Your ref: [redacted]

Karen Henderson
Assistant Coroner
c/o Lyn Ralfe
Parkside Chart Way, Horsham, RH12 1XH

BRITISH
SOCIETY FOR
DERMATOLOGICAL
SURGERY

16th August 2024

Dear Dr Henderson,

Re: **Inquest into the death of Dr Alan William Kingsbury**

Thank you for your letter of 5th July 2024 and the notification of Regulation 28: REPORT TO PREVENT FUTURE DEATHS for our attention, dated 8/7/24. We were sad to hear of the circumstances of Dr Kingsbury's passing, and wish his family our sincerest condolences on their loss.

The British Society for Dermatological Surgery (BSDS) was not in any way aware of or involved in the inquest arising from the death of Dr Kingsbury and was not invited to provide any evidence (written or oral) prior to receipt of the Regulation 28 report. The first the BSDS was made aware of the death was via the Regulation 28 report, received on 5 July 2024. The BSDS has not had sight of the Coroner's bundle or any other evidence arising from the inquest investigation itself. This makes it very difficult to be able to comment on the matters raised. The BSDS will attempt to respond to the concerns raised to the best of its ability without full disclosure and knowledge of the issues explored during the inquest.

BSDS were also uncertain which points we were expected to respond to, and thus sought further clarification from your office, with the reply being we should respond to items 5.1, 5.2 and 5.3 'if appropriate'.

We will therefore respond below primarily to the 'Matter of concern' raised in point 5.1 of the Regulation 28 notice received. However, we would like to offer some comments relating to point 5.2, which is within our purview and a current focus of our Society's educational activities. Without access to the full details of this case, we simply cannot comment on elements of surgical technique used (5.3).

5.1 BSDS (British Society of *[sic]* Dermatological Surgery) Guidelines on Anti-thrombotics and skin surgery for dermatological excisions in the community.

Our guidelines are not aimed at surgery in 'the community'. The majority of Dermatological Surgeons perform surgery in a secondary care hospital setting, in acute hospitals, or sometimes in more peripheral hospitals. There may be other guidance more appropriate for community use (e.g. surgery in primary care). This is relevant as the range of facilities, surgical expertise, and experience of supporting staff is typically more advanced in a hospital setting.

The guidance itself is composed of a 14 page text document, and accompanying risk stratification table, and a summary flowchart for quick use[1]. The flowchart cannot contain all the same information so clearly states 'see accompanying full text guideline document for details'. This guidance is designed to be used by someone with appropriate dermatological training in lesion diagnosis and treatment and is intended to support colleagues in their shared decision-making with patients, in gauging the right balance between the risk of a bleeding event from surgery, the risk from a thrombotic event, the risk and waste from unnecessary rescheduling of surgery causing delays to skin cancer diagnosis or treatment.

We highlight several highly relevant statements contained in the guidance below:

Page 2 Para 2
'Skin surgery varies in complexity and bleeding risk, as do the characteristics of individual patients, so temporary cessation of anti-thrombotic therapy is sometimes advisable on the balance of risks.'

Page 2 Para 3
'This is a guide only and clinical judgement should ultimately determine the degree of risk, particularly for complex patients. Advice from a multidisciplinary team may also be helpful.'

Page 2 Para 4 & 5
'Many surgeons already avoid stopping any anti-thrombotic drugs pre-operatively. However, the safety of this approach does depend on careful case selection, patient preparation and support, and the choice of therapy. Many high risk bleeding procedures could potentially be avoided altogether.

Individual patients vary in their attitudes towards balancing the risk of post-operative bleeding versus a thrombotic event. Achieving the patient's informed consent is crucial in decision-making for complex skin surgery, as recently redefined by the UK supreme court 'Montgomery' ruling.'

'Bleeding can also lead to falls or in-patient admission in the elderly. Serious morbidity or mortality is extremely unlikely. Risk factors can be additive (e.g. multiple drugs + repair type + age >65).

Page 2 Para 7-8; Page 3 Para 1

Clearly meticulous operative technique is always required to minimise the risk, but bleeding problems can still occur. Excessive bleeding during surgery usually responds to more meticulous electrosurgery or vessel tying, followed by a pressure dressing and patient rest and elevation where possible. However some agents can cause prolonged oozing after the local anaesthetic (LA) wears off, or for several days post-operatively, even if excellent haemostasis is achieved intra-operatively. Therefore reducing this risk by postponing surgery, altering the choice of procedure or repair, or sometimes withholding medications may be prudent. It is also crucial to pay greater attention to post-operative follow-up, considering home support, and day case vs overnight in- patient stay, especially for the elderly.'

Page 3 Para 2

Weigh up the risk factors and obtain informed consent for a plan agreed with the patient, other relevant physicians and surgeons, and the patient's family or advocate.'

Page 3 Final Para

'Consider postponing surgery until off clopidogrel if possible (e.g. surgery for BCC), especially if taking as part of dual- antiplatelet regimen.'

'**Combinations of multiple drugs'**

Page 5 Para 3

Potential to increase the risk of bleeding significantly. If procedure has high bleeding risk, delay where possible until patient on monotherapy (e.g. for patients on dual anti-platelet treatment

following percutaneous coronary intervention). If urgent, consider taking advice on modification of regimen, or changing the procedure.'

The guidance also gives a range of advice on how to minimise or treat excessive bleeding intra- and post-operatively, and stresses the importance of ensuring appropriate home support in case of bleeding problems.

The guidance and flowchart places particular emphasis on assessing patient specific risk factors, in addition to medication that may increase bleeding risk. The guidance also stresses the importance of assessing the specific risk of thrombosis versus the risk of bleeding for any individual patient, and ensuring a decision is reached with the patient by shared decision-making as to whether to stop or continue medication.

We do not know the details of the indication(s) for Dr Kingsbury's anti-platelet medications, so cannot comment on the balance of risks in his case. The guidance highlights the high risk of bleeding for patients taking combinations of multiple anti-platelet medications, and encourages discussion with the prescribing doctor about the potential cessation of at least one of these if possible, or consideration of postponement of the procedure to reduce bleeding risk, if the skin lesion is low risk.

There is a discrepancy in the Regulation 28 report as to the skin lesion diagnosis. Part 1c for the medical cause of death is recorded as *'Fall secondary to anaemia, secondary to bleeding chest wall lesion (excised* ***squamous cell cancer*** *19.10.23)'*, but the narrative conclusion states the lesion removed was *'****squamous cell carcinoma in situ'***. The distinction is important as it impacts on management and prognosis. Squamous cell carcinoma carries a risk of metastasis and often requires urgent treatment. However squamous cell carcinoma in situ is pre-invasive and can often be treated with more superficial procedures such as curettage and cauterisation, cryotherapy, or non-surgical (e.g. topical) treatment, although we recognise excision biopsy can be required to rule out invasive squamous cell carcinoma. We have highlighted this discrepancy to your office and we received a response that the index skin lesion was a presumed 'rapidly growing squamous cell carcinoma' although there is no histological confirmation as Dr Kingsbury died before a report was issued.

Depending on the full details of this case, the flowchart suggests at least one higher bleeding risk patient factor: ‘age >65’. Primary closure on a compressible site is low risk in our risk table in isolation, but the guidance makes it clear that this must be interpreted with other patient factors. The report mentions ‘the excision was larger than expected with some difficulty in obtaining primary closure.’ This is not the description of a typical low risk procedure. As such we would classify this scenario as high risk. The flowchart advice is therefore as follows:

'Stop any unintended prescription. Consider postponing until off drug Combinations: Consider stopping clopidogrel or 1 of the drugs (take advice)’

The flowchart, like the text document, also makes a range of recommendations to consider to reduce the bleeding risk:

‘- Postpone
- Choose safer surgical procedure (or radiotherapy or non-surgical)
- Increase support or admit patient
- Elevate and compress post-op
- Change operative setting (e.g. to improve equipment access, nursing support or more suitable operator)
- Give tranexamic acid (oral or infiltrated)’

The report into the prevention of future deaths states that the BSDS guidance is ‘insufficiently robust to reflect bleeding potential from a myriad of factors including the condition of the skin being excised, the position of the lesion and the underlying frailty and medical co-morbidities…’

We are not aware of any dermatological surgery evidence that ‘the condition of the skin being excised’ or ‘extremely fragile skin’ should be factored into a guideline on anti-thrombotics and skin surgery. The guideline explicitly mentions various body sites that can affect bleeding risk such as vascular sites on the face and non compressible areas such as the eye. There is recognition in the guideline that age >65 years is a high-risk patient factor.

The guideline is not intended to be an exhaustive medical reference to cover all aspects of patient assessment that would usually be expected in routine medical care by an appropriately skilled medical professional.

5.2 The lack of a Preoperative assessment and advanced consent

Page 2 Para 4 & 5

As per our own guidelines we have no disagreement about obtaining proper informed consent: ‘Individual patients vary in their attitudes towards balancing the risk of post-operative bleeding versus a thrombotic event. Achieving the patient’s informed consent is crucial in decision-making for complex skin surgery, as recently redefined by the UK supreme court ‘Montgomery’ ruling.’

The extra challenges posed by achieving informed consent for same-day ‘see and treat’ type procedures for skin cancer diagnosis and treatment are well known to our speciality. There can be benefits from this approach, in shortening the time to diagnosis and curative treatment, reducing travel and carer inconvenience, and healthcare costs. The taking of anti-thrombotic medication does not necessarily mandate the avoidance of a procedure at the initial consultation visit, but clearly requires appropriate information to be provided in advance, adequate time for the clinician to assess the risks (and any steps that might be possible to reduce those risks), adequate time for the patient to consider the risk and benefits and weigh the decision, and appropriate documentation of the shared decision-making process. Consent should be a two stage process with an appropriate period of reflection, depending on case complexity. The complexity of the decision and the amount of time required will vary between patients, so services offering same-day surgery must also be able to offer surgery at an appropriate later date if necessary. Many departments do offer such services safely. We aim to teach these principals in our courses and online learning, and a relevant journal publication is currently in press.

We would like to draw your attention to the extensive training and educational activities that the British Society for Dermatological Surgery provides on these topics for members and the wider profession in our popular online educational meetings and in-person courses for hundreds of doctors and nurses each year.[2] We also explicitly cover the complexities of pre-operative assessment, the management of frailty and anti-thrombotic medication, and informed consent in our virtual learning modules that complement our guidance:[3]

-Pre-Operative Care for Medically-Complex Patients

-Consent and Medicolegal

In summary, in response to the matter of concern raised in 5.1 of the regulation 28 report, regarding “position of the lesion”; “underlying frailty” and “medical co-morbidities”, the BSDS guidelines on antithrombotics and skin surgery does make specific mention to consider anatomical location along with patient factors including frailty due to age and medical co-morbidities. As the BSDS is unaware of any published evidence on “the condition of the skin” impacting on bleeding following cutaneous surgery, this is not included in the guideline.

Having carefully considered the Coroner’s concerns in the Regulation 28 report, it is the Society’s view that the guidelines referred to are sufficiently robust as currently drafted and based on clinical expertise and published evidence. We hope we have adequately responded to or addressed all your concerns raised in the Regulation 28 report. Thank you for giving us the opportunity to contribute to this investigation.

Yours sincerely,

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BSDS President and Consultant Dermatological Surgeon

On behalf of The Executive Committee of the British Society for Dermatological Surgery

References:

[1] British Society for Dermatological Surgery (BSDS) guidance on antithrombotics and skin surgery 2023; https://bsds.org.uk/resources/bsds-bad-guidelines/

[2] https://bsds.org.uk/events/

[3] British Society for Dermatological Surgery (BSDS) & British Association of Dermatologists British College of Dermatology Virtual Learning Modules; https://learning.bcd.org.uk