Thank you for the opportunity to contribute to the Royal College of Surgeons Commission on the Future of Surgery on behalf of the National Institute for Health and Care Excellence (NICE). Since 1999 NICE has provided the NHS, and those who rely on it for their care, with an increasing range of advice on effective, good value healthcare, and have gained a reputation for rigour, independence and objectivity.

In this submission I have outlined the current contribution that NICE makes in allowing the safe introduction of innovative surgical practice. As innovative practice evolves, NICE's role in ensuring innovation occurs within robust governance arrangements and with ongoing data collection and objective and independent analysis of that data become all the more important to ensure patients receive the optimal and most cost-effective care.

I would be delighted to discuss any of the points further with you if that would be helpful and I look forward to the opportunity of contributing to the oral evidence sessions in due course.

Background

It is widely accepted that both the burden of disease is increasing and changing in nature. At the same time the technologies available to treat disease are evolving rapidly. This trend is likely to continue with innovation in clinical practice being driven by both clinical need and research outputs from clinicians working collaboratively with the Life Sciences Industry. Such advances in medical technology will impact on the potential types of surgical treatments likely to be available in the future.

Specialists in their respective fields are likely to be best placed to predict the precise nature of the changes to clinical practice that innovation might bring. However more broadly, the health care system has to ensure it has the capacity and capability to realise any benefits that such innovation may bring. Clinicians, healthcare organisations and the NHS as a whole will need to be supported in the process of introducing innovation in a responsible way which protects the needs of patients and ensures any investment truly delivers the value to the NHS and its patients that is expected. At the same time innovators and the Life Sciences Industry need to be supported by an environment in which clinicians and local NHS organisations can rapidly adopt and diffuse transformative innovations.

These principles are set out in the government's Accelerated Access Review (https://www.gov.uk/government/organisations/accelerated-access-review). It "sets out an ambitious framework for how we can transform our NHS, pulling innovation – medical technologies, diagnostics, digital and biopharma products alike – through the system for the benefit of patients and improving the international competitiveness of our country". That review highlights the importance of working with NICE as part of that process.

Safe introduction of innovation

Safe introduction of innovation requires:

- Advice (guidance) on the efficacy and safety of new procedures as well as guidelines outlining how such procedures are best deployed in the management of a patient's condition.
- Recommendations on the training and other conditions for use of the innovation in the NHS
- Data collection and analysis of the patient outcomes resulting from the innovation.

At the same time rigorous evaluation techniques to assess the clinical (including comparative) effectiveness and cost-effectiveness of the innovation are required to ensure such innovation delivers the value expected of it by society as a whole.

The role of NICE in supporting innovation

NICE offers an extensive and varied portfolio of services that that can help Clinicians and Commissioners improve outcomes for people using the NHS (see: https://www.nice.org.uk/about/what-we-do). Our services are also utilised and valued by the Life Sciences Industry both within the UK and globally.

Specific programmes which will be essential to supporting the appropriate introduction of safe and effective surgical innovation in the future include:

1. The Interventional Procedures Programme (https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance): This programme assesses the safety and efficacy of interventional **procedures** to determine whether they work well enough and are safe enough for use in the NHS. The programme's aims are to protect the safety of patients and to support doctors, other clinicians, Clinical Governance Committees, healthcare organisations and the NHS as a whole in managing clinical innovation responsibly. To date it has produced over 600 pieces of guidance and published about 30 pieces of guidance per year. Approximately 60-70% of the procedures it now considers require a specific (often innovative) device (technology) to be used in order to carry out that procedure. Over the years it has seen a progressive trend for the notification of more minimally invasive procedures, including those which can be used as an alternative to more invasive procedures. It has a programme for regularly reviewing and updating guidance as new evidence becomes available.

   For any procedures that are considered innovative but not well established, named registers are often recommended for future data collection with the aim of collecting more evidence to inform future decision-making. To date only a limited number of these registers have proved mature enough to deliver evidence of sufficiently high quality to inform funding decisions. In order to support safe and effective innovation moving forwards **NICE would support the establishment of robust, and effective national registers for procedures (and their comparators) to allow observational data gathering for use by decision-making bodies**[1].

2. The Medical technologies Programme (https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-guidance).

This programme formulates guidance on specific **technologies (devices)** notified to NICE usually by manufacturers. A number of the technologies are those used in procedures already considered by the Interventional Procedures Programme. The programme considers potentially clinically non-inferior, resource-releasing technologies and undertakes a value assessment to determine as 'case for adoption' based on the claimed advantages of introducing the specific technology compared with current management of the condition. To date over 35 pieces of Medical technology guidance have been published. In addition the medical technology programme also produces Medtech innovation briefings which provide early advice on technologies by summarising the evidence and the place in therapy but contain no recommendation.

3. The Technology Appraisal Programme (https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance). Technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS. To date over 500 Technology Appraisals have been published. Although many relate to the use of medicines, they can also cover the use of medical devices and surgical procedures if the evidence base is sufficiently mature and robust to be able to do so. The recommendations are based on a review of clinical and economic evidence. The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE's technology appraisals.

The NICE guideline programme (https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines) provide evidence-based recommendations for health and care in England. They set out the care and services suitable for most people with a specific condition or need, and people in particular circumstances or settings. Recommendations are based on the best available evidence, for the care of people by healthcare and other professionals. They are relevant to clinicians, health service managers and commissioners, as well as to patients and their families and carers.

Good clinical guidelines change the process of healthcare, improve outcomes for patients and ensure efficient use of healthcare resources. They can be used to develop standards for assessing the clinical practice of healthcare professionals, to educate and train healthcare professionals, to help patients make informed decisions, and to improve communication and shared decision-making between patients and healthcare professionals.

For new procedures of already proven safety and efficacy they "position" the appropriateness of that procedure in the overall care pathway making judgments on clinical and comparative and cost effectiveness of treatments and ways of managing a particular condition with the aim of improving the quality of care.

The future

As the healthcare challenges we face increase and the innovative solutions we develop in response to this challenge evolve it is likely that a more flexible, rapid and

multi-dimensional approach will be needed to fully assess the impact of new forms of surgical technologies.

NICE is committed early dialogue with innovators and to ensuring a more streamlined and responsive approach. Where necessary it will adapt its assessment processes and develop new methodology, whilst maintaining the robustness of its internationally recognised evidence based approach. This will allow the assessment of the value of strategically important novel medical technologies and digital products such as apps. In this way the UK will be able to deliver truly transformative innovative healthcare treatments rapidly to its population.

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1. Kate L Mandeville, Hannah Patrick, Tristan McKenna, Kevin Harris. Assessing the Quality of Health Technology Registers for National Guidance Development. Eur J Public Health. 2017 Sep 12.