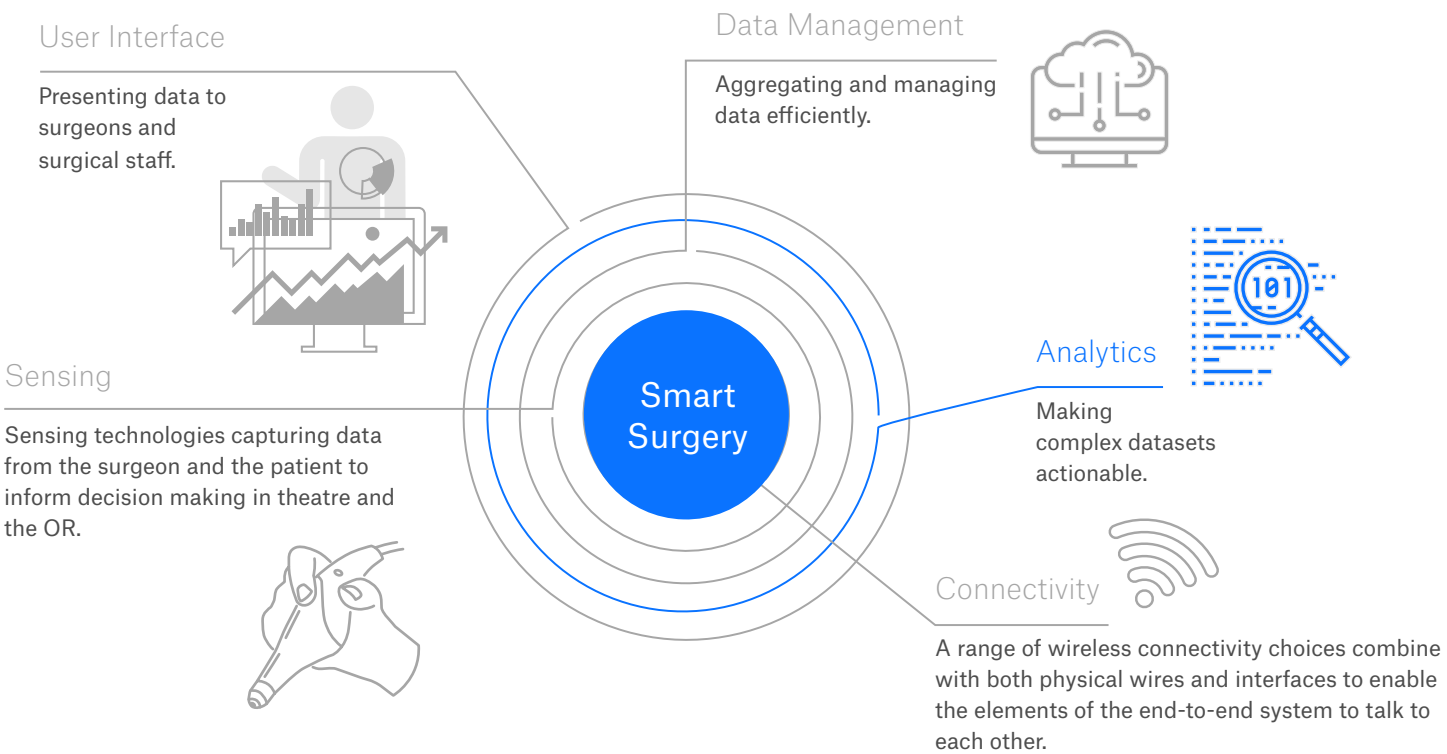


Acting smarter with data

In this article, Ross Jones and Chris Warwick, members of the Applied Science Team at Sagentia, look at the role analytics could play in the smart surgery phenomenon, as regulatory and perceived performance risks are overcome.



Smart surgery, part of a new era of intelligent medical technology, provides surgeons with real time information to improve decision-making in the operating room and across the care continuum. The technologies that enable smart surgery can be characterised by the infographic below:



Introducing the potential for analytics in smart surgery

Data analytics has wide ranging potential in surgery, encompassing surgeon training, pre-operative planning, intra-operative data fusion and navigation, performance analysis and improved intra-operative diagnostics based on machine learning.

However, regulatory hurdles, and in some cases insufficient robustness of the algorithms themselves, have limited smart algorithms to advisory and time saving applications outside of the operating room (OR). The uptake has also been limited by the difficulty of integrating new software products into existing workflows, for example integrating any proprietary software systems such as an intra-operative visualization system.

Sagentia believes that there are two emerging technology trends that will challenge this status:

1. Advances in the transparency of algorithms

Part of the reluctance to use algorithmic approaches is transparency, for example why a diagnostic algorithm has made a specific diagnosis. In order to gain the trust of medical practitioners and regulatory bodies, significant research is underway that is focussing on developing algorithms that can give such explanation.

How might an algorithm present such an explanation? For example, an algorithm that diagnoses prostate cancer from an optical micrograph of a biopsy could highlight regions of the image salient to the diagnosis and display similar images from its training data that received the same diagnosis.

2. Advances in the production of high quality synthetic data

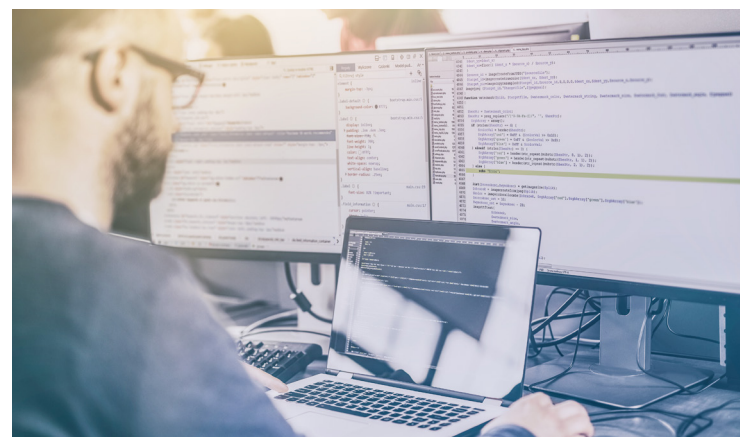
Synthetic data is data that has been manufactured not from direct measurement or real world examples – it is created from representative but fictional scenarios. It is very useful, in the following ways:

- a. Improving algorithm accuracy: typically machine learning algorithms are trained on data for which the ground truth is the opinion of a medical expert. However in many diagnostics applications the opinions of medical experts are highly variable and therefore the accuracy of the algorithm is limited to the chosen expert. The production of synthetic data from a known (but fictional) ground truth (for

example generating artificial mammograms from a fictional segmentation of a breast tumour) enables training beyond the accuracy of human experts. Human experts can also be evaluated on the same synthetic data set for comparison.

To validate the quality of the synthetic data, generated images can be subjected to Turing-like tests in which a medical expert is asked to attempt to differentiate between genuine and synthetic images. In some cases deep learning networks or other algorithms may themselves take this role of validating and training synthetic data generation, for example in the use of Generative Adversarial Networks (GANs).

- b. Compensating for insufficient or skewed medical data: medical data is typically skewed due to relatively little data on healthy individuals or those with rare diseases. Additionally it is difficult to collect sufficient data from all relevant demographics. Synthetic data sets can be made to represent the full range of patients' anatomies and health conditions. In this way smart algorithms can be trained to deal better with patients not represented well by available medical data.
- c. Compensating for low quality medical data: recording procedures vary from hospital to hospital, change with time, and are not always adhered to, resulting in missing, incorrect or inconsistent data entry. Synthetic data sets, designed to be representative of genuine data, can save time 'cleaning' medical records.
- d. Enabling open data sharing: synthetic data sets, designed to be representative of genuine data, do not require patient permissions to be shared, enabling collaborative and open-source development of smart algorithms.



There are also several commercial challenges that will need to be addressed to allow these approaches to be truly mainstream.

- **Integrating software solutions from multiple vendors:** The first challenge is that analytics software needs to be easily integrated into existing systems (hardware and software) and human processes and workflows to achieve widespread use in hospitals. Not only do hospitals struggle to work with a wide range of software vendors but integration is a major obstacle, particularly given the diversity of patient management systems.

The radiotherapy market perhaps provides some insight here. In this case, pre-operative planning is a must, providing an easy entry route for most manufacturers of hardware systems. However, the players with dominant hardware (Elekta, Varian, Siemens) also dominate the software space, so that smaller players often have to interface their hardware to this software. Only a few companies with a highly differentiated strength in pure analytics (e.g. Brainlab) have succeeded in gaining traction. This suggests that a non-dominant surgical company with a traditional focus on instruments may need a strong partner to establish data analytics as an offering.

- **Monetization:** Good data analytics are expensive to develop and maintain. The business case can be hard to establish especially in terms of new reimbursement or expanded market for existing products.

The industrial automation market provides some insight here. Its main routes to monetization have been:

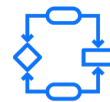
- Working as a system integrator, closest to the needs of multiple stakeholders – data analytics is one tool for meeting those needs. For example, analytics software could provide an interface between an intra-operative system and a cloud AI system, or between an imaging tool and a treatment tool.
- Addressing high value/high risk applications, where the incremental cost of data analytics is easily justified. An example here might be transplant surgery which is both generally very high cost (with costs for individual procedures running to more than a million dollars) and high risk and therefore a small analytics cost is more easily offset by improved outcomes.

- Switching to selling Products-as-a-Services (PaaS), taking the burden for maintenance and logistics away from the customer. Predictive maintenance, enabled by algorithms, could minimise downtime of big ticket capital items. Or, at the other end of the cost spectrum, a logistics system could populate trays of surgical tools, to minimize cost.

- **The regulatory approach to safety:** Regulation, robust across all of healthcare, can be particularly demanding in surgery.

It has been a barrier to adopting even the simplest image processing tools as, simply put, it's very difficult to demonstrate conclusively that complex software will do no harm. The standard mitigation is to make the distinction that data analytics provides information (higher level interpretation of data) and people make decisions based on that data.

The real value of data analytics in surgery is then to make decision making easier, faster and more accurate. This requires as much understanding of human behaviour as it does of algorithms.



In other applications with similar constraints, a quick win has been to use algorithms to reduce the drudgery of data interpretation, particularly for the kind of complex 3D imagery that is common in surgery.



Conclusion

Analytics functionality remains a potentially game changing tool for surgeons. There are challenges to its adoption and we believe that the technological ones are well on the way to being overcome. As confidence in analytics improves, bolstered by some of the technological solutions we outline above, then the commercial obstacles also become surmountable. If the perceived benefits of algorithmic approaches are significant and the risks greatly reduced, then the routes to monetization become more obvious and the desire to overcome issues such as integration grows. Regulation, rightly, is robust but as the artificial tools are seen to take on the burden of data interpretation, they free up humans to focus on accountable decision making, enabling greater patient throughput and better patient care.