A Victorian Government initiative

RESIDENTIAL AGED CARE CORONIAL COMMUNIQUÉ

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Next Edition: March 2009

EDITORIAL

This edition of the Coronial Communiqué examines a commonly prescribed medication, warfarin, which is a potentially lethal pharmaceutical product. Three cases highlight systems issues about effective communication and co-ordination of care between clinicians, laboratory services, patients and their family. The cases also demonstrate the complexity of managing warfarin with the need for regular laboratory testing, close monitoring of the dose, being prepared for an appropriate response for 'out of range' results, adhering to protocols and awareness of common drug interactions.

The dangers and benefits of warfarin are well known. Our challenge is to ensure we improve the systems and practices for safer use of this medication. Resources and an expert commentary are included in the contribution jointly written by a haematologist and pharmacist.

This is our final issue for 2008 and brings to a close a hectic and busy year. With your help we have completed five issues and a subscriber evaluation survey. We also thank DHS (Aged Care Branch) for their ongoing support in and funding of this publication through 2008-09.

We wish you all a safe and happy festive season.

BRIEF REPORT: KEY SURVEY RESULTS

Of the 778 subscribers about half (426) completed the survey. Over half said they had changed their practice (215/426), approximately 90% said the Communiqué was easy to understand, with over 95% agreeing that reading the Communiqué was a valuable use of time and would recommend it to colleagues.

Results from more detailed analyses will be reported next year.

CLARIFICATION

Dr Sam Scherer, Clinical Associate Professor, University of Melbourne and General Manager Medical Services at the Royal Freemasons' Homes of Victoria brought to our attention our wording in Volume 3 Issue 4: Case 1038/05 "Unascertained the mystery of hypoglycaemia" created confusion about L-dopa or antiparkinsonian treatment, hypoglycaemia, glucose monitoring and pharmacist recommendations. The intention of our presentation was to highlight the need to consider the recommendations of a pharmacist who conducted a medication review. Some readers may have gained the incorrect impression that people on L-dopa or antiparkinsonian treatment should have routine glucose monitoring.

The pharmaceutical product information does not identify hypoglycaemia as an adverse effect of L-dopa nor are there any published case reports.

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Other publications including the Coronial Communiqué and WorkWISE can be found on our website at **http://www.vifm.org/n961.html**

FEEDBACK

The CLS team is keen to receive feedback about this communication especially in relation to changes in clinical practice.

Please email your comments, questions and suggestions to: **racc@vifm.org**

FALLING THROUGH THE CRACKS

CASE NUMBER 1368/02

Case Precise Author: Dr Nicola Cunningham FACEM, (CLS)

CLINICAL SUMMARY

Ms S was a 74-year-old female who presented with a new breast lump. She had a past history of atrial fibrillation and stroke, for which she was prescribed the anticoagulant medication warfarin 2.5mg daily for several years.

Ms S' General Practitioner (GP) ceased the warfarin one week prior to admission to a regional hospital for a mastectomy. The day after surgery warfarin was recommenced with a loading dose of 5mg for three consecutive days. On day-3 post-surgery Ms S was transferred to a rural hospital for ongoing care under the doctors attached to her GP's practice. The warfarin was continued at the same dose until day-5 when it was increased to 7mg because of a sub-therapeutic International Normalised Ratio (INR) of [1.5]. On day-6 the INR had risen to [2.8] and the warfarin dose remained unchanged at 7mg daily.

On day-10, the day of discharge, Ms S had blood taken for an INR test, before leaving the hospital accompanied by her husband to attend the surgeon's rooms. The surgeon did not discuss the warfarin dose with Ms S, as her GP had managed this while she was in hospital.

Ms S arrived home and shortly afterwards received a telephone call from the hospital explaining the INR result was high at [5.8]. She was advised to cease her warfarin for the next two days before having a repeat INR test. That evening, Ms S developed severe abdominal pain, rapidly deteriorated and died en-route to hospital.

PATHOLOGY

The cause of death following an autopsy was hypovolaemic shock due to haemorrhage probably originating in the retroperitoneum and extending into the peritoneal cavity.

INVESTIGATION

The case proceeded to an inquest. The Coroner obtained statements and heard from the doctors involved in Ms S' clinical care and the laboratory pathologist. Expert opinions were obtained from forensic pathologists and specialist physicians.

The key issues explored included; anticoagulant therapeutic INR range for Ms S, dosing and monitoring of warfarin at the rural hospital and the appropriate course of action following a high INR result.

The opinions about the therapeutic INR range for Ms S who was described as frail and elderly varied between [1.5-2.5] or [2.0-3.0]. However, the experts considered this debate was immaterial as the main concern was the high INR of 5.8.

During the admission at the rural hospital three different GPs were involved in the dosing and monitoring of warfarin. Also, it was Ms S' husband who questioned the warfarin dose of 7mg, which prompted the ward nurse to consult a doctor who requested the INR test, as it had been four days since the last INR test. The experts agreed Ms S should not have continued on a dose of warfarin 7mg per day without close monitoring.

International guidelines on the use of Vitamin K therapy for an elevated INR were presented and indicated that the management advised by the rural hospital in response to the INR level of [5.8] was not unreasonable.

CORONER'S COMMENTS AND FINDINGS

The warfarin therapy had been adequately controlled prior to, and during her initial hospital admission. However, testing at the rural hospital for warfarin was found to be inadequate.

The coroner found that the actions of the doctors in continuing Ms S on warfarin 7mg daily without appropriate INR testing, and the elevated result, contributed to the bleeding which caused the death.

The involvement of three different doctors at different times during the hospital stay was a significant factor in their oversight to monitoring her anticoagulation.

The coroner cautioned: *"while warfarin therapy is an important prophylaxis against a number of serious medical conditions, it is vital that it be administered strictly in accordance with the relevant guidelines and INR levels appropriately monitored for it is a potentially lethal pharmaceutical product."*

WHAT ABOUT THE PROTOCOL?

CASE NUMBER 0317/98

Case Precise Author: Amanda Charles RN, (CLS)

CLINICAL SUMMARY

Mrs A, a 79 year old female with a past medical history of chronic airways disease was admitted to a regional hospital following a fall. A fractured neck of femur was diagnosed and surgically repaired.

Several days later Mrs A was transferred to a smaller district hospital for rehabilitation. Shortly after, Mrs A developed atrial fibrillation and was commenced on warfarin with a loading dose of 10mg. On that same day she also developed a chest infection and was commenced on two antibiotics. Three days after commencement of warfarin the INR was measured at [3.4] after which warfarin 3mg daily was prescribed. The next test was five days later and the INR was very high at [11.6]. The warfarin was withheld for two days and Vitamin K was not administered. Two days later, without measuring the INR, the warfarin was recommenced at a reduced dose of 1mg daily. On this day the initial antibiotics were ceased and a third antibiotic was prescribed to treat the chest infection.

Six days later Mrs A had a blood test that showed a low haemoglobin of 92g/l and she died that day.

PATHOLOGY

The cause of death following an autopsy was an extensive subdural haemorrhage. The other findings included a haemo-pericardium consistent with haemorrhage secondary to iatrogenic anticoagulation.

INVESTIGATION

An inquest was held and the investigation included obtaining the hospital policy for the administration of warfarin, a statement from the treating doctor and an expert opinion from a consultant haematologist. The treating doctor indicated that monitoring with INR had been overlooked.

The expert opined that more regular INR testing may have very likely avoided the outcome. He also indicated that, although the use of antibiotics was appropriate, this may potentiate the effects of the warfarin. The hospital policy stated that the INR should be measured daily.

CORONER'S COMMENTS AND FINDINGS

"In this case the value of using and following an established hospital protocol was obvious." The coroner stated the doctor involved in the care of the deceased had contributed to the death.

AUTHOR COMMENTS

Another point of interest in this case from 1998 is how the coroner specifically named the doctor's 'contribution to death' in the finding. It was acknowledged that the finding of contribution to death may lead to unwarranted feelings of guilt or blame of the person involved. Therefore, on 1st July 1999 changes were made to the Coroner's Act removing the obligation of a coroner to make a finding about the identity of a person contributing to the death of another person. The removal of this obligation does not preclude a coroner from making a finding of contribution in appropriate cases under existing provisions of the Act.

TOO MUCH, TOO LITTLE OR JUST RIGHT?

CASE NUMBER 1273/08

Case Precise Author: Carmel Young RN, (CLS)

CLINICAL SUMMARY

Ms T was an 81 year old female who was admitted to hospital with dehydration and nausea. During the admission she developed paroxysmal atrial fibrillation and was commenced on warfarin 2mg daily. Despite the INR test [1.1] indicating the warfarin treatment was sub-therapeutic, the dose remained unchanged.

About a week later, Ms T developed chest pains with palpitations and was dry retching so an ambulance was called. When the paramedics arrived Ms T's condition had deteriorated significantly and did not respond to resuscitation efforts.

PATHOLOGY

The cause of death following autopsy was a saddle pulmonary embolus. The pathologist did not identify a deep vein thrombosis.

CORONER'S COMMENTS AND FINDINGS

The coroner noted: the combination of dehydration and decreased mobility may have led to the development of a deep vein thrombosis and the subsequent pulmonary embolism. Furthermore, if the warfarin dose was at a therapeutic range it may have prevented the formation of an embolus.

The coroner also noted that the warfarin was initiated for atrial fibrillation and not to treat venous thromboembolism.

No recommendations were made.

RESOURCES

National Patient Safety Agency (United Kingdom) has a range of resources to help manage the risks associated with anticoagulants. http://www.npsa.nhs.uk/nrls/alerts-and-directives/alerts/anticoagulant/

Australian Government Department of Health and Ageing. Guidelines for Medication Management in Residential Aged Care Facilities - 3rd edition: http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-pdf-resguide-cnt.htm.

National Prescribing Service is an independent, non-profit organisation providing medicines information: http://www.nps.org.au/home.

ANOTHER CASE

Our November 2008 issue of the *Coronial Communiqué volume 6 issue 4. Case number: 1387/04 'Knowing what the right hand is doing'* is another example of the need to improve our systems of care for managing warfarin.
Available at: http://www.vifm.org/communique.html

EXPERT COMMENTARY

Dr Merrole F. Cole-Sinclair, Haematology Department, St Vincent's Hospital email Merrole.COLE-SINCLAIR@svhm.org.au & **Melita VanDeVreede,** Pharmacist, Eastern Health email: melitavandevreede@easternhealth.org.au.

Warfarin is one of the most commonly prescribed medications in older persons. It is prescribed in a variety of clinical settings for therapy of venous thromboembolism (VTE) and thrombo-prophylaxis (e.g.,atrial fibrillation; prevention of recurrent VTE; and in patients with prosthetic cardiac valves).

Haemorrhagic adverse events occur because warfarin has a narrow therapeutic index, an inherently variable metabolism and a propensity for interaction with other medications. These adverse events occur especially in situations with an increasing PT-INR above the therapeutic range. However, patients with well controlled anticoagulation may also have a haemorrhagic event.

These bleeding events may be overt (e.g., epistaxis, subconjunctival haemorrhage) or 'concealed' (e.g., subdural or retroperitoneal haemorrhage). Patients, families, carers and health professionals need to be aware and reminded of the relevant symptoms (e.g., headache, back pain).

There are periods of particular risk that require more frequent laboratory monitoring. These include: patients who are clinically unstable (e.g., post-operative period); where there is change in diet or alcohol intake; development of an interacting co-morbidity (e.g., heart failure or infection); transition from parenteral to oral anticoagulation; and when medications are commenced, ceased or dosages altered. It is quite common for one or more of these factors to be present in patients who are or have been recently hospitalised.

The system of oral coagulation management is complex because it involves the flow of information between many people. Gaps in the flow of information are often the cause of warfarin-related adverse events, especially where medical care is transferred from an acute care to residential setting. This is not surprising when we consider the number and range of people involved: patient, carer/s, general practitioner (GP), specialist/s, hospital medical officers, nursing home, pathology staff and pharmacists.

Specialised anticoagulant dosing services are available through pathology providers and sophisticated information technology-based decision support systems are employed in a number of settings. However, the optimal clinical utility of such approaches is absolutely dependent on timely communication of accurate and current information relevant to dosage recommendations including clinical status; current warfarin dose; duration of present dose; changed medication/s; inter-current illness; presence of haemorrhagic symptoms.

Systematic, timely handover and clear definition of responsibilities about the arrangements for specimen collection, dosing and communication to relevant carers, GPs etc is essential.

When PT-INR results are above the therapeutic range appropriate management requires consideration of: factors that may have contributed to this result (e.g., commencement of an antibiotic); whether there is associated bleeding; adjustment of the warfarin dosage; adjustment of PT-INR testing interval.

The Australasian Society of Thrombosis and Haemostasis has published consensus guidelines for the management of an elevated PT-INR in adults in the presence or absence of bleeding. Prompt action should be taken to reverse the effects of an elevated PT-INR by withholding the warfarin for an appropriate period & in some circumstances administering Vitamin K, coagulation factor replacement or other therapy.

There are also significant and potentially fatal risks associated with sub-therapeutic anticoagulation (i.e., PT-INR below the desired therapeutic range). A significant number of patients spend a considerable proportion of the time (20% to 40%) with sub-optimal anticoagulation.

Harm minimisation from oral anticoagulation therapy requires careful initial and ongoing consideration of the risks and benefits, especially in frail older persons. It is important to establish clear protocols for timely, accurate handover of information and clearly delineate responsibilities for: provision of patient/carer information; PT-INR monitoring; checking of results; timely provision of dosage information; and action for sub-optimal oral anticoagulation (i.e., sub-therapeutic or over-anticoagulation).

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All cases that are discussed in the Residential Aged Care Coronial Communiqué are public documents. A document becomes public once the coronial investigation process has been completed and the case is closed. We have made every attempt to ensure that individual clinicians and hospitals are de-identified. However, if you would like to examine the case in greater detail, we have also provided the coronial case number.