

25 MAR 2019



Royal College
of Surgeons

ADVANCING SURGICAL CARE

Mrs Karen L Dilks
HM Senior Coroner
Civic Centre, Barras Bridge
Newcastle upon Tyne
NE1 8QH

20 March 2019

Dear Mrs Dilks,

Re: Inquest concerning Stephen Pettitt (deceased)

Thank you for your letter of 1 February enclosing the Regulation 28 Report to prevent future deaths in light of your investigation into the death of Stephen Pettitt. I was naturally very sorry to hear about the circumstances and complications surrounding his surgery, and I offer my sincere condolences to his family and loved ones.

The Royal College of Surgeons (RCS) is committed to enabling surgeons achieve and maintain the highest standards of surgical practice and patient care. We play a central role in the training, development and support of surgeons throughout their careers, and provide advice on a range of standards for the profession.

In compiling my response, I have discussed your report and the issues it raises with RCS Council members and colleagues. I have also consulted the Society for Cardiothoracic Surgery (SCTS), the organisation representing surgeons specialising in cardiothoracic procedures, including mitral valve surgery.

Training and education

The postgraduate curriculum for surgical training is organised and overseen by the four UK Royal Colleges of Surgery. The Colleges also set and run examination processes at intermediary (Member) and exit (Fellow) level. However as robotic surgery is at such an early stage of development throughout surgery, it does not form part of the higher specialty training curriculum, and training would be expected to be taken through a number of routes once the Certification of Completion of Training (CCT) has been obtained from the General Medical Council. These may include a post-certification Fellowship programme which could be offered by academic or specialist healthcare institutions in the UK or overseas. We anticipate that the UK Colleges of Surgery will play a greater part in the recognition of UK fellowship schemes in the future.

RCS Good Practice Guides

The RCS supports good practice in surgery and service provision through the development of clinical standards and guidelines on specific areas. I should emphasise that they have no legal force, and while we strongly advise surgeons and hospital trusts to follow our guidelines, we have limited powers if they choose not to. Although we are not aware of the

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exact circumstances of Mr Pettitt's death, the RCS would like to point to our Good Practice Guides that outline the training and consent requirements in relation to the introduction of new surgical techniques. We believe these may have been applicable in this case and will help to prevent similar circumstances occurring in the future.

In 2014, we published *Good Surgical Practice*, a baseline of clear and assessable standards for individual surgeons and their practice, which contains a chapter on the 'introduction of new techniques'. The guidance seeks to exemplify the standards required of all doctors by the GMC in the context of surgery. In relation to Mr Pettitt's robotically assisted mitral valve operation, the guidance states:

"If you are introducing new surgical techniques and technologies you should:

- *Discuss the technique with colleagues who have relevant specialist experience and seek formal approval from your medical director.*
- *Follow local protocols with regard to obtaining approval by the local ethics committee or the local clinical governance committee*
- *Obtain appropriate training in the new technique, take part in regular educational activities that maintain and develop competence and performance, and enable the training of other surgeons.*
- *Ensure that patients and their supporters know that a technique is new before seeking consent and that all the established alternatives are fully explained prior to recording their agreement to proceed."*

In the last few years, the RCS has been undertaking work to understand the impact of innovation and technology, such as robotic surgery, on patients, the surgical workforce and the healthcare system. In October 2017, we established the independent Commission on the Future of Surgery to identify the likely advances in medicine and technology in the next twenty years. The Commission published its report in December 2018, which outlined how these technological changes may affect the delivery of surgical care. Following on from this, we will shortly be publishing a *Good Practice Guide on Surgical Innovation, New Techniques and Technologies*. This will contain a chapter on 'training in new techniques' that will state:

"When the technique has been performed previously by others, training might comprise:

- *hands-on experience of the procedure under supervision*
- *scrubbing in to observe another surgeon operate*
- *undertaking a fellowship*
- *participating in a formal training programme*
- *performing the procedure under mentorship from a trained surgeon."*

As you will be aware, the National Institute for Health and Care Excellence (NICE) expects hospital trusts to have their own clinical governance processes in place for introducing new interventional procedures that employees, including surgeons, will be required to follow. We welcomed Newcastle upon Tyne Hospitals NHS Foundation Trust's review of its guidance on the *Introduction and Development of New Clinical Interventional Procedures* since Mr Pettitt's death and understand they will be making further amendments following your inquest.

Supervision of new techniques

The RCS is planning to publish the *Good Practice Guide on Surgical Innovation, New Techniques and Technologies* this month. The Guide will provide the following advice that

surgeons will be able to apply in relation to the use of mentors in a chapter on 'training in new techniques':

"The surgeon should have a surgical mentor experienced in the technique to allow oversight for a defined number of initial procedures, sufficient to ensure proficiency before operating independently".

It will also state in a chapter on 'clinical governance and oversight': *"Local arrangements should include provision of evidence that the new technique is safe and that all clinical staff who plan to use the new technique will undertake relevant training, mentorship and assessment."*

We believe that mentors should be present throughout the procedure in question, have relevant expertise in the new technique, and be registered with the GMC. They should also have the appropriate indemnity cover because we would expect them to be able to intervene if necessary.

The RCS understands from surgical colleagues that the proctors supervising Mr Pettitt's surgery attended in relation to the placement of an aortic balloon, rather than the robotic procedure. Once the aortic balloon was implanted and functioning appropriately, they left the operating theatre. It is alarming that there was therefore no mentor attending with expertise in robotics who would have been able to intervene when the complications occurred during Mr Pettitt's surgery.

Although we were pleased to see the Newcastle upon Tyne Hospitals NHS Foundation Trust's guidance on the *Introduction and Development of New Clinical Interventional Procedures* includes a section on the use of proctors, we believe there may be some confusion over terminology within the document. As the RCS understands it, proctors do not have a training role. The terms proctor, mentor, trainer, supervisor and coach, are often used interchangeably as terms to describe a person identified to provide support and education. The College has used the term mentor to describe this role in its guidance as that is the term most surgeons use and understand in this context. We will be writing to the Newcastle upon Tyne Hospitals NHS Foundation Trust to this effect.

Registry for new surgical procedures and devices

In contrast to medicines, many surgical innovations are currently introduced without clinical trial data or long-term follow-up data, making it difficult to objectively assess benefits and risking patient safety. The RCS has been echoing the call from the Commission on the Future of Surgery's report for all new surgical procedures and devices to be registered, with related data collected in appropriate national audits before they are routinely offered to patients. This would cover the use of innovative treatments, such as robotically-assisted surgery, in both the independent and NHS sectors. It would also require Government funding and support, and potentially national guidelines on the introduction of new procedures and technologies. In addition to enhancing patient safety, this would help to further emphasise the clinical governance system and protocols for introducing new technologies.

Mitral valve surgery

Although mitral valve operations continue to be carried out routinely using minimally invasive techniques, the SCTS is aware of only one hospital in the UK where a programme of robotic mitral surgery is in place. Following the inquest in December 2018, the circumstances surrounding the death of Mr Pettitt have been discussed within the SCTS executive. The

enclosed email has been sent to SCTS members emphasising the importance of teamwork, appropriate training, the use of proctors and full engagement with hospital governance procedures when the new surgical procedures are being planned. Both the RCS and SCTS will continue to regularly remind their members about the standards we expect of surgeons throughout the UK.

Next steps

The RCS is deeply concerned by the death of Mr Pettit and is keen to ensure that our members are aware of relevant guidance in relation to training and consent when introducing new surgical techniques and technologies. To coincide with the publication of our *Good Practice Guide on Surgical Innovation, New Techniques and Technologies*, we are planning to highlight all the relevant guidance to our members and fellows through our newsletters, and communications with NHS hospital trusts and independent hospitals. We will also continue to monitor advances in technology and innovation to support the quality of surgical care and enhance patient safety.

I hope you find this information useful and would be happy to discuss these issues in more detail. Your office is welcome to contact Jasmin Rafiq on 020 7869 6009 or JRafiq@rcseng.ac.uk to arrange a convenient time.

Yours sincerely



Andrew Reed
Chief Executive

Cc: Matt Hancock MP, Secretary of State for Health and Social Care
[REDACTED] Case Manager – Coroner Prevention of Future Deaths Reports,
Department of Health and Social Care
Dame Jackie Daniel, Chief Executive, Newcastle-upon-Tyne Hospitals NHS Foundation
Trust