ABHI

ROBOTIC ASSISTED SURGERY

ABHI WHITE PAPER

ROBOTIC-ASSISTED SURGERY AND NEW MODELS OF SURGICAL CARE

PREFACE

The *ABHI White Paper: Robotic-Assisted-Surgery and New Models of Surgical Care* summarises the industry view on Robotic Assisted Surgery (RAS) in the UK. The RAS group operates under the umbrella of ABHI.

ABHI is the largest health technology (HealthTech) trade association in the UK and the ABHI RAS group represents a wide range of the UK HealthTech sector. Member companies are manufacturers and suppliers of surgical robotic technologies across specialities e.g. soft tissue, cancer, urology, musculoskeletal etc.

This document highlights the common themes and challenges across the environment for healthcare providers (NHS & private), clinicians and the industry, and the actions needed to accelerate the widespread adoption of minimal access surgery/ robotic procedures for patients and the associated benefits, as well as positioning the UK as an attractive country for healthcare investment and technology adoption.

This White Paper requests collaboration from the various stakeholders in this sector to improve and enhance the future of Robotic Assisted Surgery.

Corporate members of the ABHI Robotic Assisted Group:

- Members of the ABHI Robotic Assisted Group:
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- Globus Medical UK Ltd
- Intuitive Surgical Ltd
- Johnson & Johnson Medical Devices
- Link Orthopaedics UK Ltd
- Medtronic Limited
- NuVasive UK Ltd
- Smith & Nephew
- Stryker UK Ltd
- Zimmer Biomet UK Ltd

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EXECUTIVE SUMMARY

- This paper sets out the case for a national multi-stakeholder strategy for RAS to support its wider sustainable uptake and growth across the NHS.
- RAS provides opportunities to improve quality of care and outcomes, and to reduce costs to the health and social care system by enabling patients to return to better health quicker, when compared to conventional/open surgery[1]. Consequently, RAS should be seen strategically and a key consideration when looking at future surgical care configuration and patient pathway design.
- Whilst there have been improvements in the uptake of RAS, there remain opportunities to accelerate adoption further. These opportunities can only be delivered safely, effectively and efficiently through collaboration between industry, the NHS, Government, and patients. We believe working together on an aligned strategy is in the interests of all.
- Training standards will be important to provide reassurances to the public on the efficacy of RAS; set levels of expectation of surgical competency and standardise approaches to training across hospital Trusts and Health Boards, and surgical Colleges and societies; and establish transparency and benchmarks that all companies will have to comply with when developing training programmes for their robotic systems[2].
- Appropriate payment mechanisms for RAS in the NHS and independent healthcare providers are essential for widespread adoption.
- The post-Brexit environment presents the opportunity to incentivise and encourage HealthTech investment in the UK. However, without a regulatory environment that supports the aspirations of the NHS and industry, this may not be realised.

In summary, there are opportunities to:

1. **Build an agile regulatory environment that protects patient safety and drives the efficient evaluation of new RAS technologies as the UK develops the new UKCA marking system for medical devices.**
2. **Enable the efficient evaluation of clinical and economic value of RAS through the utilisation of validated real-world evidence.**
3. **Support the development of professional education, training, and expanding the knowledge of RAS to non-surgical NHS staff.**
4. **Improve the general understanding of RAS and its benefit, to positively inform the development of patient pathways and integrated care strategies.**
5. **Harness the value and benefits of RAS when formulating policy, for example, in response to the current backlog of elective surgeries and in future life sciences strategy.**

INTRODUCTION

This paper sets out the case for a national multi-stakeholder strategy for robotic assisted surgery to support its wider recognition, uptake and growth across the NHS.

The benefits of RAS versus conventional surgery are well catalogued[3-5]. Reduced trauma to patients [6-10] that can lead to quicker recovery[11-14] and better experience[15], fewer days spent in hospital[11,16] freeing up much needed capacity including Intensive Care Units and High Dependency Units, less physical stress on surgeons[17], potentially extending their working life[18-20], and procedures being performed on high- risk patients or patients with complex conditions where open surgery would not be an option[21-23]. The impact of RAS on operational efficiencies within hospitals will continue to develop as the technology adoption accelerates[24].

The NHS is going through a period of reform, some of it planned, some of it driven by necessity. The expected changes are in part, a response to the underlying challenge the NHS faces - ensuring healthcare remains accessible and free at the point of need - despite an ageing population, rising demands and cost pressures, and a fatigued NHS workforce facing an endemic challenge of recruitment and retention. In parallel, the NHS will for the foreseeable future deal with the elective surgery backlog and insulate the NHS from future shocks.

In England, a move to integrated care with regional strategies directing future investment and working across multiple Trusts, could lead to different models of elective surgery emerging to address local/regional requirements and objectives. This could be an opportunity to recognise RAS, in a similar way to how Scotland and Wales have recognised the role of RAS in their national planning.

The timing of this paper is important. The NHS in England is at an important juncture, with political decisions about how the healthcare system is structured and what is prioritised post-Covid all to be made in the coming months. This will set the direction and course of the NHS for a generation. Ensuring that the NHS and patients can realise the benefits from RAS is a key motivation behind this paper.

The NHS Triple Aim is our Triple Aim. This group believe RAS can support better health and wellbeing, better quality of health services for all, and a sustainable use of NHS resources. We believe RAS will be an integral and recognised strategic platform in a modern NHS.

BUILDING BLOCKS FOR ADOPTION AND SUSTAINABLE GROWTH OF RAS

This group has identified five areas that it believes are critical to driving acceptance and uptake of RAS across the NHS.

Build an agile regulatory environment that protects patient safety and drives the efficient evaluation of new RAS technologies.

- For the UK to remain a key global player in the research, development and use of new and emerging health technologies, such as RAS, it needs a regulatory environment that is supportive, nurturing and agile, with patient safety at its heart.
- In addition, the speed and breadth of new innovations will require a regulatory environment that in turn is speedy in its evaluation and conformity assessment of new products for use in the UK, while maintaining its integrity and not compromising in safety. Current regulatory frameworks are rigid and not fit for AI and machine learning, for example. These frameworks need to be future proofed, enabling responsiveness and less reactivity.
- Industry understand the challenge this may pose and would work with the regulatory authorities to design a regime that meets the needs of all.

Enable the efficient evaluation of clinical and economic value of RAS through the utilisation of real-world evidence.

- The capacity to generate, capture and analyse data can drive a revolution in our ability to understand more quickly the safety, effectiveness and value of new digitally enabled technologies.
- However, this capacity and the potential benefits it can offer, also needs to be accompanied by clarity in thinking on what data needs to captured, for what purpose, how will it be used to inform decisions and by whom.
- There are other benefits beyond those outlined above. The move in England to population based healthcare strategies delivered by integrated care systems and providers could pave the way for understanding the benefits of technologies beyond the setting in which they were utilised[25-29].
- While RAS has well reported benefits supporting patients to recover quicker and leave hospital sooner following surgery, how this benefit is maintained and enables them to return to normal life, is less understood. Demonstrating the potential 'ripple effect' of RAS through perioperative care, is one area that requires further attention.

Support the development of professional education, training, and expanding the knowledge of RAS to non-surgical NHS staff.

- RAS is a revolution and a significant leap forward from how surgery was performed even 20 years ago. Nevertheless, while the technology can significantly enhance the skills of the surgeon and their team, it still requires surgical competency, knowledge and understanding to deliver outcomes safely and efficiently.
- As RAS becomes more widely adopted, the need to train more surgeons and NHS staff will continue to grow.
- The industry recognise that training will necessarily vary because of the different RAS platforms that are being used, and the different specialisms they are being used for. Ensuring high standards in training and continuous professional development will be critically important.

Improve the general understanding of RAS and its benefits, to positively inform the development of patient pathways and integrated care strategies.

Equity of access to minimally-invasive-surgery, let alone RAS, remains a problem in the NHS. This can have serious implications for the patient, their treatment choices, and their overall wellbeing and recovery[30].

- The patient benefits of RAS, including reduced trauma leading to quicker recovery, are not always recognised beyond the surgeon and their team. Raising awareness of RAS and demonstrating its benefits to those supporting patients through their treatment journey will be important for them to make informed choices about their treatment.
- More pressing is the need to address the surgical backlog that has grown significantly since the start of the COVID-19 pandemic. Greater awareness amongst NHS planners of RAS, especially its positive impact on reducing length of stay of patients and reliance on ICU and HDU, could help alleviate the burden on capacity that some Trusts are facing.
- Lack of payment for RAS procedures can be a disincentive for Trust investment in robotic surgery. Current block contracts do not support uptake of RAS due to a lack of legacy payment mechanisms for such technologies outside urology[31,32].

Recognise RAS when formulating policy, for example, in response to the current backlog of elective surgeries and in future life sciences strategy.

- For the UK to take a leading role in research and development of digitally enabled technologies such as RAS, it needs to positively and proactively recognise it in key policies and strategies.
- This recognition would provide a welcome signal that the Government and NHS sees value in nurturing this fast-growing sector. An active partnership with industry is needed to demonstrate the value it can bring to patients and improved efficiencies in health delivery.

KEY RECOMMENDATIONS

Regulation

- Clarity on pre-CE/CA marking and CE vs. CA marking mechanisms.
- Leverage approvals from trusted third-party regulators, such as the FDA and EU Notified Bodies. This would circumvent the need for duplication of work by regulators and industry. Unilateral recognition would enable sharing the burden and would speed timings and reduce costs.
- Use validated Real-World Evidence and Real-World Data to support streamlined pathways to market and increase adoption of innovation.

Evidence

- Support industry, academia and NHS collaboration to integrate data that demonstrates RAS benefits not just for patients, but to the broader health system.

Training

- Understand what innovative, standardised, measurable training and education should look like.
- Establish how RAS trained surgeons and care teams can be recognised/certified.
- Assess use of kinematic/telemetry data and surgical outcomes data to inform ongoing training and development.
- Increase exposure and access to RAS for those undergoing surgical training.
- Facilitate standardisation of patient care through surgical workflow analysis by creating a digital environment that supports hospitals in combining pre, peri and post-operative data with EHRs (electronic health records).

Awareness and Understanding

- Industry to work with surgical societies, colleges, NHS bodies and patient groups to convey the value of RAS.
- Engage with local and regional NHS organisations to review and inform local treatment pathway development.
- NHS Digital and NHS Casemix collaboration via ABHI RAS group to support work towards an appropriate payment mechanism for the NHS and independent healthcare providers.

Policy Impact

- Government and NHS to work with industry to identify ways in which RAS can be integrated into healthcare policy and investments, in ways that recognize the benefits it can offer.
- NHS England to work with industry to form a digital surgical robotics working group bringing together industry, clinicians, patient groups and researchers.
- Assess use of RAS to improve capacity in NHS and how this may enable capital funding and activity reimbursement.

CONCLUSION AND NEXT STEPS

The ABHI RAS group supports RAS adoption across all geographical regions, healthcare providers and surgical specialities on the assumption that RAS should become "standard of care", improving clinical outcomes and delivering more consistent reproducible results which can support reduced costs to the health and social care system.

This paper highlights opportunities to accelerate adoption and identifies areas that require industry support and collaboration.

The White Paper is to be shared with the key stakeholders identified in the Recommendations to formulate robust strategies for the sustainable growth of RAS.

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