

## What Is a Surgical Complication?

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Quality assessment programs have been well-established tools in industry for decades. A unique focus on quality assessment significantly contributed to the economic success of Japan in the early 1950s, and this philosophy of steadily improving quality by continuous measurement of specific outcome variables reached the Western world only many years later. In medicine, these principles have been adopted very slowly and are still incomplete in many areas, possibly because of a lack of true competition among health care providers.

Competition remains the most obvious driving force for the development of quality assessment programs. Thus, rising costs associated with constrained resources in most health care systems over the past decade, together with evidence of variations in clinical practice, have triggered growing interest in measuring our work. In the United States, large databases, such as the National Surgical Quality Improvement Program (NSQIP) established in 1991 to study surgical performance in Veteran Affairs Hospitals, have been established to record surgical outcome, to rate hospital quality, and to benchmark performance. The incidence of postoperative complications is still the most frequently used surrogate marker of quality in surgery. However, the definition of complications in surgery still lacks standardization, hampering the interpretation of surgical performance and quality assessment.

In 1992, we and our colleagues defined “negative outcome” by differentiating among complications, failure to cure, and sequelae [1, 2]. Complications were defined as “any deviation from the normal postoperative course” and

a classification of complications by severity was proposed [1]. Complications were differentiated from *sequelae*, which cover conditions that are inherent in the procedure, and that thus will inevitably occur (such as scar formation or the inability to walk after an amputation). Similarly, diseases or conditions that remain unchanged after surgery are not complications, but rather a *failure to cure*. For example, early recurrence of inguinal hernia or incompletely resected malignant tumors, while clearly reflecting a negative outcome, are better covered under the term “*failure to cure*.”

Twelve years later, while gaining experience with the routine use of the three categories of negative outcome (complications, sequelae, and failure to cure), as well as the classification of complications in our surgical practice [1–3], we introduced a revised system to grade surgical complications [4]. It was validated through a large cohort of patients and an international survey. The basic principle of the classification remained unchanged; i.e., it was based on the therapy needed to correct the complication. In the modified system, we eliminated the length of hospital stay as a criterion measuring the severity of a complication. We also took into greater account complications requiring an ICU stay or an intermediate care stay and those dealing with the central nervous system, and we gave special emphasis to long-term disability resulting from a complication [4]. This novel therapy-oriented five-scale classification appears to be used more and more, according to reports in the surgical literature [5–14].

The definition of surgical complications is a challenging task. Many surgeons would argue that the surgeon’s intuition is an appropriate guide to defining what a complication might be. The appropriateness of the surgeon’s intuition for risk assessment has recently been emphasized in this journal [15]. However, the value of the

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surgeon's intuition is unreliable in many situations because it lacks objective criteria and is strongly dependent on the experience of the individual clinician [16]. One can argue that intuition was also involved in our initial definition, in which we used the term "normal postoperative course." In our new version we changed this terminology to "*ideal postoperative course*" as it is less subject to subjective interpretation. In an ideal postoperative course, no pathological findings may be observed unless inherited from the procedure. In other words, any deviation from that course would constitute a complication.

In the article by Sokol and Wilson [17], the authors attempt to provide a more sophisticated definition of complications; they define a complication as "*an undesirable, unintended, and direct result of an operation affecting the patient which would not have occurred had the operation gone as well as could reasonably be hoped.*" The authors should be congratulated for their effort to provide new insights into the simple term "complication." However, a few considerations need to be taken into account.

First, Sokol and Wilson state that a complication has to be a "*direct result of an operation,*" and this limitation may lead to the oversight of important postoperative events. Is a myocardial infarction after abdominal surgery in a patient with severe atherosclerosis a *direct* result of an operation or a result of the pre-existing disease (atherosclerosis)? Are nosocomial infections in transplanted patients after hip surgery a *direct* result of an operation or a consequence of compromised immunity and hospitalization? In our opinion, such events must be recorded as complications, and a definition should prevent any risk of underreporting complications.

Next, the concept that complications are undesired conditions "*which would not have occurred had the operation gone as well as could reasonably be hoped*" might be debatable. For clarification, the authors provide an example of a ruptured aortic aneurysm after surgical repair of an aneurysm yielding a spontaneous risk of rupture of 60% to underscore that the rupture was highly expected, and therefore may not be seen as a complication of surgery. Here, we agree with the authors that conditions associated with a high risk to occur without surgery should not be regarded as complications of surgery, but rather as a failure to cure. We believe, it is important to record such negative events, but we fear that they may not be recorded at all according to the definition proposed by Sokol and Wilson [17]. Moreover, an incomplete resection of a tumor (R2-resection) is—following the given definition—a condition that is "*undesirable, unintended, and would not have occurred had the operation gone as well as could reasonably be hoped,*" and is therefore a complication. We do not agree with this terminology, which for us is a failure to cure, but not a complication.

Finally, the article by Sokol and Wilson [17] nicely underlines the need for a consistent definition of surgical complications. However, the proposed definition does not withstand criticisms. The *direct* cause–effect relationship between surgery and complications is often difficult to assess. This uncertainty carries a risk of underreporting surgical complications, with substantial consequences. Moreover, failure to cure and sequelae should be distinguished from complications. Therefore, based on our former thoughts on the topic [1], we would like here to define a complication as "any deviation from the ideal postoperative course that is not inherent in the procedure and does not comprise a failure to cure."

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