INTUITIVE SURGICAL®

Response to the Call for Contributions Commission on the Future of Surgery

Thank you for the opportunity to contribute to the ***Commission on the Future of Surgery***. Intuitive Surgical pioneered the field of, and is a global technology leader in, robotic-assisted, minimally invasive surgery (RAS) with the creation of its *da Vinci* Surgical System. We commend the Commission for this forward-looking consultation, which could be transformative for surgery in the UK.

The original prototype for the *da Vinci* System was developed in the late 1980s at the Stanford Research Institute under contract to the U.S. Army. While initial work was funded to develop a system for remotely performing battlefield surgery, broader surgical applications were even more compelling. In 1995, Intuitive Surgical was founded to explore this forward-looking theory. In January 1999, Intuitive launched the *da Vinci* System; in 2000 it became the first robotic-assisted surgical system cleared by the FDA for general laparoscopic surgery. More than two decades later, Intuitive is on its fourth-generation system. More than 5 million robotic-assisted surgical procedures have been performed worldwide, and the *da Vinci* systems' benefits have been explored in over 15,000 peer-reviewed scientific publications.

Surgeons throughout the UK have been at the forefront of driving innovation using robotic-assisted surgery following the introduction of the *da Vinci* system in the UK 10 years ago. During that time, surgeons have advanced improvements in patient care and reduced length of hospital stay for a number of procedures. This has led to savings associated with the total cost-to-treat patients, which has saved the national healthcare system money.

Our two-plus decades' experience in robotic-assisted, minimally invasive surgery has taught us that the successful implementation of innovation is about ***more*** than just the technology. Training and education, customer service and support, data analytics – our surgical systems are surrounded by an "ecosystem" of customer-oriented programs and solutions. These elements have been crucial to the successful adoption of our surgical systems, and will be essential to supporting the full realization of future surgical innovations.

Within this context, Intuitive Surgical continues to invest in what we see as 5 key pillars of innovation to advance minimally invasive care: less invasive approaches/technologies, intelligent systems, enhanced imaging, data analytics and optimized learning. We believe innovation in these areas will support the advancement of minimally invasive care that will decrease variability in surgery which can enable improvements in patient outcomes (quicker recovery, leading to productivity and improved quality of life), drive efficiencies in hospitals and provide solutions to wider systemic challenges (e.g. increasing surgical capacity within the NHS to cope with an aging population; increasing hospital bed availability by reducing length of stay and/or facilitating the use of "day case" surgery).

Please find below relevant information responding to the consultation's "Questions to Consider." We would be happy to provide further information in any area.

1. Innovations that will have a significant impact on surgery

Minimally invasive Surgery/Robotic-Assisted Surgery

Intuitive's *da Vinci* Surgical System enables surgeons to perform complex operations through a few small incisions. The system consists of several key components including: an ergonomically designed surgeon console, a patient-side cart, interactive robotic arms, a 3D-HD vision system, and wristed instruments. The system enables the surgeon's hand movements to be scaled, filtered and translated into precise instrument movements inside the patient's body.

Intuitive has introduced a range of systems at a variety of price points to meet customers' clinical needs today and in future. These include systems optimized for complex, multi-quadrant surgery, and those designed for simpler, single-quadrant surgery. When determining which features and technologies to incorporate into our products, we look for those with promise to positively impact surgeon productivity, patient outcomes, and quality of life for both. And we work with surgeons from around the world, seeking their input, as well as their hands-on testing of prototypes. Their contributions to the evolution of our systems have been invaluable in improving patient care and outcomes.

Additionally, we have developed a wide range of vision and instruments to meet surgeons' needs, including:

- Enhanced 3D-High Definition vision capabilities that provide surgeons and OR staff with a crystal-clear view inside the patient's body.
- Staplers with fully wristed articulation that detect when instrument jaws are adequately closed on target tissue, and enable stapling control from the surgeon console.
- *Single-Site*® instruments that enable surgeons to operate through a single small incision.
- *EndoWrist*® wristed instruments that provide surgeons with natural dexterity and greater range of motion.
- A dual-purpose simulation console, developed with surgeon feedback, that can help facilitate proctoring and/or mentoring, as well as training and skill development by offering procedure-based simulation practice.

We are continuing work on the *da Vinci SP (single port)* platform, developed to enable natural orifice and single-port surgical approaches. Three instruments and an endoscopic camera enter the body through a single orifice/port, and the instruments and camera have snake-like, flexible shafts for positioning after entering the body. This is just one of the innovations we are working on to further our aim of creating less invasive approaches.

We also are looking to the future and developing new technologies to enhance minimally invasive procedures, including a flexible robotic catheter to enable earlier diagnosis of lung cancer.

The breadth of literature regarding *da Vinci* surgery is extensive: there have been over 15,000 peer-reviewed publications examining the use of the *da Vinci* system in various procedures (data summaries can be provided on request). Within this body of evidence, many benefits of RAS have been demonstrated including: less pain, less blood loss, fewer complications, shorter hospital stays and fewer readmissions, and faster recovery/return to daily life.

Despite decades of progress, ***variability*** in surgery is still a major challenge. For example, evidence in laparoscopic bariatrics surgery shows that the bottom quartile of surgical skill has 3x more complications and a 2x increase in re-admissions than the top quartile (reference can be provided on

request). This variability may be underrepresented in academic research where laparoscopic surgeons with clinical research interest may be more likely to be from the top quartile and thus over-represented. RAS and, specifically, the use of data analytics may help address some of this variability.

Robotic-assisted, minimally invasive surgery and its benefits are well-established globally, and worldwide procedure trends demonstrate continued growth. In the UK, robotic-assisted surgery is well-established in urology, and is expanding within gynecology, general surgery, thoracic, colorectal and cardiac. Its use is emerging in newer fields, like head & neck cancer. As system use grows within and across indication areas, this will drive efficiencies for surgeons, OR theater teams, hospitals and healthcare systems.

Augmented Reality

At Intuitive Surgical our focus is not on *Artificial Intelligence* but rather on *Augmented Intelligence*, which enables surgeons to pull in information from other sources (e.g., overlaying an MRI over the surgical screen/field) and enhanced imaging to provide an array of information to surgeons pre-surgery and during a procedure.

Intuitive Surgical has already developed:

- Fluorescence imaging that offers real-time visual assessment of vessels and blood flow, and identification of target anatomy (*Firefly*™).

Augmented Reality is an area where we expect to see more development in the future that enables better, sharper and more defined view and identification of tumours, blood vessels, nerves, biomarkers and more.

Virtual Reality

Virtual Reality Surgery Simulators

Beyond the technologies listed above, we want to highlight the value of Virtual Reality **"Surgical Simulators"**, which already exist. These are useful for *training* purposes (for new doctors and for continuing medical education) and for team *preparation* in advance of a complex surgery. Greater use of simulators has the potential to improve quality of surgery/patient safety. Currently, Intuitive Surgical has over 2,000 *da Vinci* simulators at customer sites globally. 84% of U.S. customers at academic institutions use a simulator, and we believe further adoption of virtual reality simulators in other key geographies, including the UK, may have great potential to further accelerate learning and improve outcomes.

2. Are there any areas not listed above that we should consider or on which we should focus?

Data Collection & Data Analytics

Data collection and analysis has the potential to provide important feedback to individual surgeons and hospitals, but could also in future inform the creation of a broader platform for the collection of real-world evidence that could be used to optimize surgery.

At its core, the data our robotic-assisted surgical systems currently collect (non-identifiable, anonymized) is used to help optimize system use and maintenance. It can also help to inform and advance product development.

Surgeons and hospitals can additionally use this data to help improve surgeon technology training and skills, and to identify opportunities for optimizing efficiencies in the OR.

Harnessing data analytics more broadly and the learning from this growing base holds tremendous potential at the individual, hospital, country and world-wide level.

An Integrated Innovation Ecosystem

Although an individual technology is an important component of innovation, it is only through the creation and implementation of an integrated/supported ecosystem that it can be fully realized. Two decades of experience has taught us that an integrated ecosystem of support including: training/education (initial and advanced; via simulator and proctored; across surgeons, OR and wider hospital teams); customer service and support and data analytics will be vital parts of fully realizing the potential of this technology.

3. Direct or Indirect Benefits of Robotic-Assisted Surgery and Related Innovation

When looking forward to the next ten to twenty years, we strongly believe that RAS and associated technologies can assist in delivering the increased – and increasingly efficient - surgical capacity needed for an aging population in the UK. Furthermore, RAS can reduce variability in surgery, increase OR team efficiency and improve patient outcomes, including reducing length of stay, which could help address increasing demand on hospitals (and bed shortages) across the UK. RAS is a key example of how investment today in technology and training across disciplines may deliver efficiency and capacity today and in the future. We have outlined some specific potential benefits below:

Patient safety & clinical outcomes; enabling a choice of treatments in a rapidly changing health and social care system

Minimally invasive, robotic-assisted surgical approaches increase treatment options and improve patient outcomes. Current benefits of RAS include: less blood loss, fewer complications, shorter hospital stays, and faster recovery & return to work and life. This latter point means that there is often a reduced need for social care after a patient leaves hospital, again contributing to an overall reduced total-cost-to-treat per patient, saving the healthcare system money.

The surgeon's intraoperative decision-making and skill will continue to be critical in RAS in the future; however, new "Augmented Reality" features in upcoming years that enable the surgeon to visualize blood vessels and/or nerves etc., beyond what the naked eye can see, offer great potential for aiding intraoperative decisions. This also has the potential to lead to greater precision, standardized quality and less variability in surgery, resulting in improved patient outcomes. Furthermore, fully leveraging additional features such as monitoring/data analytics may help bring improved patient safety and outcomes.

In a society with an aging population, alongside a rapidly diminishing social-care provision, there is increased need for hospital beds. Adoption of technologies like RAS, which can lead to shorter bed stays, faster recovery and quicker return to daily life, will be key for patients, hospitals, the healthcare system and wider society.

The training and role of future surgeon/Staffing and career pathways of the surgical team

RAS holds great potential to transform the training and career paths of surgeons. RAS could potentially reduce the learning curve/training time required to become proficient in performing complex surgeries. Furthermore, data analytics could also help to understand how we can reduce variability by improving and "standardizing" performance and performance measures. Together, these

trends could help to improve outcomes and patient safety while reducing the resources and time needed to produce expert surgeons. Furthermore, one could extrapolate that this potentially larger pool of surgery capacity could free up the most experienced surgeons to deal with the most complex cases.

In order to fully realize this potential of RAS, training will be key; not only for surgeons, but for the entire surgical team in addition to pre- and post-operative care teams. Technological advancement plays an important role in making such improvements possible, but skilled OR and hospital staff will remain essential to successfully realizing all of the potential benefits that RAS systems have to offer. Similarly, in order to drive efficiency and maximise the benefits from training and building teams, an institution's processes and management of surgical systems across-disciplines will also be key.

Ethical and regulatory challenges

It is our viewpoint that the current UK healthcare evaluation system is designed more with innovation in medicines rather than new medical technologies in mind. For example, single discipline clinical and economic evaluation of a technology does not make sense when the value of a technology is predicated on cross-discipline utilization and system-wide economic benefits that require a holistic analysis, rather than a simple review of costs associated with a single operation or hospital stay.

A clear, certain pathway for technology innovation introduction, adoption and evaluation of medical devices is needed if we are to fully realize some of the transformative changes needed to meet the UK's future healthcare needs. Successful uptake of tomorrow's innovations requires action ***today***. While initiatives that look to foster the "new" and "next" are important, attention must be given to supporting innovations that already exist in the market. We would strongly recommend that a more in-depth exploration of the innovation pathway for technologies is conducted that takes into account the need to foster uptake of innovations once they reach the market.

4. Areas not Listed

One of the areas not listed above is the **'Benefit to Surgeons'**. RAS offers ergonomic benefits to the surgeon. Anecdotally, surgeons describe that although an experienced, skilled laparoscopy surgeon may achieve a similar patient outcome in complex cases, the stress level required to do so is greatly increased as the operation is more physically exhausting and challenging when steadiness of hand and small movements are totally reliant on surgical skill alone. The ergonomic advantages provided by RAS can help surgeons with physical challenges (e.g., back or knee pain) extend their surgical careers. It can also positively impact surgeons who otherwise would need to stand for up to 6-8 hours a day in laparoscopic or open procedures, often bent over patients with increasingly higher body mass indexes (BMI). If this was scaled up to the surgical capacity needs of the future, one can envision the impact this could have on the surgical workforce.

5. What will be the challenges of such innovations?

Some of the key challenges we foresee include the following:

- **Innovation Pathway:** A clear pathway tailored to technology innovation that facilitates adoption *and* uptake. There is no defined, clear path for innovation for medical devices today in the UK.
- **Evaluation Parameters:** Related to above, an evaluation paradigm that solely looks at cost, rather than considering system-wide value (including total-cost-to-treat, downstream cost savings, and decreased need for social care due to improved patient outcomes) may need to

change for technological innovation. Changing the focus from "point of sale" costs to a focus on investing in platforms that can deliver *system-wide* savings through improved efficiency, reduced downstream costs, and the ability to attract and develop the next generation of surgical professional, while meeting the needs of the changing UK demographics, may be needed. One of the biggest challenges is that the greatest efficiencies will be delivered once systems are fully utilized, adoption is widespread and experience is broad. Our current evaluation system is not set up to enable the full realization of transformative technology. Making procurement and adoption decisions would need to be moved to what delivers/has the potential to deliver clinical and future economic value.

- **Recognizing the importance of the Ecosystem:** As mentioned previously, technology is only ***one*** component of innovation. Adoption of new technological innovations must be fully supported by an "ecosystem" that meets the training/service/support and other needs of surgeons, staff, and hospital management. Evaluations of new, increasingly complex technologies must adapt in a corresponding manner to consider whether new technologies can be supported with training and technical expertise.

6. What will be the opportunities brought about by such innovations?

We believe RAS has potential to have a transformative impact on:

1. Patient-centered outcomes: RAS has demonstrated less blood loss, fewer complications, shorter hospital stays, smaller incisions for minimal scarring, and faster recovery and return to daily life. Furthermore, through wider system benefits, patients may also benefit from shorter waiting times for surgery. Additionally, through augmented reality and data collection/analytics better and more consistent quality of surgery may be achieved, and variability decreased.
2. Wider System Benefits: In an increasingly challenging environment, we believe that RAS could help increased surgical capacity, increased hospital capacity and efficiency, which will be critical to meet the future healthcare needs of the UK. (Please see answers to previous questions for examples).

7. What steps do you think would be desirable or necessary, if any, to prepare for such innovations and their impact?

The key steps that will be needed (already been mentioned earlier in the response) are summarized below:

- A clear 'Innovation Pathway for Transformative Technology', including evaluation of system-wide value and benefits
- An 'Ecosystem of Training/Support' across surgeons and wider teams in order to fully realize the technology potential
- Harnessing data collection & analytics to optimize learning

8. Would you be happy for your work/contribution to be featured in future media coverage about the Commission?

Yes, we would be happy to collaborate with you to be featured in future media coverage about the Commission.