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Surgical Practice

The Registration of Complications in Surgery: A Learning Curve

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Abstract. Registration of complications in surgery is an important method used for quality improvement. Unfortunately many different definitions and classification systems have been used, which influences the interpretation and the outcome of complication registration. Since 1986 complications have been registered on a daily basis in our surgical department. We focus in this article on the influence of changes in interpretation of the definition and registration methods used on the incidence of registered complications. Between 1986 and 1993 complications registered were strictly related to surgical procedures. In the second period, between 1993 and 2001, the interpretation of the definition changed and all adverse events were registered in a patient-centred way, not only related to the surgical procedure. The definition used in both periods did not change. In 1993 we started with the implementation of a fully automated registration system in our surgical department. In the first period 1699 (7%) complications in 24,201 surgical procedures were registered and in the second period 8335 (27%) complications were registered in 31,161 surgical procedures. A dramatic increase in the total number of registered complications was seen with the implementation of a fully automated registration system and a patient-centred way of registering complications. In the context of the evolving discussion of quality of care, a uniform definition and registration system has to be used to assure reliable outcome data in surgery and to form a basis for comparison.

Unlike the situation now existing in many other countries, the registration of complications by Dutch surgeons has more to do with quality assurance than with legal and financial concerns [1–5]. Regarding quality assurance, complications are frequently used as outcome measures for quality of care in surgical literature. Literature shows immense inconsistency in reporting complications, which demands development of uniform definitions and registering methods to collect adequate data [6, 7]. The Association of Surgeons of the Netherlands (ASN) has developed a uniform definition, classification system, and software for registering complications [5, 8, 9]. We prospectively registered and documented complications over a period of more than 15 years according to the definition of the ASN [8]. That definition did not change during this long period, but the interpretation of this

definition and the methods of registration did. In this article we focus on the influence of this evolution at the incidence and type of registered complications in the evolving discussion on outcome and quality measurement.

Patients and Methods

Patients

Between 1986 and 2001 51,738 patients were admitted at the surgical department of the St. Elisabeth Hospital in Tilburg, the Netherlands. Minor surgical procedures in an outpatient setting were excluded from this analysis. In 75% of these patients one or more surgical procedures had been performed. Until 1993 all documented adverse events were strictly related to surgical procedures. Since 1993 all adverse events were registered in a patient-centered way, and not just as they related to surgical procedures.

Adverse events that became clear at the outpatient control clinic in the first period, were only registered if the patient had to be readmitted for treatment. Patient characteristics and surgical diagnosis did not differ substantially during this 15-year period; neither did the type of surgery. The St. Elisabeth Hospital is a teaching hospital where about half of all surgical procedures are performed by surgical residents. The proportional distribution of surgical procedures, according to period, is listed in Table 1.

Methods

Definition of a complication

During the study period we used the definition of a complication developed by the ASN as mentioned above: A complication is a condition or event, unfavorable to the patient's health, causing irreversible damage or requiring a change in therapeutic policy, including prolonged hospital stay. If an event resulted in prolonged hospital stay, which was judged by the responsible physician at that moment, it was registered as a complication. We did not use a mean duration of prolonged hospital stay as a reference. For instance, a patient with a hernia repair and postoperative hematoma that is treated conservatively necessitates a long period of clinical observation, and this is judged as an adverse event.

Table 1. Surgical procedures between 1986 and 2000 at the department of surgery of the St. Elisabeth Hospital Tilburg.

Type of surgery	Hernia/(*)	Vascular/(*)	Gastro intestinal/(*)	Fractures/(*)	Pulmonary/(*)	Breast/(*)	Other/(*)	Total
1986–1988	972/(10%)	1251/(12%)	1000/(10%)	1282/(13%)	171/(2%)	496/(5%)	4726/(48%)	9898
1989–1991	1084/(10%)	1503/(15%)	934/(9%)	1307/(13%)	230/(2%)	612/(6%)	4695/(45%)	10365
1992–1994	1204/(10%)	1524/(13%)	959/(8%)	1099/(10%)	147/(1%)	740/(6%)	5995/(52%)	11668
1995–1997	944/(9%)	1280/(11%)	924/(8%)	1170/(11%)	135/(1%)	768/(7%)	5937/(53%)	11158
1998–2000	1009/(8%)	1486/(12%)	1023/(8%)	1165/(10%)	132/(1%)	937/(8%)	6521/(53%)	12273

*Percentage of procedures performed by surgical residents.

Table 2. Classification list of complications as developed at the Department of Surgery of the St. Elisabeth Hospital, Tilburg, and used in the period from 1986–1993.

Category of complication	Type of surgical procedure
	Head and Neck
	-Oropharyngeal
	-Salivary glands
Error in diagnosis	-(Para) thyroid
	-trachea
Hemorrhage	Thorax
	-Lungs
Infection	-Chest wall
	-Breast
Pulmonary	-Esophagus
	Abdomen
Thrombosis/embolism	-Stomach
	-large bowel
Cardiac	-small bowel
	-rectum
Wound dehiscence	hepatobiliary/pancreas/spleen
	Vascular
Neurological	-Intrathoracic
	-carotis
Anastomotic leakage	-intra or retroperitoneal
	-extremities
Urinary tract infection	-shunts
	Fractures
Other	-extremities
	-spine
	-pelvis
	Hernia
	-Inguinal
	-Femoral
	-Incisional
	-Umbilical

Classifying Complications

Until 1995 the classification system contained a simple list of criteria developed in our surgical clinic (Table 2). Since 1995 we have used a system based on an elaborated list of criteria developed by the ASN (Table 3).

Registration of Complications

The method of registration evolved substantially during the study period: Between January 1986 and December 1992 all complications occurring during hospital stay were presented by the responsible resident or surgeon during the early morning conference the day the patient left the hospital, or the day the patient died. The data were documented in a dedicated folder by one of the senior surgeons. In 1993 a fully automated registration system was implemented in our surgical clinic. At first this continued to involve registration at the early morning con-

ference as we were used doing. Gradually, as personal computers with an electronic data collecting system were installed on all clinical wards of our surgical department, registration was performed immediately by the physician who diagnosed the complication, in 1995 we reached total coverage, and registration of complications was also possible in the intensive care unit, operating room, emergency department, and outpatient clinic as well. The (client-server) software used for the electronic record was a self-developed Microsoft Access application with an Oracle database as back-end. The system is connected to ICD-10 codes [10]. The opening screen of the electronic medical record gives access to the most important information needed for daily practice. It contains one icon that will provide information on all admitted patients. From this screen information about daily progress, diagnoses, diagnostic tests, and complications can be accessed or added. The complication screen shows the form illustrated in Figure 1. During the study period discussion of the registered complications remained a standard part of the daily surgical conferences.

Results

In the period from January 1986 until January 2001 we prospectively registered 10,034 complications in 5904 patients during their clinical stay. The incidence of registered complications increased dramatically over time. Between January 1986 and January 1993, the incidence of registered complications remained quite stable (Fig. 2): 1699 (1217 patients) registered postoperative complications after 24,201 surgical procedures (7%). Infection ($n = 539/32%$) and hemorrhage ($n = 318/19%$) were the most common registered complications. When we started registering in our electronic database, the incidence of complications increased, although the total amount of surgical procedures did not change substantially.

In the first two years (1993–1994) after we started with the implementation of our electronically database and only had access to it during the early morning conference, there was no rise in the incidence of registered complications. The rise in the total number of registered complications started at the time that implementation of the automated registration system was completed and reached total coverage on all clinical wards of our department. Since then — January 1995 until January 2001 — we performed 23,431 surgical procedures and registered 7731 (33%) complications in 4183 patients. Table 4 shows the type and number of complications registered between 1986 and 2001 in our surgical department. Since 1995 classification of complications differed from the first period. For instance, cardiopulmonary complications were classified as “Disturbed function.” To interpret the incidence of complications over the years, we analyzed

Table 3. Classification of complications according to the Association of Surgeons in the Netherlands and used in the second period at the Department of Surgery of the St. Elisabeth Hospital, Tilburg, from 1993.¹

Category of complication	Localization ^a	Specify	Additional description
Result insufficient afterwards	Shoulder/arm ^b	Arterial (Sub)Cutis	Anticoagulants Catheter; intravascular drain
Leakage (seroma/chylus/gall, etc.)	Thorax Wall	Lymphatic system	
Hemorrhage	Lungs Heart	Muscles	Drugs (medication/ infusions contrast etc.)
Disturbed function	Esophagus	Nerves/brain	
Dehiscence	Abdomen Wall	Skeleton/bones	Human material (transplant/ Autologous vascular prothesis)
Mechanical problem/lesion	Stomach/duodenum Pancreas/liver/spleen	Veins	
Shock	gallbladder small bowel		Management problem
Fistula	large bowel/rectum kidney/bladder		Died/obduction
Necrosis/ischemia/ infarction/decubitus	Genitals		Died/No obduction
Other	Legs/pelvis ^b No localization		Remaining materials/equipment
Thrombosis/embolism			
Infection	Circulation/blood Multiple organs		internal fixation implant problem.
	Endocrine		Urinary catheter
	Remaining		Vascular prothesis
			Wound problem

^aEach anatomic localization has been numbered.

^bThese localizations can be further specified in different parts of the limbs.

Fig. 1. Complication sheet as used in electronic patient file at the department of surgery of the St Elisabeth Hospital Tilburg.

the categories used in the ASN classification system (Table 2) for complications that could be classified in categories used in the first period (Table 1). Infection-related complications remained the most common between January 1993 and January 2001 (23%). The other two categories registered most commonly since 1995 were “Disturbed function” (19%) and “Other” (17%). “Additional description” (Table 2) in the classification system of the ASN made it possible to specify the registered complications in

the category “Other.” The 1183 (90%) complications in this category were categorized as management problems, which include complications like delay or error in diagnosis, error in judgment or technique, or logistical complications (postpone a surgical procedure because there is no bed available in the ICU). The management problems are a new group of complications, born at the time we focused no longer on operative procedures, but purely on patients.

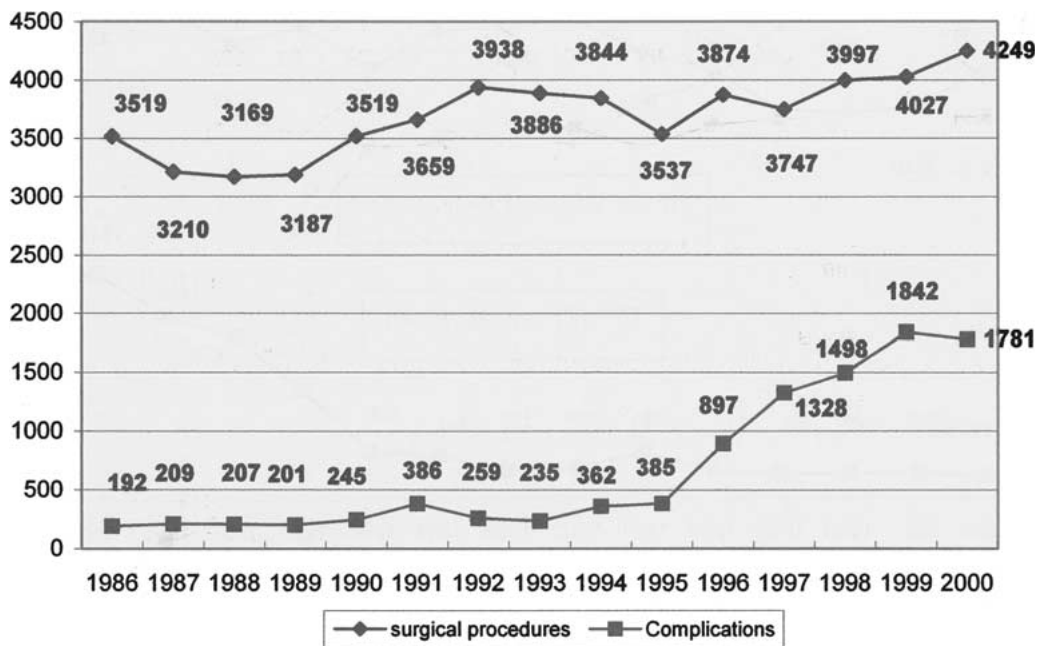


Fig. 2. Number of registered complications and surgical procedures performed between 1986–2001.

Discussion

In 1986, the year we started our prospective surgical complication registration program, 3057 patients were admitted to our surgical department. We registered 192 complications in 160 patients. This means that, according to our registration system, hospitalization in 95% of the patients with or without surgery was uneventful. In the year 2000, 3889 patients were admitted to our surgical department and we registered 1781 complications in 935 patients. Hospitalization at that tune was uneventful in only 76% of the patients, a rise of almost 20% in complications.

In the literature, the reported incidence of surgical complications varies from 3% to 75%. The variability of registered complications and methods of registration is mentioned in Table 5 and a few patterns are recognizable [11–19].

1. Inconsistencies in registering adequate data. Most studies mention inconsistencies in retrieving adequate data, and this necessitates a cautious approach toward using use registered data as indicators of health outcomes. Clinical indicators monitoring health care outcome should be reliable and valid and must be designed, defined, and implemented with scientific rigor [20]. In the process of registering complications, focus should be on the development of uniform definitions, registration methods, who registers, and classifications systems used.
2. Underreporting in morbidity and mortality rounds. A few studies recognized that the majority of complications are not recorded and discussed by Morbidity and Mortality rounds. Only complications of major sequelal are discussed in these rounds, and a prospective general surgery database is necessary to document all types of adverse events [21, 22].
3. Detection and importance of management problems/provider errors. An important issue is the detection of management problems / provider errors registered as adverse events. Almost

all studies focus discussion on this category of adverse events because they are often avoidable. Analyzing our data and the issues mentioned above, we tried to answer the questions explored in the sections that follow.

What to Register

The reliability of data concerning complications in surgical patients depends mainly on the reliability and quality of the process that generates these data[23–30]. This process starts with the definition of surgical complications. In their book: “Complications in Surgery and Their Management” Artz and Hardy in 1960 defined complications as “the dangerous reefs and sunken ledges in surgery” and focused on the management and prevention of complications [31]. In preventing complications, other authors emphasize the prediction of complications and develop risk scoring systems, without defining the problem in general [32, 33]. The lack of standardized reporting of complications and other adverse events in the surgical literature hinders interpretation of different results[6, 34, 35]. Several definitions are proposed but none is widely accepted so far. Generally, two ways are used to define surgical complications: in most reports surgical complications are a limited set of more or less adverse events related to surgical procedures, like anastomotic leakage and wound infection[11, 13]. Others advocate the use of a uniform definition of adverse events in hospitalized patients, not only surgical patients: an adverse event is an injury caused by medical management, either requiring prolonged hospitalization, or resulting in disability at the time of discharge, or both [36–38]. As surgical complications are, in fact, adverse events, this definition almost matches our definition, although we do not use “caused by medical management” as a criterion, in many cases it is difficult to prove if adverse events were caused by medical management.

Table 4. Type and number of registered complications between 1986 and 2001.

Type of complication	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	total
Error in diagnosis	10	2	1	0	0	6	9	12	15	3	37	35	41	38	42	251
Hemorrhage	35	27	39	39	48	72	58	52	38	46	68	109	79	97	91	898
Infection	69	57	74	62	79	121	71	43	94	96	186	302	280	330	327	2197
Pulmonary	14	25	14	21	21	31	28	10	40	32	133	181	227	271	210	1258
Thrombosis/embolism	12	17	12	12	17	28	7	10	29	12	10	33	22	40	28	289
Cardiac	19	11	12	12	16	15	18	9	29	29	69	129	137	157	104	766
Wound dehiscence	9	10	8	13	6	18	4	7	12	1	20	18	16	13	25	180
Neurological	8	4	6	3	14	9	9	12	16	9	29	45	51	54	40	309
Anastomotic leakage	2	7	6	3	6	15	3	6	6	3	11	11	7	22	15	123
Urinary tract infection	3	7	4	5	5	5	4	8	9	3	14	65	46	65	35	278
Result insufficient afterwards																
Leakage (seroma/chylus/gall, etc.)																
Disturbed function																
Dehiscence																
Mechanical problem/lesion																
Shock																
Fistula																
Necrosis/Ischemia/infarction/Decubitus																
Other	11	42	31	31	33	60	48	66	81	14	109	135	247	279	351	1586
T total	192	209	207	201	245	386	259	235	369	385	897	1328	1498	1842	1781	10034
Percentage of registered complications ^a	5%	6%	6%	6%	7%	11%	7%	4%	9%	11%	23%	35%	37%	46%	42%	18%
No. of patients with complications	160	142	154	133	177	274	177	172	332	287	505	797	758	901	935	5904

^aOf the total amount of surgical procedures.

ASN: The Association of Surgeons of the Netherlands.

Discussions about cause generally create discussions about guilt and blame, and such discussions quickly become discussions about legal and financial aspects, creating a defensive attitude of medical professionals against defining and reporting postoperative complications [1, 39–41]. If measuring and improving the quality of care is the ultimate goal, we think that only those adverse events that result in substantial damage to the patient or a change in treatment plan or length of hospital stay should be documented as a complication. During our first period, like many others, we only registered postoperative complications. We later realized that it is worthwhile to register all adverse events occurring during hospitalization in surgical patients, whether they were primarily caused by surgical procedures or not. This approach, from surgery centered evaluation to patient-centered concerns, appears to have been a significant contributor to the increase of complication incidence during the second period, and this is an ongoing process. However, in our view, the patient-centered approach is an important basis for improvement of care. It is clear that management problems, for example, can have major emotional impact on the patient and substantial financial consequences for the hospital organization, although they do not cause complications from a traditional point of view.

From the patient's point of view, the fact that a major operation has to be postponed for several days because there will be—if necessary—no place for him postoperatively at the ICU, is really a major complication. In the year 1986 we certainly planned operations that were subsequently cancelled for various reasons, and we certainly mismanaged all kinds of things, but we did not at that time-considered such errors to be complications. In 2000, management problems accounted for 23% of the total number of complications, causing substandard care in 401 patients.

Who Registers?

An important issue in the process of registration is who should register? In the American literature, data managers or surgical risk assessment nurses generally collect and transmit the data. They are trained in clinical medicine and quality assurance and they use well-defined variables and definitions. This has proven its value and reliability in the Harvard Medical Practice study; however, there are some limitations as Gawande et al., Brennan et al., and Lease et al., mentioned [19, 36, 37]. The review of records is retrospective and time-consuming, and secondly it captures only adverse events documented in patient records. Our method of registration is prospective and is performed internally by physicians, with daily discussion and feedback which provides continuing education and quality assurance. In our opinion the one and only person qualified to diagnose and report a complication is the surgeon, and we agree with Healey et al., that surgeons must take a leadership role in the development of definitions, registration methods, and classification systems [16]. The role of specific trained nurses or data managers in this aspect should be supportive and not be involved in the process of documentation itself [14].

Some people would claim that surgeons analyzing their own results would be an example of the fox guarding the hen house, and there are data suggesting that physician review is influenced by perceived outcome [42, 43]. In the study of Volk et al. about reliability of audit, it was the surgeon who was primarily responsible for inconsistencies in data collection. Because sur-

Table 5. Definitions, registration, methods, and incidence of registered complications in the literature.

Author	Population	Year	Definition	No. of patients analyzed	No. of registered complications (%)	No. of patients with complications (%)	Classification	Registration method	Who registers	Prospective
Veltkamp [14]	General surgery	1996	ASN definition ^a	3075	1367 (44%)	743 (24%)	ASN classification (Table 3)	Daily meeting, Recording on a separate sheet, in hospital and 30 days after discharge.Database.	Physician and researcher	Yes
Feldman [11]	General surgery	1995	No definition	311 ^b	179 (58%)	106 (34%)	Clavien et al. (2)	Resident team caring for patient, as well as from medical charts	Surgical resident	Yes
Wolters [17]	General and thoracic surgery	1989–1992	Every specific complication was defined separately	6228 ^b	Not mentioned	1342 (21.5%)	Not mentioned	Daily report of all complications	Surgical residents and medical students	Yes
Remmelt-Veen [18]	General surgery	1993–1996	Every unwanted development of the illness of the patient or of the treatment of the patient's illness that occurs in the clinic	7445	1078 (14%)	Not mentioned	Establishing the effect of the patient and identifying possible errors technique or management	Daily report of complications	One of the residents	No
Gawaride [19]	All specialists	1992	Adverse events related to an operation or a surgeon's non-operative care or occurring within 30 days after an operation	14,700 ^b	Not mentioned	402 (3%)	10 mutually exclusive categories	Chart review (randomly selected)	Trained nurses and local physicians	No
Wanzel [35]	General surgery	1996 (two months)	Unintended, adverse outcome that occurred after medical management or a surgical procedure, that was not caused by the underlying disease, and that resulted in impaired health	192	144 (75%)	75 (39%)	Classified as directly related to the operation, indirectly related to the operation, or unrelated	Daily chart reviews	Observer, members of the surgical team, and medical students	Yes
Healey [16]	General and cardiothoracic surgery	2000–2001	Service specific list	4658	1494 (32%)	925 (20%)	Minor and major sequelae	Daily assessment of complications	Individual surgeons	Yes
Mason [12]	General and thoracic Surgery	Unknown	Disease process or condition that appeared or was aggravated during hospitalization and was harmful or potentially harmful to the patient.	2686	Not mentioned	314 (12%)	Minor and major sequelae	Reviewing the charts	Nurses	Yes
Westbrook [13]	All surgical specialist	1989–1990	No definition	673,888 ^b	20,191 (3%)	18430 (3%)	ICD9-CM codes	New South Wales Inpatient Statistics Collection	Physician	No
Veen	General surgery	1986–2001	A complication is a condition or event, unfavorable to the patient health, causing irreversible damage or requiring a change in therapeutic policy, including prolonged hospital stay.	55,362	10,034 (18%)	5904 (11%)	ASN classification (Table 3)	Daily report of all Resident complications	Resident	Yes

^a Any state or event, unfavorable to a patient's health, that arose during admission or within 30 days after discharge, that either causes unintentional injury or requires additional treatments.
^b Only patients with surgical procedures more analyzed.

geons thus far are not used to proper registration and data management, adequate definitions, regular feedback of audit, and process guidelines are essential [44]. Second, all members of the team have to be aware of the fact that recording complications creates reliable data only if everyone cooperates. Therefore, the registration of complications has to be used only as an outcome measure for quality assurance and not as the basis for pointing out who is guilty while the question of guilt is not relevant [45].

When and Where to Register?

During the first period of our study, complications were reported at the early morning conference on the day the patient left the hospital or the day the patient died. Much depended on the reliability and memory of surgeons and residents. As in many other people, a surgeon's good conscience is often related to his or her bad memory, so we were not surprised by the fact that the incidence of postoperative complications immediately increased from the day we were able to register them in real time. Real time registering makes data more adequate, for reliable audit, it is advisable to collect data as close as possible to the tune that it is generated [44].

How to Register?

The process of how to register complications is an ongoing question experience. Registration and documentation in the past often depended on the effort of one enthusiastic surgeon; nowadays it requires the concerted effort of a surgical team [15, 46–52]. Tutoring new staff or surgical residents about the registration process is now an aspect of clinical practice. However, still not every surgeon or surgical resident knows what and when to register, nor is he or she always motivated. This may be a weak link in our system as long as there are inconsistencies in registering complications by new physicians. This necessitates an active attitude on the part of the physicians familiar with the system; it is up to team to observe and report inconsistencies in registration or classification. For that reason, we discuss every patient discharged at the morning conference and every registered complication at the daily conference.

The next thing was to develop software simple enough to be used without too much frustration by such a large group of surgeons. At first an electronic database was used in our clinic at one place and only one surgeon had access to enter data into this system. As our experience grew, a computerized medical audit program was developed by one of the authors (Loek P. H. Leenen). This fully automated system is now implemented in all areas within our department, which makes it easily accessible. The system used for classifying complications should be straightforward and easy to handle; otherwise it will be confusing and inconsistent documentation will result. There are different systems applied in literature, but still there is no standard reporting system for classifying complications [18, 53]. The ASN has as its goal to implement her system in all Dutch surgical clinics to establish a basis for quality surveillance. However, a recent report about the introduction of the National Surgical Adverse Event Registration (LHCR) software was disappointing, because it was operational in only 24.6% of The Dutch Surgical Clinics [5, 9].

Whether our system leads to complete and accurate data has yet to be evaluated. We therefore recently started a study to

validate our registration process, as the usefulness of a clinical database strongly depends on the quality of collected data [54]. Although there are still some imperfections in our registering methods, we think that it serves as a base for adequate data retrieval.

Conclusions

Our results show a dramatic increase in the total number of registered complications over a period of 15 years. New types of adverse events have been registered and defined as management-related problems, and these need further assessment because means of them appear to be preventable. The change in interpretation of definition, classification systems, involvement of information technology, and an open approach to registering complications are responsible for the rise in incidence of complications over the years. In the discussion of using complications as indicators for quality of care, emphasis should be placed on developing uniform definitions and registering methods to assure reliable outcome data.

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