Institutional Economics in Robotic Colorectal Surgery

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130.1 Introduction

Robotic surgery represents a further step forward in the evolution of minimally invasive surgery and is one of the major advances and innovations in the surgical field of the last decades from a technological standpoint.

Nevertheless, although there is clear evidence that robotic surgery is safe and effective, higher costs and a still lacking evident clinical proof of superiority, when compared to conventional laparoscopic colorectal surgery, have limited its widespread acceptance.

Herein, we present our institutional economic plan to introduce and implement robotic colorectal surgery, focusing on and trying to address issues related to organizational aspects, business plans, multidisciplinary use and the development of a robotic school for training purposes.

130.2 Market Analysis

Robotic surgery has been gaining considerable acceptance in recent years in different surgical fields and specialties. The increase in the number of robotic procedures performed, when compared to its minimally invasive laparoscopic and open counterpart, has been demonstrated in the literature [1].

Recent market analysis foresees that the development of a new robotic platform that will enter into the market in the next few years will further increase the diffusion of this technology, not only in general surgery but also in orthopaedics and other surgical specialties [2]. The estimated growth of robotic surgery is supposed to be around 13.5% per year up to 2024. To date, many companies have invested in the development of robotic surgical systems, some of them being already available on the market for clinical use.

When other competing products will enter the market in the next few years, overall costs should decrease by stimulating the increase in demand from healthcare providers: a tenfold market growth is consequently expected as a result [2].

130.3 Potential Benefits of Robotic Surgery

Potential clinical benefits have been reported over the last years in the literature. The main areas of interest for robotic surgery are related to the potential increase in the number of procedures performed with a minimally invasive approach, thus reducing post-operative complications, narcotic use and length of hospital stay. The concept may be of utmost importance especially when related to procedures that may be technically demanding with a conventional minimally invasive laparoscopic approach.

Moreover, the development of a robotic surgical program may potentially allow to initiate or participate in national/international research protocols with subsequent increase in scientific publications, thus gaining institutional visibility.

130.4 Development of an Institutional Business Plan

130.4.1 Evaluation of Feasibility

The whole process is summarized in Fig. 130.1. Before approving and introducing the business plan, it is necessary to assess for the presence or the eventual establishment/development of the following organizational elements:

130.4.1.1 Internal Resources

Availability and cooperation with the clinical engineering department is mandatory in order to evaluate the new technology and the relationships with the company for the

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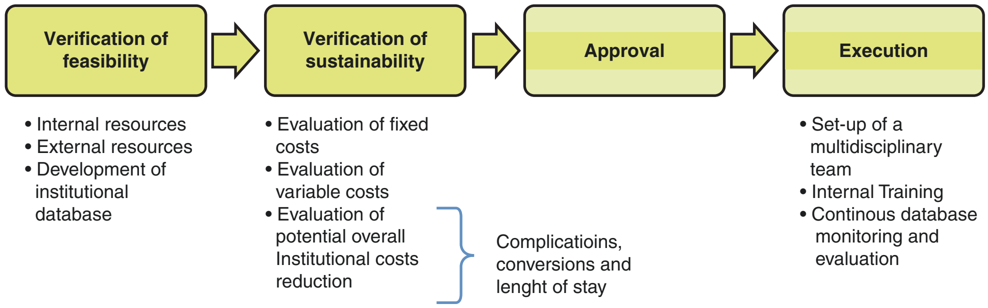


Fig. 130.1 Different steps of an institutional business plan

purchase/installation, maintenance, and eventual upgrades of the robotic system. Moreover, a preliminary logistic evaluation is of utmost importance for the adaptation and eventual implementation of the available operating theatres that will be specifically allocated for robotic surgery.

It is also necessary to identify the human resources (clinician and administrative staff) that will be involved in the multidisciplinary surgical program in order to plan the daily surgical activity and develop/maintain an institutional database for continuous quality control. All the available surgical specialties must be involved: general surgery, urology, gynaecology, thoracic surgery, ENT, anaesthesia, and operating room nurses. A team leader and a limited group of clinicians should be then identified and specifically assigned for the project. The involvement of all the above-mentioned healthcare providers is of utmost importance in order to define a multidisciplinary core that should be strongly motivated to reach the goal. This concept is strategically crucial to efficiently implement the use of the robot because, as it will be specifically discussed in the business plan, the greater the use of the new technology is, the better the results will be (even from a strictly financial standpoint).

130.4.1.2 External Resources

Training service development.

The implementation of the program requires proper training for all the clinicians involved: surgeons, anaesthesiologists, and OR nurses.

To date, in addition to courses and user meetings that are organized by the companies, proper training for robotic surgery is provided by the International School of Robotic Surgery in Grosseto. The availability of one or more experienced robotic surgeons within the Institution will eventually allow for training through utilization of internal resources and subsequent reduction of additional costs.

It is also important to emphasize the need to plan and eventually complete proper and efficient staff training before starting the clinical activity, in order to reduce, as far as possible, the steepness of the learning curve, operating time, postoperative complications and length of stay. All these factors are also strictly related to a possible overall increase in institutional cost burden [3].

130.4.1.3 Development and Maintenance of Institutional Database for Clinical Outcome Evaluation and Monitoring

Development, implementation and maintenance of an institutional database will potentially allow for:

A precise assessment and selection of patients to be included in the program. It is strongly recommended to start with easy and straightforward cases and procedures.

An analysis of the intraoperative results, with particular regard to the organization and efficiency of the surgical team, which includes anaesthesiologists, surgeons, and nursing and paramedical staff. Operative time (including setup and docking time, console time and overall OR time) will be carefully monitored. Operative times have been often reported in the literature to be longer when compared to conventional laparoscopic surgery. Nevertheless, recent studies have shown that, once the learning curve is completed and if adequate training is provided, robotic surgery OR times are comparable to those achieved with conventional laparoscopic surgery [4].

A constant assessment of postoperative outcomes, paying particular attention to the length of hospital stay and postoperative complications.

It is almost universally accepted that minimally invasive surgery can reduce post-operative complications, length of stay, hospital readmissions and wound/surgical site infections. In particular, in-hospital post-procedural infections are, to date, one of the most common cause of medical litigation.

A continuous analysis and revision of clinical data. This aspect will allow for program monitoring and appropriate corrections to improve performance and results, when needed.

An accurate monitoring and recording of clinical data. This will allow for the maintenance of a continuous reporting and analysis to evaluate the improvement of the surgical program and if the achieved results are better or worse than expected, both from a clinical and financial point of view.

Maintenance of a clinical database that will provide data to be entered in retrospective or prospective clinical studies after formal Ethical Committee approval.

130.4.2 Evaluation of Sustainability

To date, the absence of strong evidence on cost-effectiveness of robotic surgery and the availability on the market of a single robotic platform for clinical use, with a subsequent monopoly regimen in this area, has limited the diffusion of this technology because of a high-cost investment.

To date, however, some studies have demonstrated the sustainability of a business plan for robotic surgery along with its possible clinical advantages, which are strictly related to further indirect benefits for the Institution itself.

130.4.3 Business Plan

The establishment and implementation of a robotic surgical program requires the introduction of technologies that increase the costs of minimally invasive surgical procedures, at least in the short-term period. Therefore, in order to support the acquisition and use of the robot for the Institution, it is mandatory to preliminarily assess fixed costs, variable costs and the potential advantages (clinical and financial) of the new platform.

130.4.3.1 Evaluation of Fixed Costs

Fixed costs include the purchase and maintenance (fixed annual fee), recruitment and training of dedicated personnel (clinicians and nurses) and eventually structural modification/adaptation of the available operating rooms, when required.

130.4.3.2 Evaluation of Variable Costs

Variable costs include all the activities, instruments and medications that are necessary to carry out each surgical procedure. OR occupation time and related costs should be included as well as costs related to disposable surgical instruments (both robotic and laparoscopic instruments for table assistance, when required). Performing a higher number of robotic surgical procedures reduces the variable costs, with the maximum reduction taking place between 20 and 100 interventions per year; the variable costs can be further reduced by 18% if more than 100 procedures per year are carried out (range 100–500 procedures).

The main goal of the medium/long-term budgetary strategy is to gradually improve robotic surgical activity and to achieve a balanced budget (breakeven point), taking into account the different health-care systems and organizations that are available around the world.

The public health-care system in Italy, for instance, does not consider and provide for any specific additional reimbursement fee related to robotic surgery (only few exceptions can be recorded in Italy—as in Tuscany area—where additional reimbursement fees are provided for robotic rectal resection and radical prostatectomy).

Therefore, revenues and incomes can be assessed mainly in terms of cost-saving (reduction in complications and length of stay) or revenues coming from private practice.

The "productivity" in terms of cost-reduction will need to be indirectly valuated essentially considering the possible reductions in overall costs related to a better clinical performance.

130.4.3.3 Evaluation of Potential Overall Institutional Costs Reduction

Cost reduction may occur as a result of the increase in the number and percentages of complex surgeries performed with minimally invasive access (lower GI surgery, upper GI surgery, hepatobiliopancreatic surgery), which may potentially and gradually balance the initial financial burden related to the purchase of the robotic system. To date, the diffusion and penetrance of the complex laparoscopic surgery in Italy is still very low. On a nationwide basis, penetrance of laparoscopic colorectal surgery is around 30–35%; when taking into account HPB and upper GI surgery, the available literature shows even lower figures (less than 10% of overall procedures performed laparoscopically).

The main advantages of minimally invasive surgery, related to potential cost savings, are the reduction of postoperative complications, such as surgical-site infections and respiratory complications (especially in elderly and frail patients) [5, 6].

The costs related to hospital-acquired infections are globally and steadily increasing and are one of the most frequent causes of litigations.

Unfortunately, data related to potential cost-savings are difficult to be assessed and quantified and should necessarily be compared with historical data and figures available in a specific setting, specialty or hospital, before the introduction of the new technology on a case-by-case basis (including the evaluation of number of complications, length of hospital stay, conversion to open surgery, outpatient office visits and postoperative need for imaging studies per each different type of procedure).

130.5 Robotic Colorectal Surgery: Reduction in Complications, Length of Stay and Conversion to Open Surgery

To date, several studies have reported the higher costs related to robotic surgery, especially when compared to its laparoscopic counterpart. Unfortunately, most of these studies have focused only on direct costs related to the purchase and maintenance of the robot along with the related instrumentation per procedure. Reductions in post-operative complications, length of stay and conversion to open surgery are often not included in the total episode cost-analysis per patient, although all of these factors may strongly influence the overall financial burden for each Institution.

Better clinical outcomes are probably related to the concept of "precision surgery" in robotics, which allows for a reduction in tissue trauma through a more precise exposure and dissection along embryological planes, thus also reducing intraoperative blood loss.

To date, several studies have demonstrated a reduction in post-operative complications for robotic surgical procedures, when compared to conventional open or laparoscopic surgery [7–10], even on a nationwide basis.

An ACS NSQUIP nation-wide database analysis including patients submitted to low anterior rectal resection has recently showed a statistically significant reduction in overall septic complication rates and surgical site infection rates (1.6% in robot vs. 3.1% in lap, *p* value = 0.02). Bivariate analysis and logistic regression models were used [7].

Different studies have shown a reduction in conversion rates of robotic colorectal surgery when compared to conventional laparoscopy. Sun et al. analysed data from the US National cancer database including 6000 patients and demonstrated a reduction in conversion rates (8% vs 16%, $p < 0.001$) in favour of the robotic group. It is worth to underline that in the robotic group a higher number of male patients submitted to pre-operative radio-chemotherapy for locally advanced rectal cancer (cT3N+) were registered, all these factors being well-known predictors of technical procedural complexity [11].

Similar results regarding robotic vs laparoscopic low anterior resection were reported by other US population-based studies from the ACS NSQIP database and Michigan Surgical Quality Collaborative Registry carried out between 2012 and 2014 [7, 12].

Reduction in complications and conversion to open surgery can conceptually and potentially reduce the length of hospital stay, thus finally reducing overall indirect cost related to hospitalization and eventual subsequent need for outpatient visit and return to normal daily activity and practice.

The ACS NSQIP study including more than 11,000 patients supports this finding, having demonstrated a reduction in postoperative length of stay for patients submitted to robotic vs laparoscopic rectal resection (4.5 vs 5.3 days, $p < 0.001$) [7].

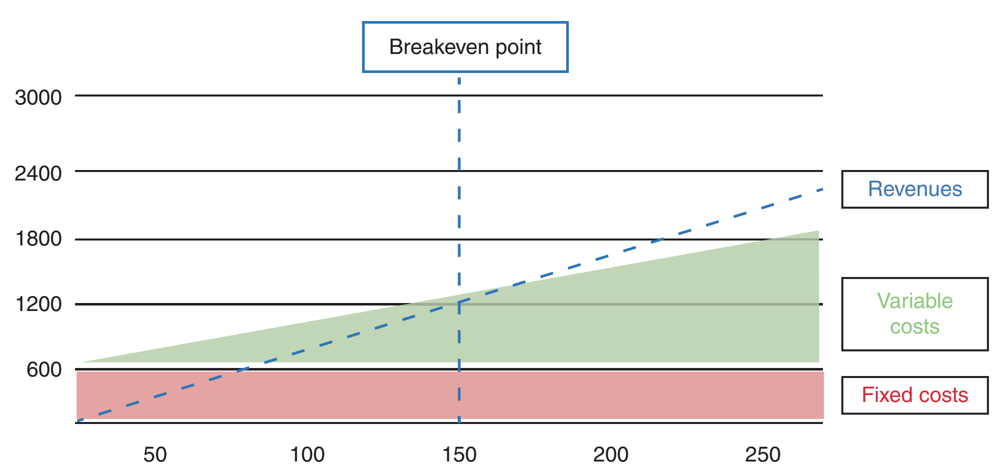
The Michigan Surgical Quality Collaborative Registry, including patients submitted to minimally invasive colorectal resection (from 2012 to 2014), further corroborates the above-mentioned data and has tried to specifically focus on the relationship between reduction in complication/conversion rates and costs. In this case, the total episode cost (namely, in-hospital direct costs plus 30-day post-discharge overall costs) was considered: total costs were comparable in the robotic and laparoscopic group, with the lower conversion rates of robotic surgery (and subsequent reduction in complications and length of stay) balancing the higher direct costs related to instrumentation and OR occupation time [12].

Salman et al. also showed similar results (Am surg 2013). When the overall cost is considered, hospitalization cost involving robotic surgery appears to be cheaper than its laparoscopic and open counterparts, because of lower complication rates, less ICU stay and shorter length of stay [13].

130.6 Breakeven Point

The so-called "breakeven point" can be achieved by evaluating the potential savings related to reduction in complications, length of stay and conversion to open surgery as well as any additional income related to an implementation of private practice, as shown in Fig. 130.2. It is possible to reduce the variable costs of the procedures by increasing the number of procedures per year. In order to optimize and

Fig. 130.2 Breakeven point evaluation



implement the use of this technology, a multidisciplinary approach is essential and the robotic system should be used by as many surgical specialties as possible.

The introduction of new technologies such as robotics and the subsequent expansion in the offer of advanced minimally invasive surgical procedures allow to effectively compete with other Institutions. This aspect is directly related to increased chances for scientific surgical research and increased visibility, which could actually further implement patients' recruitment and private practice to ensure that the breakeven point is reached as faster as possible.

130.7 Structured Training Program in Robotic Colorectal Surgery

In order to achieve the above-mentioned goals, the planning of a structured training program for all the involved subspecialties is fundamental to flatten the learning curve and speed up the process of optimization of both short-term and long-term surgical outcomes.

Adequate training enables for a faster implementation of the use of the technology within the surgical team, thus avoiding underutilization of the robot platform.

The effectiveness of the educational program is strictly related to the availability of an expert senior robotic surgeon. The internal training program will allow senior surgeons to have access to the platform according to a weekly schedule of distribution of the operating rooms, thus enabling junior surgeons to follow an innovative and structured program of learning in minimally invasive surgery.

We have demonstrated the safety and efficacy of a structured training program for young novice surgeons [14] without prior experience in both open and laparoscopic colorectal surgery, who were autonomous in basic minimally invasive surgical procedures. Right colectomy with intracorporeal anastomosis was chosen as a model and divided into three main learning modules (colonic mobilization, vascular control, intracorporeal anastomosis). Each step was carried out by the trainees at least two times under direct supervision of the senior surgeon. After the initial robotic cases completely performed under formal proctoring, they were privileged to perform robotic right colectomy independently without a mentor, accounting for a total of 20 procedures. This structured stepwise approach allowed junior surgeons to safely and effectively perform right colectomies with intracorporeal anastomosis. Neither conversion to open surgery nor intraoperative and major postoperative complications were recorded, thus allowing the novice to achieve results that were comparable to the senior surgeon's case-series.

130.8 Conclusions

Defining an institutional business plan in robotic colorectal surgery is a complex process and many factors should be taken into account. After an initial assessment of feasibility and sustainability, surgical volume, multidisciplinary use and adequate structured team training are fundamental to reduce per-case share of capital investment/fixed costs and avoid underutilization of the platform. The high cost of robotic acquisition and maintenance can be sustained by the adoption of a mix among private and public health system patients, with different modalities from different countries. Evaluation of the overall institutional financial burden should consider the potential reduction length of stay, septic and respiratory complications, thus shifting from a traditional direct costs' assessment to a "total-episode" costs' evaluation.

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