sup> However, it is recognized that the risk of torsade de pointes is greater at longer QTc intervals, with the upper limit of normal for a QTc interval ranging from 440 to 480 ms and ventricular types of arrhythmia being more commonly reported for individuals with QTc interval longer than 500 ms.<sup>1,3,4,6</sup> Several other factors contributing to the development of QTc prolongation and subsequent torsade de pointes have been identified, including advanced age, female sex, electrolyte abnormalities (e.g., potassium, magnesium, calcium), recent conversion from atrial fibrillation, severe bradycardia (heart rate < 50/min), myocardial ischemia or infarction, heart failure, subarachnoid hemorrhage, and QT-prolonging medications.<sup>3,4,6</sup> Zelster and others<sup>7</sup> showed that patients who experience drug-induced torsade de pointes usually have at least one of the following risk factors: female sex, heart disease, hypokalemia, drug toxicity, drug interactions (taking more than 2 drugs that prolong the QTc interval),

history of familial long-QT syndrome or drug-induced torsade de pointes, or prolongation of the QTc interval at baseline. It appears that administration of a QTc-prolonging medication to patients whose QTc interval is already prolonged may put them at a higher risk for development of ventricular arrhythmia.

In the hospital setting, many patients have combinations of the above-mentioned risk factors for drug-induced torsade de pointes. With such a high prevalence of risk factors, it can be difficult to vigilantly screen for, monitor, and modify risks when a QTc-prolonging medication is ordered. However, a 12-lead ECG is often recorded for hospital inpatients, particularly those who are actively monitored. It therefore seems reasonable to consider information from the ECG when assessing whether a medication is safe for a particular individual, but it is difficult to ascertain if ECGs are being used in this way.

This prospective, observational study was designed to examine the use of QTc-prolonging medications in patients with pre-existing prolongation of the QTc interval and the potential role for clinical pharmacists in minimizing the risk of consequences of such medications. Interdisciplinary teams in the hospital setting typically include a clinical pharmacist, who provides valuable services to optimize patients' medications. The role of the clinical pharmacist is continuously evolving to include new and varied aspects of patient care.

The primary objective was to determine, from all patients for whom QTc-prolonging medications were ordered, the number of patients with pre-existing prolongation of the QTc interval. Patients meeting the inclusion criteria were identified by first screening a list of orders for QTc-prolonging medications for patients admitted to the monitored wards of a community hospital and then reviewing prior ECGs for prolonged QTc interval. The study also examined the effect of adding monitoring of a patient's QTc interval to routine practice when QTc-prolonging medications were ordered. As such, secondary outcomes included patterns of interventions by clinical pharmacists for patients with orders for QTc-prolonging medications, as well as the frequency of ventricular arrhythmias



and cardiac events. The number of patients from the population of interest who experienced further prolongation of the QTc interval was also documented.

## METHODS

The Burnaby Hospital is a community-based, 309-bed acute care facility within the Fraser Health Authority of British Columbia. Full-time (24 h) telemetry monitoring capabilities are available in the emergency department, intensive care unit (ICU), and cardiology ward. Adult patients were eligible for inclusion if they were admitted to beds monitored by telemetry in the ICU or the cardiology ward, if one or more QTc-prolonging medications were ordered for them, and if QTc interval longer than 450 ms was recorded on the most recent 12-lead ECG obtained before the medication order. This upper limit of normal (450 ms) was chosen for consistency with Health Canada's recommendations for the lowest threshold above which noteworthy prolongation is indicated.<sup>8</sup> Patients were excluded if the QTc-prolonging medication was discontinued before the first dose was given. Although monitoring capability was available in the emergency department, this department was excluded from the study because of high patient turnover.

Data collection was performed over a 4.5-month period (November 2, 2009, to March 19, 2010). Patients were identified through nonprobability sampling of the hospital's computer system, which was programmed to generate daily reports of patients admitted to the study wards for whom one or more QTc-prolonging medications had been ordered within the past 5 days. The report was cross-matched daily to remove duplicates. The list of QTc-prolonging medications was adapted

from the most recent version of the Saskatchewan Health Region's *RxFiles Drug Comparison Charts* (7th edition)<sup>5</sup> and the Arizona Center for Education and Research on Therapeutics website.<sup>9</sup> For each patient, a clinical pharmacist assessed the QTc interval before the medication order and performed any necessary interventions as deemed appropriate on the basis of clinical judgment. Figure 1 provides additional detail about this process.

Patients were monitored daily for cardiac events, if a clinical pharmacist was available. Cardiac events of interest were selected for their significant impact on a patient's clinical outcome and were based on the American Heart Association's guidelines for management of cardiac arrest.<sup>10</sup> The 4 rhythms that produce pulseless cardiac arrest were used as outcomes in this study: ventricular tachycardia, ventricular fibrillation, pulseless electrical activity, and asystole.<sup>10</sup> Torsade de pointes was also included, as it is the ventricular rhythm most commonly associated with QTc prolongation. Sudden death was also documented. Events were detected by examining nursing records, which noted their occurrence and included a copy of the telemetry strip from the time of the complication. Patients with daily monitoring for whom subsequent 12-lead ECGs were ordered were also assessed for further prolongation of QTc. Clinically significant QTc prolongation was defined as more than 60 ms from baseline, in accordance with the most recent American Heart Association statement on prevention of torsade de pointes in hospital settings.<sup>6</sup>

## RESULTS

During the study period, at least one QTc-prolonging medication was ordered for a total of 207 patients in the ICU

**Table 1. Demographic and Medical Characteristics of the 53 Patients Included in the Study**

Characteristic	No. (%) of Patients*
<b>Demographic</b>	
Age, mean $\pm$ SD (years)	72.2 $\pm$ 11.7
Sex, female	23 (43)
<b>Current medical history</b>	
QTc interval, mean $\pm$ SD (ms)	487.3 $\pm$ 31.3
Obesity (BMI $\geq$ 30) ( <i>n</i> = 46)	16 (35)
Hypokalemia (serum K <sup>+</sup> < 3.5 mmol/L) ( <i>n</i> = 52)	17 (33)
Hypomagnesemia (serum Mg <sup>+</sup> < 0.7 mmol/L) ( <i>n</i> = 27)	3 (11)
Hypocalcemia (serum Ca <sup>2+</sup> < 2 mmol/L) ( <i>n</i> = 24)	5 (21)
<b>Cardiac history</b>	
One or more cardiac condition† present	44 (83)
Hypertension	36 (68)
Cardiomyopathy	2 (4)
Congestive heart failure	10 (19)
Myocardial infarction	9 (17)
Coronary artery disease	19 (36)
<b>No. of QTc-prolonging medications ordered</b>	
1	42 (79)
2	7 (13)
3	2 (4)
>3	2 (4)

BMI = body mass index, SD = standard deviation.

\*Except where indicated otherwise.

†Hypertension, cardiomyopathy, congestive heart failure, severe bradycardia, myocardial infarction, coronary artery disease.<sup>1,3</sup>

and the cardiology ward. Fifty-three (26%) of these patients had a prolonged QTc interval on the 12-lead ECG obtained before the medication order (Table 1). A total of 71 QTc-prolonging medications were ordered for these 53 individuals. Clinical pharmacists screened every order for QTc-prolonging medication and made recommendations for 28 of the orders. Of these, 16 (57%) were accepted by the physician. The majority of these recommendations suggested discontinuing the medication or switching to an alternative with less risk of prolonging the QTc interval. The most common reasons for clinical pharmacists not intervening or physicians not accepting recommendations included patient's requirement for the therapy; lack of better alternatives; medication being a stand-by order, as part of the admission protocol (e.g., amiodarone as needed, in case of arrhythmias); or physician's determination, by manual calculation, that the QTc interval was not prolonged (for one patient).

After screening and intervention by the clinical pharmacist, the QTc-prolonging medication was discontinued for 2 of the patients before they received any doses. These 2 patients were excluded from further monitoring, and a total of 51 patients (96%) were followed daily for cardiac events. Of these 51 patients, 9 (18%) experienced at least one cardiac event. Ventricular tachycardia, experienced by 8 patients (16%), was the most common arrhythmia documented. Some combina-

tion of ventricular fibrillation, torsade de pointes, pulseless electrical activity, and asystole was experienced by 2 patients, both of whom subsequently died. Further clinically significant prolongation of the QTc interval was observed in 2 of the 46 patients for whom subsequent 12-lead ECGs were recorded, but neither of these patients experienced a cardiac event. Various secondary and additional outcome data are presented in Table 2.

## DISCUSSION

This observational quality assessment study quantified a potentially modifiable risk factor for QTc prolongation and subsequent cardiac arrhythmias in the telemetry-monitored wards of the Burnaby Hospital. By observing usual practice and the number of QTc-prolonging medications ordered for patients with pre-existing prolongation of the QTc interval, we established the prevalence of this combined risk in a local setting. It appears that QTc-prolonging medications are ordered despite ECG evidence of pre-existing prolongation of the QTc interval. Interventions by pharmacists appear to be helpful in identifying patients who are already at increased risk of cardiac arrhythmias and in preventing exposure to further risks (i.e., QTc-prolonging medications). Clinical pharmacists are able to assess patients and discuss medication regimens with

**Table 2. Secondary and Additional Outcomes**

Characteristic	No. (%)
<b>Orders for QTc-prolonging medication</b>	<i>n</i> = 71
PRN medication or medication on hold*	16 (23)
Pharmacist interventions for QTc-prolonging medication	28 (39)
Pharmacist interventions accepted by physician	16/28 (57)
<b>Cardiac events</b>	<i>n</i> = 9
Baseline QTc interval, mean (ms)	488.6 ± 43.9
Baseline QTc interval, range (ms)	451–619
Further prolongation of QTc interval (< 60 ms)†	4 (44)
Complication after discontinuation of drug (< 48 h)	1 (11)
<b>Deaths</b>	<i>n</i> = 51
Among all patients	4 (8)
Among patients who experienced at least one cardiac event	2 (4)

SD = standard deviation.

\*Unclear how many doses were given.

†No patients who experienced cardiac events had further prolongation of the QTc interval exceeding 60 ms.

physicians. These activities represent opportunities to optimize patients' treatment regimens, for example, by reducing the risk of torsade de pointes. The results of this study emphasize the role of clinical pharmacists in reducing the incidence of adverse drug reactions.

Ideally, for a quality assessment study such as this one, patients with a prolonged QTc interval would be identified at the outset and then followed to observe whether a QTc-prolonging medication was ordered during their hospital stay. However, because of the fluctuating nature of the QTc interval, which would require constant monitoring, and limited resources, our study design was modified to screen for QTc-prolonging medications in any patient as the initial step. Then, these patients were further screened to find those whose QTc was prolonged before the medication order. Although it is arguable that looking for cardiac arrhythmias as the primary end point would have been more clinically relevant, the time and sample size required to generate sufficient power for such an outcome were not feasible for this assessment. As well, the propensity of medications to prolong the QTc and cause arrhythmias is variable and would have to be investigated individually. More importantly, this study was designed to observe daily practice and determine whether patients with baseline QTc prolongation had orders for medications that can further increase the risk for ventricular arrhythmias. We were interested in determining if such preventable patient exposure occurs, before undertaking a study to examine subsequent outcomes. The primary outcome of this analysis has brought awareness to the issue that a QTc-prolonging medication may be ordered for patients with pre-existing prolonged QTc. Secondary outcomes have provided evidence of a role for clinical pharmacists in optimizing therapy and minimizing risks when QTc-prolonging medications are ordered for patients with prolonged QTc interval.

Although some cardiac events occurred during this study, most were asymptomatic and self-terminating. Because this study was not designed to determine a cause-and-effect relationship, we cannot definitively link the addition of a QTc-prolonging medication to the cardiac events that occurred. However, occurrence of cardiac arrhythmias, such as torsade de pointes, in association with QTc-prolonging medications has been widely described in the literature.<sup>4,6,9,11</sup> This study had confounding variables that likely contributed to the occurrence of cardiac events. For example, most patients had underlying cardiac conditions. Likewise, the 2 patients who experienced the most severe cardiac events (torsade de pointes, pulseless electrical activity, asystole) and died were those deemed to have a poor prognosis, such as post-cardiac arrest. Furthermore, data for other patient factors (e.g., electrolyte status) that might contribute to prolongation of the QTc interval and ventricular arrhythmias were not available for all patients. Therefore, baseline risk could not be established for everyone.

The study had other limitations. For example, the list of QTc-prolonging medications was not updated during the study; therefore, any changes made to the online database<sup>9</sup> were not reflected in the protocol. However, the study was conducted over a short period, and we did not anticipate any major changes that would have affected our results.

The QTc interval is a dynamic parameter that may fluctuate daily and that has great individual variability.<sup>1,2</sup> By basing our inclusion criteria on only one 12-lead ECG, we may have enrolled patients whose prolonged QTc returned to normal soon after, or we may have overlooked patients whose QTc interval was generally prolonged but normal at the time of the ECG. For example, of the 46 patients who were followed daily and for whom subsequent 12-lead ECGs were ordered, 2 experienced a significant increase in the QTc interval. However, for one of these patients, the QTc interval returned to near

baseline the next day. It is difficult to determine the relative contributions to this fluctuation of adding a QTc-prolonging medication and the patient's inherent variation. As well, there was often a time lapse between the "baseline" 12-lead ECG tracing and the medication order. Given the observational nature of this study, new baseline ECGs (i.e., immediately before starting the medication) were not ordered as part of the protocol. Instead, in an attempt to preserve usual practice patterns, the most recent ECG available in the chart was used. This ECG may have been obtained days or even weeks before the medication order. As such, it might not accurately represent the patient's current myocardial status. However, the focus of this study was on determining the number of QTc-prolonging medication orders for patients with pre-existing prolongation of the QTc interval documented in their charts.

The ECGs likely had an inherent margin of error. For one of the patients, the QTc interval was reported to be prolonged according to the computerized interpretation. However, after discussion between the clinical pharmacist and physician, the QTc interval was manually recalculated by the physician and was deemed not to be prolonged. Although it is not practical to manually confirm every patient's QTc interval, this serves as a reminder that computerized measurements can differ from manual readings because of the machine's limitations. Thus, the ECG should serve as a screening tool to prompt further discussion; manually checking results may be indicated if concerns arise.

For patients who experienced cardiac events, the QTc at the time of an event was not captured, as the QT interval cannot be identified in the cardiac arrhythmias of interest. Furthermore, we did not manually calculate the QTc interval from telemetry strips before or after a cardiac arrhythmia, as the physician usually assesses the 12-lead ECG in the event of a true cardiac emergency. Also, because of the limitations of the telemetry machine, information related to an event that occurred more than 48 h ago could not be accessed, which might have been problematic over weekends. Therefore, for patients who experienced a cardiac event, it is not known if his or her QTc interval was prolonged just before the event.

The applicability and generalizability of this study's results, in terms of the number of patients for whom QTc-prolonging medications are ordered, are limited to the wards of the hospital where it was conducted. This analysis involved physicians who specialize and practise on these particular wards, and their prescribing patterns cannot be deemed representative of all physicians. Also, the interventions of clinical pharmacists rely on the professional judgment of individuals, which varies with experience, as well as acquired skills and knowledge. Undoubtedly, the types of recommendations made by the pharmacists and whether they were accepted by the physicians were highly dependent on the particular

situations and available alternatives. Nevertheless, clinical pharmacists' assessments and suggestions to physicians led to changes in the management of some patients, with potential for significant safety benefits. This study further emphasizes the advantage of interdisciplinary care involving clinical pharmacists.

The most recent scientific statement on the prevention of torsade de pointes in hospital settings from the American Heart Association and the American College of Cardiology Foundation<sup>6</sup> suggested regular monitoring of the QTc interval, before and at least every 8–12 h after initiation, increase in dose, or overdose of QTc-prolonging medications. This level of monitoring was not used in this study because it is not usual practice at the study site. Symptomatic, emergent cardiac events were observed in 9 patients but were not clearly linked to the addition of a QTc-prolonging medication, given that the study was not designed to accurately capture such information. Ideally, guideline recommendations on monitoring should be followed, but doing so may be difficult, given the recommended frequency of monitoring. If further studies show a high incidence of fatal consequences as a result of adding QTc-prolonging medications for patients with prolonged QTc interval at baseline, the suggested monitoring frequency should be considered.

This study has demonstrated the importance of clinical pharmacists being involved in the care of patients with prolonged QTc interval, and we encourage other hospital sites to examine their current practice patterns in this regard. Integrating simple steps into daily practice, such as inquiring whether a recent ECG is available for high-risk patients for whom QTc-prolonging medications are ordered, as well as clear documentation of such information in the chart, could be valuable in enhancing patient safety. Further discussions with the physician about a medication's adverse effect on the QTc interval might help to mitigate any unnecessary risk to which a patient may be exposed. In addition to spreading awareness of this issue and encouraging more vigilant screening of patients' ECGs, it is hoped that this study will serve as a platform for discussion within the collaborative health care team.

## CONCLUSIONS

At the site where this study was conducted, 26% of patients for whom QTc-prolonging medications were ordered already had a prolonged QTc interval, indicating a role for clinical pharmacists in reducing risks of subsequent harmful cardiac consequences.

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