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Effective national guidance for the introduction of innovative surgeries is lacking - Lessons from the Newcastle inquest.

Richards H, Cousins S, Blencowe N, Blazeby JM on behalf of the NIHR Biomedical Research Centre Surgical Innovation Theme

An overhaul of the guidance related to the use of new or modified procedures and techniques in the NHS has been recommended in the wake of the death of a 69-year old patient who underwent an innovative robotic heart-valve surgery at the Freeman Hospital, Newcastle in 2015 (BMJ, 2018).

The procedure, which had never been performed with robotic assistance before in the UK, was considered by the Coroner to be directly responsible for the patient's death; had the patient undergone conventional open-heart surgery the mortality risk would have been 1-2%. Included in the Coroners conclusions were recommendations for national guidelines relating to the introduction of new procedures and technologies. This was echoed by the Royal College of Surgeons of England (RCS), who issued a statement in response to the inquest highlighting the "need for much clearer national guidelines" (RCS Statement, 2018).

The Bristol Biomedical Research Centre Surgical Innovation theme, funded by the National Institute for Health Research, is working to directly address this issue. A major step towards improving guidance is currently underway in the form of an in-depth analysis of policies in place across England and Wales. This work will provide a comprehensive overview of local regulations surrounding how innovative procedures are delivered to patients and will highlight required areas for improvement. The RCS stated that "surgeons are also subject to the governance structures that are in place where they work. A majority of NHS trusts have guidelines for introducing and performing innovative surgical techniques" (RCS Statement, 2018). Although the Department of Health made recommendations in 2003 to ensure all new procedures are approved by trusts Clinical Governance Committee prior to clinical use (DoH HSC2003/011), little is known about the prevalence, function, content or use of these guidelines in practice.

The RCS also noted in their statement a major factor in this case was that the surgeon undertaking the procedure had not received adequate training in the use of the robotic surgical equipment. Training of clinicians is one of several key issues to be explored in the work of Bristol BRC Surgical Innovation theme. In addition, issues such as when procedures should be considered innovative, whether procedures should be first evaluated within a research study (which necessitates formal ethical approvals), how and what information is conveyed to patients, and how decisions to abandon or proceed with innovative procedures/technologies are made, will be informed by work across the theme.

The need for standardised fit-for-purpose national guidelines has never been more evident. We need to ensure new procedures and technologies are introduced in a way that encourages positive innovations whilst maintaining patient safety by reducing unnecessary risks.