Hemodynamic Optimization
HOW TO IMPLEMENT?

Why Hemodynamic Optimization?

Are post-surgical complications exceptions?

Patients undergoing surgery may develop post-surgical complications. The morbidity rate, defined as the proportion of patients developing at least 1 (1+) post-surgical complication, increases with co-morbidities (patient risk) and the complexity and duration of the surgical procedure (procedure risk). Morbidity rates are often underestimated by clinicians when not measured from objective data. The primary post-surgical complications are listed in Table 1. A study published in the New England Journal of Medicine in 2009 by Ghaferi et al.[1] showed in *over 80,000 patients undergoing general and vascular surgery an average morbidity rate of 25%.* Post-surgical complications are not exceptions.

Table 1: List of most common post-surgical complications.

Infection	Cardiovascular
• Pneumonia • Urinary tract infection • Superficial wound infection • Deep wound infection • Organ-space wound infection • Systemic sepsis or septic shock	• Deep venous thrombosis • Pulmonary embolism • Myocardial infarction • Hypotension • Arrhythmia • Cardiogenic pulmonary edema • Cardiogenic shock • Infarction of GI tract • Distal ischemia • Cardiac arrest (exclusive of death)
Gastrointestinal	**Neuro**
• Nausea and vomiting • Ileus (paralytic or functional) • Acute bowel obstruction • Anastomotic leak • Gastrointestinal bleeding • Intraabdominal hypertension • Hepatic dysfunction • Pancreatitis	• Stroke or cerebro-vascular accident • Coma • Altered mental status or cognitive dysfunction or delirium
Respiratory	**Hematologic**
• Prolonged mechanical ventilation (>48h) • Unplanned intubation or reintubation • Respiratory failure or ARDS • Pleural effusion	• Bleeding requiring transfusion • Anemia • Coagulopathy
Renal	**Other**
• Renal insufficiency (increase in creatinine levels or decrease in urine output) • Renal failure (requiring dialysis)	• Vascular graft or flap failure • Wound dehiscence • Peripheral nerve injury • Pneumothorax

Table 1. Complications underlined are those used by Ghaferi et al. to calculate the mentioned morbidity rate of 25%.[1]

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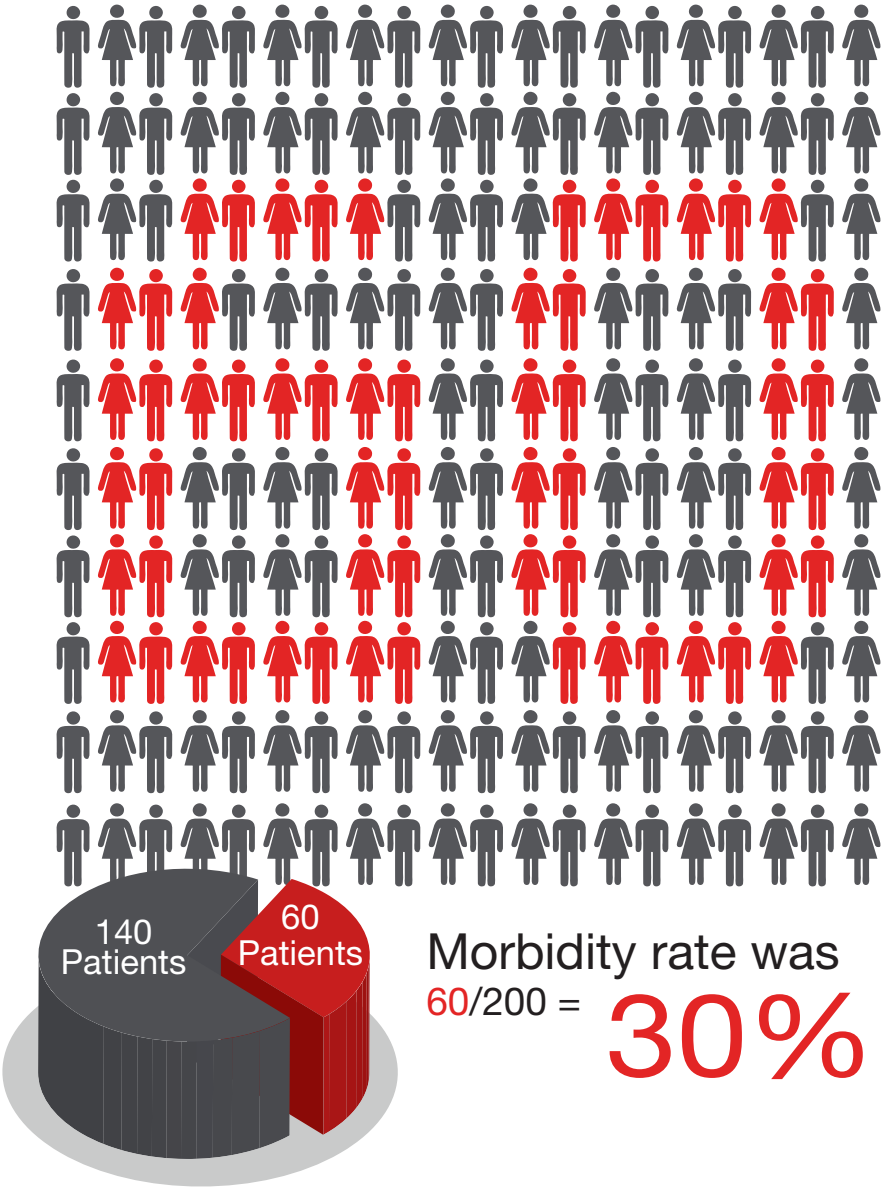
Example 1: Calculation of your morbidity rate for a specific surgical population.



Example 1: If 200 patients had a colorectal resection last year in your institution and 60 developed at least 1 complication (e.g. 12 patients a urinary tract infection, 11 a prolonged paralytic ileus, 10 a wound infection, 9 a hypotension, 7 a nosocomial pneumonia, 6 an acute renal insufficiency, 3 a myocardial infarction, 1 an anastomotic leak, and 1 a pulmonary embolism), your morbidity rate was 60/200 = 30%.

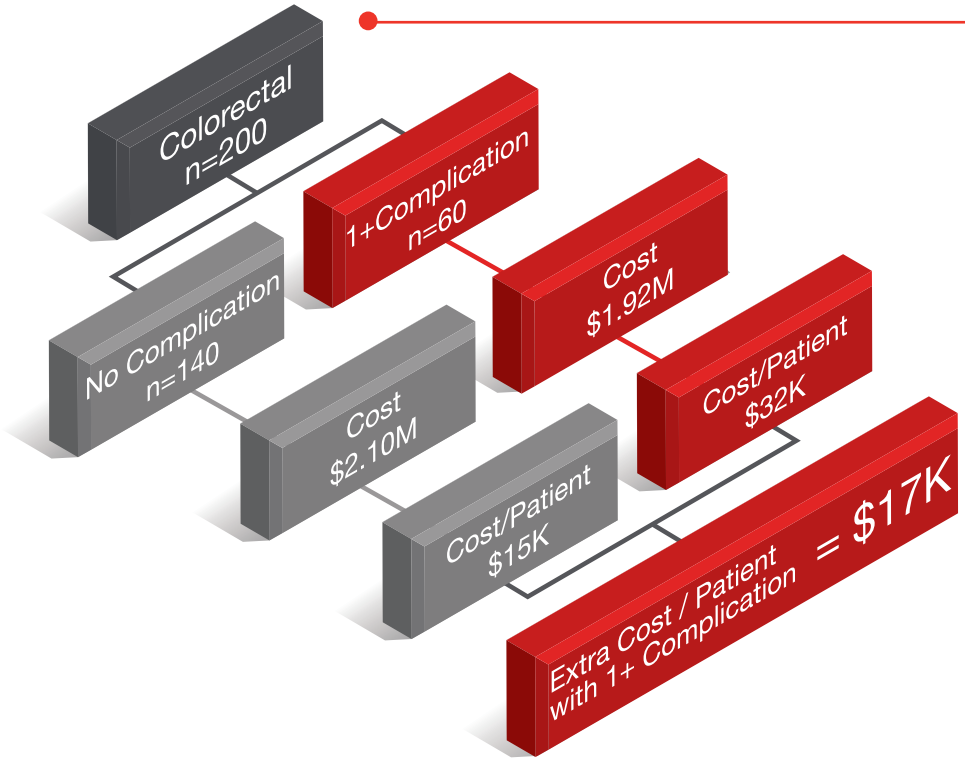
What are the clinical consequences of post-surgical complications?

On a short-term basis, complications increase hospital length of stay and hospital readmission rates.[2,3] *On a long-term basis, complications do affect patients' survival*. An 8-year follow-up study[4] done in more than 100,000 surgical patients showed that the most important determinant of post-surgical survival was the occurrence, within 30 days post-surgery, of any complication. Independent of preoperative patient risk, the occurrence of a complication reduced median patient long-term survival by 69%[4].

What is the cost of post-surgical complications?

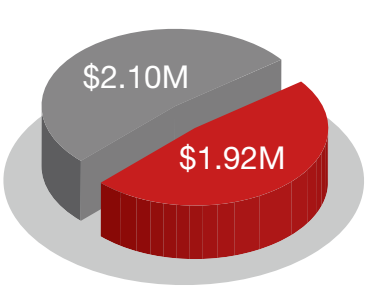
Treating complications has a cost. It is related to the specific therapies needed to treat the complication (e.g. antibiotic, reintervention, anticoagulation, etc.) and to additional lab tests and investigations often necessary, as well as prolonged hospital length of stay. In the US the average extra cost for treating a patient developing 1+ complication is approximately *$18,000*.[2] Any complication-related increase in length of stay or re-admission will also decrease your *efficiency* (i.e. the number of patients you can treat and the related revenues every year).

Example 2: Calculation of the average extra cost per patient with 1+ complication in your own institution

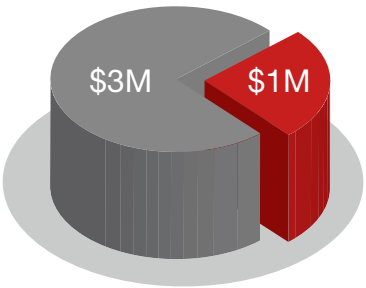


Example 2: Among your 200 colorectal patients, 60 developed 1+ complication (morbidity rate 30%). If the total cost for the 60 patients with 1+ complication was $1.92M (i.e. $32K per patient) and the total cost for the 140 remaining patients without any complication was $2.10M (i.e. $15K per patient), then the average extra cost per patient with 1+ complication was $17K.

Example 3: Calculation of the economic burden of complications in your own institution.



Total Costs = $4.02M



$1.02M / $4.02M
25% of your budget to treat
post-surgical complications

Example 3: The average extra cost per patient with 1+ complication was $17K. If 60 patients developed 1+ complication, you spent last year $1.02M (60 x $17K) to treat post-surgical complications in this specific surgical population. This represents 25% of your budget ($1.02M / $4.02M).

Can we prevent post-surgical complications?

Many post-surgical complications are related, at least in part, to insufficient or excessive fluid administration during the perioperative period[5]. A U-shape relationship is classically described as being between the amount of fluid administered and the morbidity rate[5]. Standard fluid management is usually based on clinical assessment, vital signs and/or central venous pressure (CVP) monitoring. However, clinical studies have shown that CVP is not able to predict fluid responsiveness[6] and that changes in blood pressure cannot be used to track changes in stroke volume (SV) or in cardiac output induced by volume expansion[7]. In patients at risk of developing complications, *hemodynamic optimization with treatment protocols based on flow parameters (e.g. stroke volume, SV) and/or dynamic predictors of fluid responsiveness (e.g. stroke volume variation, SVV) is useful to decrease post-surgical morbidity.*[8] Over 30 randomized controlled trials and several meta-analyses have demonstrated the superiority of hemodynamic optimization over standard fluid management to decrease renal, gastrointestinal, respiratory and infectious complications, as well as the overall morbidity rate[9-14]. Average reductions in post-surgical complications (odd or risk ratios) reported in meta-analyses[9-14] are summarized in Table 2.

Table 2: Clinical benefits of hemodynamic optimization with treatment protocols over standard fluid management.

Reduction in	Average odd or risk ratios (confidence interval)	Author (reference)
Acute kidney injury	0.64 (0.50-0.83)	Brienza (9)
	0.71 (0.57-0.90)	Grocott (13)
	0.67 (0.46-0.98)	Corcoran (14)
Minor gastrointestinal complication	0.29 (0.17-0.50)	Giglio (10)
Major gastrointestinal complication	0.42 (0.27-0.65)	Giglio (10)
Surgical site infection	0.58 (0.46-0.74)	Dalfino (11)
	0.65 (0.50-0.84)	Grocott (13)
Urinary tract infection	0.44 (0.22-0.88)	Dalfino (11)
Pneumonia	0.71 (0.55-0.92)	Dalfino (11)
	0.74 (0.57-0.96)	Corcoran (14)
Respiratory failure	0.51 (0.28-0.93)	Grocott (13)
Total morbidity rate	0.44 (0.35-0.55)	Hamilton (12)
	0.68 (0.58-0.80)	Grocott (13)

The decrease in post-surgical morbidity obtained with hemodynamic optimization with treatment protocols was shown to be associated with a decrease in hospital length of stay ranging between 1 and 2 days (see Table 3).

Table 3: Effects of hemodynamic optimization with treatment protocols on hospital length of stay.

Reduction in	Average reduction in days (confidence interval)	Author (reference)
Hospital length of stay	1.16 (0.43-1.89)	Grocott (13)
	1.95 (0.57-0.90)	Corcoran (14)

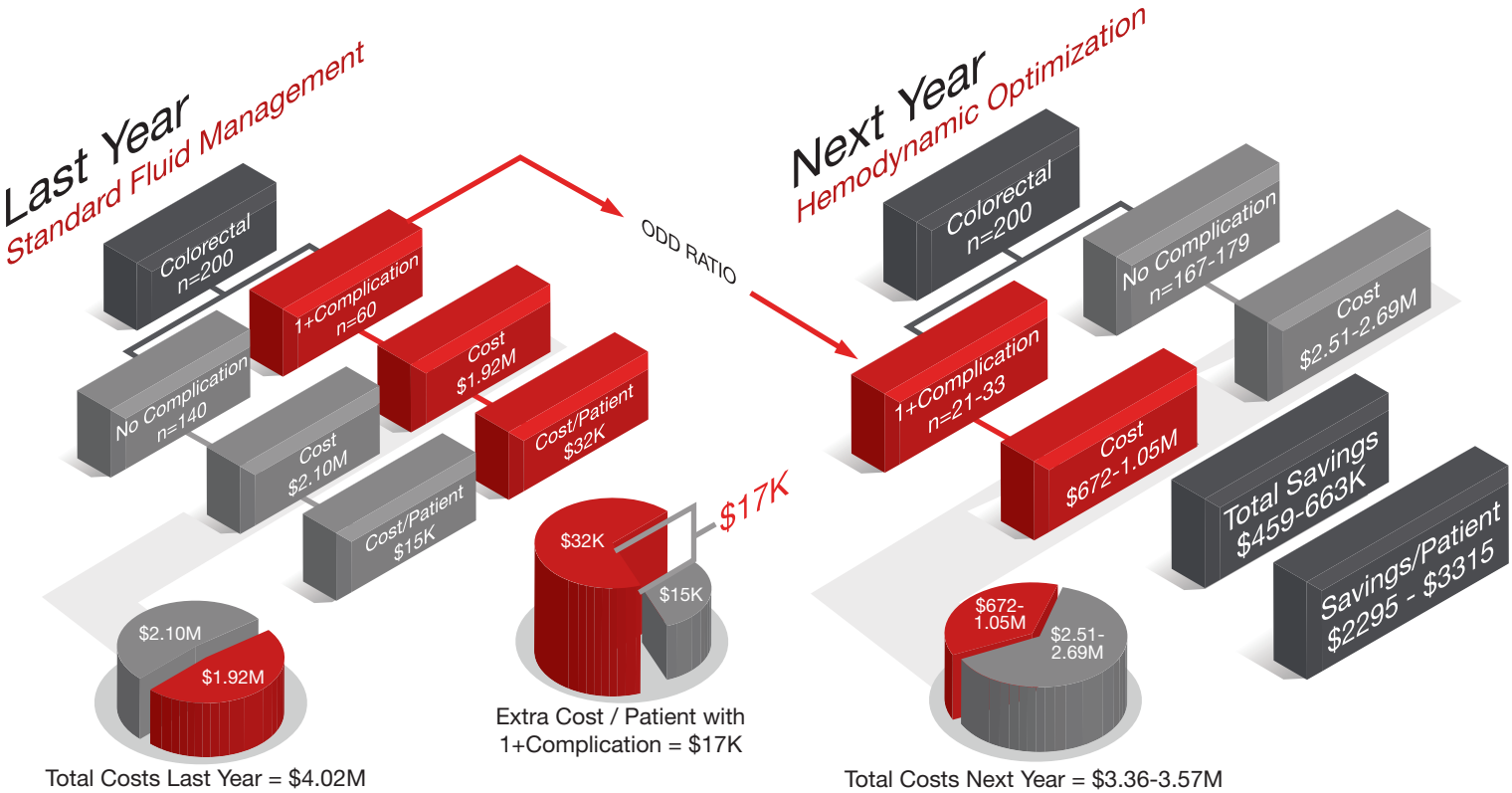
Predicting the clinical and economic benefits of hemodynamic optimization through Perioperative Goal-Directed Therapy (PGDT).

Example 4: Multiplying your current morbidity rate by the odd or risk ratio gives you an estimation of what should be your morbidity rate after implementing PGDT. If your morbidity rate is today 30% for 200 colorectal procedures, according to the odd ratio (0.35 to 0.55) reported in the meta-analysis of Hamilton et al.,[12] it should range between 10.5% (0.35 x 30%) and 16.5% (0.55 x 30%) after implementation. If the average length of hospital stay for your 200 colorectal patients was 9 days, then you can expect it will range between 7 and 8 days (refer to Table 3).

Example 5: If next year your morbidity rate drops from 30% to somewhere between 10.5% and 16.5%, only 21 to 33 out of your next 200 colorectal patients should develop 1+ complication. Last year 60 patients developed 1+ complication. With the implementation of PGDT you will then protect between 27 (60 – 33) and 39 (60 – 21) patients from complications. The previously estimated extra cost related to the treatment of 1+ complication was $17,000. With the implementation you should then save a total of $459-663k next year for this surgical population, i.e. $2295-3315 per patient.

Example 4: **Predicting the clinical benefits of hemodynamic optimization through Perioperative Goal-Directed Therapy.**

Example 5: **Predicting the economic benefits of hemodynamic optimization through Perioperative Goal-Directed Therapy.**



Are there official recommendations and guidelines?

Fueled by the growing number of clinical studies and meta-analyses demonstrating the value of Perioperative Goal-Directed Therapy, official recommendations have been published in the UK by the Enhanced Recovery Partnership (ERP)[15] and the Association of Surgeons of Great Britain and Ireland[16], in France by the French Society of Anesthesiology (SFAR)[17], and in Europe by the Enhanced Recovery After Surgery (ERAS) Society[18]. In the UK, financial incentives have even been created by the National Health Service (NHS) to ensure hospitals are going to implement hemodynamic optimization as standard care for at least 80% of eligible patients[19]. The Patient Safety Foundation of the European Society of Anesthesiology (ESA) recently released a Safety Kit which contains a summary of *PGDT treatment protocols*.

Given the now well-established clinical and economic benefits of PGDT protocols, and the above recommendations, more and more hospitals are interested in implementing hemodynamic optimization both to improve quality of care and to decrease costs.

Following is a simple, step-by-step guide for implementing hemodynamic optimization through Perioperative Goal-Directed Therapy in your moderate to high-risk surgeries.

How to implement hemodynamic optimization through Perioperative Goal-Directed Therapy in your moderate to high-risk surgeries.

Edwards Enhanced Surgical Recovery Program – 4-Step Process

The Edwards Enhanced Surgical Recovery Program 4-step implementation process *ASSESS, ALIGN*, *APPLY*, *MEASURE* helps standardize care and realize the benefits of PGDT.

Enhanced Surgical Recovery Program advisors have the expertise and clinical experience to help you integrate evidence-based protocols, engage your clinicians to align staff across departments, help you deliver effective metric tracking, and facilitate peer-to-peer exchange of best practices through our Centers of Excellence network.

Phase 1 = ASSESS

The objective of the first phase is to assess the current situation and to predict anticipated clinical and economic benefits.

- *Select one or several surgical procedures* where a benefit has been established and hence is also expected in your institution. Refer to the list of eligible procedures available from Edwards upon request.

You can (but do not have to) restrict the implementation to a subgroup of patients who have a higher risk to develop complications (e.g. patients with specific co-morbidities or patients with ASA score >I or patients older than 65 yrs).

- *Assess the current morbidity rate* using the list of complications provided in Table 1 and following Example 1 and/or *assess the current hospital length of stay*.
- *Predict the clinical benefits* of implementing PGDT following Example 4.
- *Predict the economic benefits* of implementing PGDT following Examples 2 and 5.

Phase 2 = ALIGN

- *Build a team*. Changing the standard of care is not a single-person initiative. You need to work with the team to communicate and ensure they understand the clinical and economic value of hemodynamic optimization. Further, the team must be able to solve any technical, medical and human challenge you may encounter during the implementation phase. Your core team should be led by a *champion and include at least one representative of the surgical team, of the anesthesia team, of the anesthesia assistant (AA) and/or certified registered nurse anesthetist (CRNA) team, as well as your quality officer*.
- *Choose a PGDT treatment protocol*. One of your first tasks will be to select the most appropriate PGDT protocol for the surgical population you have selected. Several protocols have been shown to be effective. The ESA protocol summary is available from Edwards upon request.
- *Choose a hemodynamic monitoring platform*. Most hemodynamic optimization protocols are based on the monitoring of flow parameters and/or dynamic predictors of fluid responsiveness.

Phase 3 = APPLY

To ensure a successful implementation of PGDT, it is important to provide appropriate training and track compliance.

- *Train and develop competencies*. All anesthesiologists and AA/CRNAs who will ensure and/or apply hemodynamic optimization must be trained. A training presentation is available from Edwards upon request.
- *Ensure optimal compliance*. Compliance to guidelines and recommendations is often suboptimal. To ensure PGDT protocols are followed properly, several actions and tools are useful:
  - *SOP*. Defining PGDT as an official and new Standard Operating Procedure (SOP) for hemodynamic optimization in your department.
  - *Surgical Safety Checklist*. Adding a single item to the current “Sign In” section of the surgical safety checklist, such as “the patient’s eligibility for hemodynamic optimization has been considered.”
  - *Compliance tools*. Refer to the compliance tool, which is available from Edwards upon request.
  - *Electronic data recording*. Refer to instructions for how to download hemodynamic parameters from your monitoring platform.

Phase 4 = MEASURE

Using methods described in Phase 1 (ASSESS), you can calculate the morbidity rate and real costs, and estimate hospital LOS after the implementation of PGDT in order to confirm the clinical (reduction in morbidity and length of stay) and economic benefits (net savings).

You can even publish the results of your implementation program in a good medical journal if you secure IRB approval.[20,21]

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