16th February 2018

Barbara Pitruzzella
Policy Adviser to the Commission on the Future of Surgery
Royal College of Surgeons
35-43 Lincoln's Inn Fields
London WC2A 3PE

Dear Ms Pitruzzella,

Baxter Healthcare response to the Royal College of Surgeons of England call for contributions to the Commission on the Future of Surgery

Baxter Healthcare welcomes the opportunity to contribute to the Royal College of Surgeons Commission on the Future of Surgery. We would like to comment with two broad themes: (1) where we believe there will be innovation for patient benefit; (2) where collaboration for efficiency gains will shape the perioperative landscape.

Undoubtedly, medical devices and technology will continue to define new treatment paradigms and make risky procedures less so. However, the use of many devices in combination will lead to inevitable questions about synergies, incompatibilities and comparative efficacy. In a landscape where part of the complexity of surgery is in defining which treatments benefit individual patients, partnerships to understand how to direct novel therapies will be essential. This could take the form of patient registries, or collaboration with industrial partners to responsibly introduce devices. Data capture in the form of prospective real-world evidence generation will improve the reliability of this process. Part of making this successful could be to reward clinical, academic and industrial co-operation to move beyond a vendor-payer-patient model, which leads to unwarranted variation in the uptake and utilisation of medical devices.

Embedding innovation adoption into routine processes will break down some of the current tensions between evidence and innovation. The current paradigm of reward for randomised-controlled trial publication (through the Research Excellence Framework and National Institute for Health Research systems amongst others) creates a cycle of dependence and emphasis on this as a singular source of efficacy data. This will not be fit for purpose in the fast-moving world of individualised diagnostics and therapeutics. We welcome the recommendations of the recent Accelerated Access Review, and see it as a positive step towards the inclusion of MedTech into horizon scanning, defining the responsibility for innovation within healthcare and health research, and a system that can keep pace with advancements in technology. With this foundation, the future will see an opportunity for value and outcome based collaborations to drive new tools and treatments to the clinical interface.

The regulatory challenge of managing hybrid devices that combine data, device and pharmaceuticals is extant and will continue to evolve. Learned bodies of clinicians will inform this process, and ensure that it does not become a barrier to adoption or innovation yet maintains the crucial role of ensuring patient safety. However, this challenge jars with the widespread acceptance that surgeons present and future will continue to be craft specialists and the use of their tools, instruments and devices will vary with outcomes potentially remaining similar (two different standards must continue to apply; usability and clinical benefit are not necessarily synonymous).

A focus on patient outcomes (defined both by patients and their clinicians), rather than process-led endpoints will mitigate some of this challenge. Surgery will become part of an even more complex patient journey than exists today, but the application of both real-world evidence and predictive analytics will enhance the doctor-patient relationship and guide patient specific decisions.

Another aspect of maintaining patient choice in a complex evolving healthcare environment will be to break dogmatic practices that confine surgical treatment to a hospital, or worse, to treat the events that occur in an operating theatre as an isolated event. Sustaining the autonomy of patients to have treatments, where possible, in the setting of their choice is the natural outcome of this. Quite often, this is at home (or near home), with community-based care supported by remote specialists. Facilitating the rapid, safe and appropriate discharge of patients back to that environment could be a relevant clinical endpoint. Therapies and devices designed to do this will gain pre-eminence.

Finally, while William Steward Halsted could distil the basic principles of surgery into just seven Tenets as relevant today as in the 19th Century, the educational framework required to develop the skills of a future surgeon will add numerous competencies to this list. The variation in the learning curve for devices new to a surgeon and their trainee may require both to become masters concurrently. Ensuring access to the most advanced devices at the earliest stages in training will ensure rapid penetrance of technology for patient benefit, rather than a top-down trickle of technology, stifling adoption.

Yours Sincerely,

Dr Peadar O'Donohoe
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