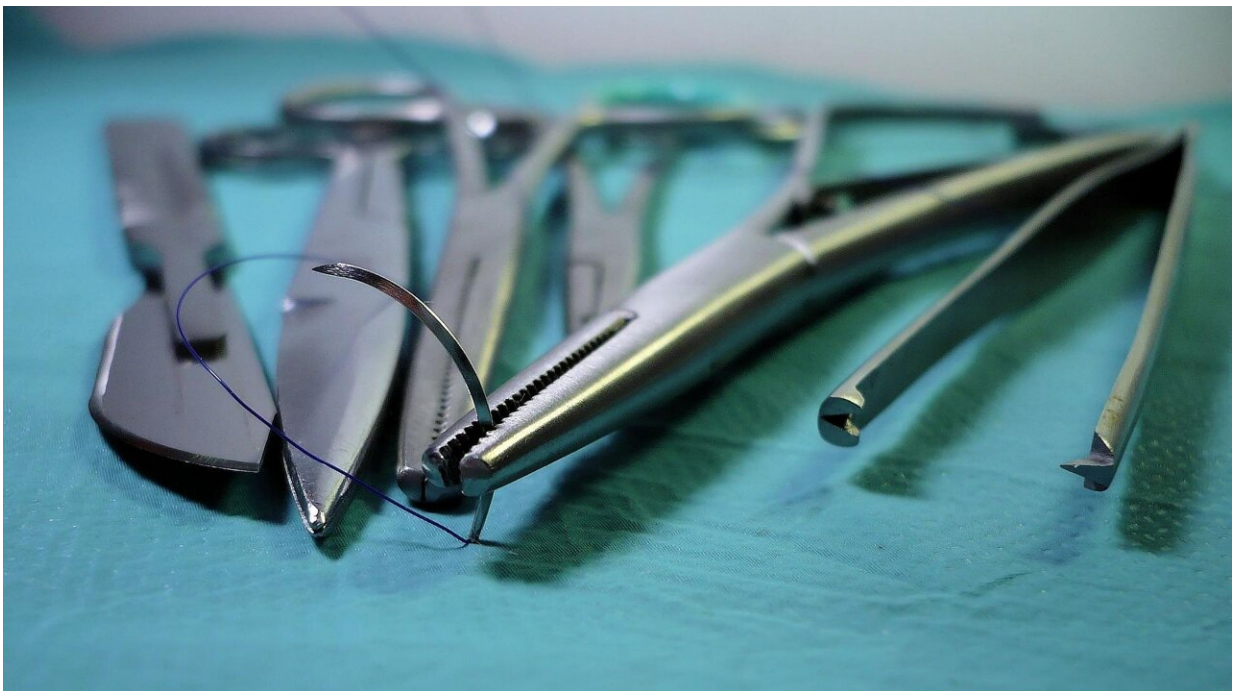


# Landmark study shows consistent approaches to surgical innovation are urgently needed

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A consistent approach to NHS policies on surgical innovation is urgently needed, a landmark study by University of Bristol researchers has shown.

The INTRODUCE study, funded by the National Institute for Health and Care Research Bristol Biomedical Research Center (NIHR Bristol BRC) published in the *British Journal of Surgery* today (3 August), examined NHS [hospital](#) policies for the introduction of new surgical and other [invasive procedures](#) and devices in England and Wales.

Researchers found that across the NHS, consistency in how surgical [innovation](#) is overseen is needed.

Surgeons innovate to improve [patient care](#). Innovation can also benefit the NHS when more cost-effective treatments are identified. Innovation requires management and oversight. It carries risk because it's not possible to know all the potential outcomes of a new procedure.

The National Institute for Health and Care Excellence (NICE) provides guidance on new surgical procedures not yet generally considered standard clinical practice in the NHS and provides recommendations about the conditions of safe use. NICE may recommend that a procedure is introduced with: "standard arrangements" (as in normal clinical practice), "special (local) arrangements" (with enhanced patient consent and close monitoring of outcomes), or in "(formal) research studies only," with research ethics committee approval.

Oversight is important because it ensures that patients are informed about how innovative their procedure is, which may influence their choice. It also means that safety data is collected and shared, which will influence whether the procedure is delivered to larger groups of patients.

The INTRODUCE research team wanted to find out how hospitals approached this. They studied hospital policies about what level of oversight was required to deliver new surgeries and invasive procedures. They investigated the policies to explore when new procedures could be delivered with standard or special arrangements, overseen by the local

hospital committee, and when instead they needed research ethics approval.

150 NHS trusts in England and seven health boards in Wales were approached to share their policies. The vast majority have a written [policy](#), although 20 did not and nine did not respond.

Of the 113 policies examined, most stated when new procedures should be referred to the local hospital committee, however, there was variation between policies in terms of what was within their remit. Few gave guidance for when research oversight was needed. Policies often stressed the need to comply with NICE guidance, but just 15 policies included explicit text stating if NICE had classified the procedure as needing research oversight only, then the procedure should only be delivered with research oversight. Policies were also contradictory. Some said that procedures with uncertain outcomes or insufficient evidence of safety and effectiveness should be referred to the local committee, other policies said that when this was the case procedures should be undertaken in research only.

Researchers from the INTRODUCE study are conducting a follow-up study to look at how NHS policies can be clarified and standardized. They are working with national stakeholders and NICE to strengthen the implementation of national guidance in local hospitals.

Jane Blazeby, Professor of Surgery at the University of Bristol and INTRODUCE study lead, said: "These new findings will help us improve how surgical innovation takes place in the NHS."

Dr. Sian Cousins, Research Fellow at the University of Bristol and lead author, added: "Our work adds to findings from the recent report from Baroness Cumberlege, which identified short comings in the process around innovation. We hope to work now with stakeholders to improve

surgical innovation in the NHS."

Mrs Paula Goss, patient representative, said: "I was shocked by these findings. I had expected that all hospitals followed national guidelines and protocols. I hope that this work will improve patients' safety and experience and that all hospitals take action immediately, making it mandatory."

"Healthcare organization policy recommendations for the governance of [surgical innovation](#): review of NHS policies," by S. Cousins et al is published in the *British Journal of Surgery*.

**More information:** Sian Cousins et al, Healthcare organization policy recommendations for the governance of surgical innovation: review of NHS policies, *British Journal of Surgery* (2022). [DOI: 10.1093/bjs/znac223 academic.oup.com/bjs/advance-a.../6651469?login=false](#)

Provided by University of Bristol

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