

Michael J H Singleton
H M Senior Coroner
Coroner's office
Blackburn Central Library
Town Hall Street
Blackburn
BB2 1AG

31st October 2016

Your ref: MJHS/JKE/C44820/2016

Dear Mr Singleton,

Re: David Wade (Deceased) – Regulation 28 Report to Prevent Future Deaths

Thank you for your letter of 8th September 2016, together with your regulation 28 report, setting out the sad circumstances surrounding the death of Mr Wade. I was very sorry to read of the circumstances around his death, and would like to express my deep condolences to his family

In your report you outline your primary concern as:

“Patients who are provided with anti-coagulant therapy are at an increased risk of the development of haemorrhagic strokes. There appears to be no system in place to provide patients with literature setting out the symptoms of a bleed on the brain and the steps patients should take in response”

In light of your concerns I would wish to bring to your attention the standard anticoagulant booklet (more commonly known as the “yellow book” – which is warfarin specific) given to patients as recommended by the former National Patient Safety Agency. A link to its content is below:

<http://www.nrls.npsa.nhs.uk/resources/?EntryId45=61777>

As you will see the yellow book does set out a list of symptoms which if any occur then urgent medical advice should be sought. This advice is also available to patients on NHS Choices. The National Institute for Health and Clinical Excellence also supports the use of the yellow book as their clinical knowledge summary on warfarin makes reference to patients being given the yellow book.

I can confirm that the ‘Yellow’ Oral Anticoagulant Therapy (OAT) book is still in

print and widely available in the NHS. Shown in the table on page 2 of this letter, is the latest available data (2015) on distribution of the booklet across the NHS.

In addition to distributing the booklet, I note the second part of your concern regarding steps to be taken by the patient should they experience symptoms of a bleed. Whilst this is an important issue it is, fortunately, an uncommon one. In terms of absolute risk, the rate of spontaneous intracerebral haemorrhage (ICH) among 70-year-old subjects not on anticoagulants averages 0.15% per year. In those anticoagulated with warfarin to an "INR" (please see below) of 2.0 to 3.0 (the usual range), the risk of ICH is increased to 0.3 to 0.8% per year. International Normalised Ratio (INR) is the measure of the degree to which clotting is inhibited by the drug and for most clinical conditions requiring anticoagulation the aim is to double the time coagulation takes when measured by the INR. The risk of bleeding is probably slightly lower with the newer oral anticoagulants which are known as Direct Oral Anticoagulants ("DOAC"s) or Novel Oral Anticoagulants ("NOAC"s).

OAT Book	264,700	This is a record book used to record the patients use of warfarin. It contains critical information concerning the patient, his or her warfarin use and the associated INR. It is the patients tracking record.
OAT Card	104,700	A patient-held credit-sized card indicating that the holder is taking warfarin. This is to communicate the fact of warfarin use to others, potentially in an emergency situation
OAT Patient Info Book	29,250	The patient-held information supporting the need for monitoring INR with Warfarin. It provides general high-level information on warfarin use but is not exhaustive in this regard.
OAT Pack	184,750	This is a pack containing the OAT Book, the OAT card, the OAT Patient information Book and the OAT Sheet.
OAT Sheet	6,300	This is an A4 sheet that can be used in a printer (suitably aligned for use) to record warfarin dose and INR against time.

When people do experience a bleed into their brain, whilst on anticoagulants, then the effect is usually obvious and profound. As a consequence patients typically nearly always arrive promptly in hospital (from your regulation 28 report this would appear to have happened in Mr Wade's case). NHS England agrees that all patients starting on anticoagulants (both warfarin and DOACs) should be given all the relevant information, including that outlined above.

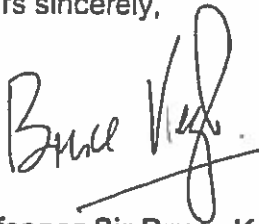
Anticoagulant clinics are where the majority of patients start their anticoagulants and usually have protocols for information provision. Currently most patients being started on DOACs have their initial few months of treatment initiated by hospital clinicians who would also be expected to provide the relevant advice.

High quality care for all, now and for future generations

Overall, there is, of course, a balance to be struck. It is important that patients are not deterred from taking a treatment where the balance of benefit over risk is usually strongly in favour of benefit so information should be provided in a considered way focussing on those benefits and not just the risks. Indeed the biggest issue in terms of population health is the failure to anti-coagulate people with atrial fibrillation. It is estimated that about 5000 people have unnecessary strokes each year in the UK because of fears about anticoagulation by patients and clinicians.

Thank you for bringing this matter to my attention and I hope this addresses your concerns.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Bruce Keogh', with a horizontal line drawn underneath the signature.

Professor Sir Bruce Keogh KBE, MD, DSc, FRCS, FRCP
National Medical Director
NHS England