A response to the SAGES TAVAC assessment of the *da Vinci*® Surgical System

Myriam J. Curet¹

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In response to the technology assessment written by SAGES' Technology and Value Assessment Committee (TAVAC) and published in this journal, Intuitive Surgical welcomes the opportunity to comment on the methodology and conclusions presented in the analysis. The TAVAC authors reviewed the *da Vinci*® Surgical System technology and evaluated clinical and economic evidence within the specialty area of gastrointestinal surgery. As the scientific representatives of Intuitive Surgical Inc., we have three main concerns with the methodology presented by the TAVAC.

First, throughout the assessment, laparoscopic surgery is used as the sole comparator for robotic-assisted surgery. However, robotic-assisted surgery provides a minimally invasive surgery (MIS) option to patients who otherwise would have undergone an open procedure. By limiting the comparator to laparoscopic surgery, the analysis does not account for the substantial number of patients still receiving open procedures in general surgery in the USA (over 50 % of colectomies, over 80 % of rectal surgeries and over 70 % of ventral hernia repairs, for example).¹ Additionally, year-over-year modality comparison data illustrate that the adoption of robotic-assisted surgery has resulted in a decrease in the proportion of open surgery procedures, not a decrease in the proportion of laparoscopic surgical techniques. In fact, for some procedures, the proportion of

laparoscopic surgical techniques has increased with the adoption of robotic-assisted surgery (Figure 1A, B). Therefore, we contend that the appropriate comparator for robotic-assisted surgery in this assessment is predominantly open surgery, not laparoscopy. Robotic-assisted surgery is an enabling technology that has been shown to increase the number of patients receiving MIS across large patient populations.

Determining which patients receive which type of MIS approach is an important issue for the surgical community. Patient populations matter, and defining the appropriate patient population for different surgical techniques should be a focus of future research.

Our second concern is with the methodology for selecting studies included by the TAVAC. These types of assessments typically use a rigorous methodology for identifying and reviewing qualified peer-reviewed literature. The selection criteria used by the Committee are not described, and a broader review shows that the authors omit a significant portion of relevant literature. The assessment primarily uses data that are more than 5 years old—while disregarding more current data that are often at a higher quality and evidence level. Based on our own systematic literature search (filtering for English language and <3b LOE), we found 250 additional, relevant publications that are not included in the technology assessment (Fig. 2; See supplementary online material for references and an appendix for the definition of level of evidence).

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✉ Myriam J. Curet
mcuret@stanford.edu

¹ Chief Medical Officer, Intuitive Surgical, Inc., 1020 Kifer Road, Sunnyvale, CA, USA

¹ The proportion of patients receiving open surgeries versus conventional laparoscopy has been analyzed in numerous public databases including the Premier Perspective Database and Truven Health Analytics Facility Report.

Fig. 1 Year-over-year modality comparison. **A** Rectal resection procedures for rectal cancer by modality (premier database 2010–2013, 2014). **B** Ventral hernia by modality (premier database 2010–2013, 2014)

Fig. 2 Number of publications (TAVAC vs. high LOE general surgery robotic)

Furthermore, the lack of randomized controlled trials (RCTs) is mentioned numerous times in the assessment. RCTs are not typically, nor frequently, used as a sole data source when making clinical decisions in the field of surgery. Throughout the medical community, over the last several years, it has been acknowledged that real-world data bring value to evaluations and assessments; that relying solely on RCTs as data sources overlook the importance of other data sources; and relying solely on RCTs is no longer necessary. Several published peer-reviewed articles speak to the limitations of RCTs and the value of real-world data (see online supplementary references concerning limitations of RCTs). In addition, Health technology assessment (HTA) institutions have acknowledged the high relevance of non-RCT data and have made conclusive recommendations on safety, effectiveness and cost-effectiveness—even in the absence of any RCT data (see online supplementary references concerning limitations of RCTs).

Our final point regarding the TAVAC analysis relates to cost comparison methods. When evaluating costs, it is essential to look at total cost of care for a patient episode encompassing direct costs, direct non-healthcare costs, indirect costs and downstream costs, which the authors have not done. Good quality cost data are based on direct cost comparisons—taking into account all relevant costs (including conversions, readmissions and reoperations) and looking at potential cost offsets between the approaches being compared. An incomplete computation of cost that omits relevant total cost drivers renders the conclusion invalid. Numerous peer-reviewed studies suggest that robotic-assisted surgery has the ability to improve functional outcomes and reduce complications, conversions, length of hospital stay and the risk of hospital readmission, which can lead to greater value and lower total cost of care. The assessment recommendations and conclusions based on the cost data used appear to be incomplete and therefore may be strongly misleading.

Very few issues in the healthcare arena remain static, and this is true of the ongoing discussion about the value and effectiveness of robotic-assisted surgery. As surgeons become more proficient with complex robotic-assisted surgery procedures and as the body of clinical literature builds, we encourage the SAGES community to continue to assess this technology and the value it brings to hospitals, surgeons and patients.