Table 1 Registered cases used to create risk models for 8 surgical procedures [6–13]

	Eso	TG	DG	RHC	LAR	Hx	PD	ADP
Registered cases	5354	20,011	33,917	19,070	16,695	7732	8575	8482
Participating hospitals	713	1623	1737	1689	1620	987	1167	1285
(%)	34.9	79.4	84.9	82.6	79.2	48.3	57.1	62.8
30-day mortality (%)	1.2	0.9	0.5	1.1	0.4	2.0	1.2	9.0
Operative mortality (%)	3.4	2.3	1.2	2.3	0.9	4.0	2.8	14.1
Cancer surgery (%)	98.4	98.5	99.9	92.6	98.5	94.5	91.4	10.8
Emergent case (%)	0.8	2.0	0.9	8.4	1.1	0.8	0.9	92.9

Esophagectomy (Eso), total/distal gastrectomy (TG/DG), right hemicolectomy (RHC), low anterior resection (LAR), hepatectomy performed for >1 segment except for the lateral segment (Hx), pancreaticoduodenectomy (PD), and operation for acute diffuse peritonitis (ADP)

assigned into two subsets that were split 80/20: the first, for model development, and the second, for validation. The two sets of logistic models (30-day mortality and operative mortality) were constructed for dataset development using step-wise selection of the predictors with a probability (p) value for inclusion of 0.05. A "goodness-of-fit" test was performed to assess how well the model could discriminate between patient survival and death. The receiver operating characteristic (ROC) curves for the 30-day and operative mortalities were created for the validation dataset. An ROC curve is a plot of a test's true-positive rate (sensitivity) versus its false-positive rate (1—specificity). Model calibration, being the degree to which the observed outcomes matched the predicted outcomes from the model across a group of patients, was examined by comparing the observed and predicted averages with each of 10 equally sized subgroups, arranged in the order of increasing patient risk.

Case number and participating hospitals for each procedure and mortality rates

The NCD is a nationwide project in cooperation with Japan's board certification system in surgery, for which more than 1,200,000 surgical cases from over 3500 hospitals were collected in 2011. The number of participating hospitals in the gastroenterological section was 2045 at the time of the analysis (July, 2012). Among these cases, approximately 120,000 were used to create the risk models. Table 1 lists the number of cases for each procedure and the number of hospitals performing the respective procedure with its ratio to the total number of hospitals (%). Most procedures, except for ADP, were performed for cancer. Emergency surgery was most common for ADP (93 %). The 30-day mortality and operative mortality rates for the eight procedures were as follows: Eso, 1.2/3.4; TG, 0.9/2.3; DG, 0.5/1.2; RHC, 1.1/2.3; LAR, 0.4/0.9; HX, 2.0/4.0; PD, 1.2/2.8; and ADP, 9.0/14.1 %, respectively (Table 1). The operative mortality for each procedure, apart from ADP, was more than twice that of the 30-day mortality.

Risk models in the eight procedures

The 30-day mortality and operative mortality risk models for the eight procedures were created, and the C-index for those in the validation data sets was as follows: Eso, 0.767/0.742; TG, 0.811/0.824; DG, 0.785/0.798; RHC, 0.836/0.854; LAR, 0.75/0.766; HX, 0.714/0.761; PD, 0.675/0.725; and ADP, 0.851/0.852, respectively (Tables 2, 3). The final logistic models for the 30-day mortality with odds ratios for the eight procedures are listed in Table 2. Age; sex; emergency surgery; ADL; ASA class; BMI; cardiovascular, pulmonary, and renal comorbidities; and other patient conditions such as disseminated cancer, ascites, preoperative transfusion, bleeding disorder, diabetes, weight loss, sepsis, and chronic steroid use, including 121 variables, were found to be risk factors for certain procedures. Age, ADL ASA, BMI, disseminated cancer, bleeding disorder, and weight loss appeared to be common risk factors in most of the procedures. Table 3 lists the final logistic models for the operative mortality with odds ratios for the eight procedures, including 159 variables. New and additional 38 variables were captured for these models.

Feedback implementation (risk calculator)

A risk-adjusted analysis based on nationwide data allows personnel to establish and provide feedback on the risks that patients face before undergoing a procedure. On the basis of these objective data, healthcare professionals can then determine the treatment indicators and obtain informed consent. The risk calculator for all eight procedures will be available soon, on the websites of the hospitals that are a part of NCD, although the calculators for TG, PD, Hx, Eso, RHC, and LAR are currently available (February, 2015). The real-time feedback system gives the predicted mortality of patients simultaneously with data input. Standardized information on patient risk and predicted mortality can be reformulated as case reports and shared at conferences.

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Table 2 Risk models for 30-day mortality after 8 gastrointestinal procedures (refs 6–13)

Variables	Eso	TG	DG	RHC	LAR	Hx	PD	ADP
Age category	1.5	1.2	1.2		1.3	1.4	1.3	1.2
Male sex						1.6	2.0	
Ambulance transport								1.4
Emergent surgery				1.9		3.8	4.3	
ADL within 30 days before surgery								
Any assistance	4.2					2.1		
Total			3.0					
ADL immediately before surgery								
Any assistance		2.1		2.8				
Total								1.4
ASA								
Class 3				2.3				2.7
Class 4								4.3
Class 5								8.7
Class 3, 4, 5			2.0			2.0	2.2	
Class 4, 5		9.4		4.0				
BMI								
>25 kg/m^2							2.4	
>30 kg/m^2					7.0			
Congestive heart failure				2.3				
Previous cardiac surgery		2.3						
Myocardial infarction			3.1					
Previous PCI								2.0
Previous PVD surgery					6.2			2.5
Cerebrovascular disease			2.1					
COPD							2.4	
Preoperative pneumonia			2.8					
Respiratory distress								1.6
Acute renal failure				3.2				
Preoperative dialysis		3.9						
Cancer with multiple metastases				2.2				
Disseminated cancer		2.6			4.9			2.2
Preoperative transfusion		1.9			5.4			1.6
Bleeding disorder without treatment			3.2		5.2			1.6
Bleeding disorder							4.4	
Diabetes		2.2						
Smoking within 1 year	2.6							
Ascites		2.0				2.1		
Without control			3.0					
Chronic steroid use								1.7
Weight loss	2.4		2.3					
Sepsis				2.0				
Habitual alcohol consumption			1.6					
WBC								
>12,000/μl	3.7		3.7					
>9000/μl				1.5				
<4000/μl	2.8							1.4

Table 2 continued

Variables	Eso	TG	DG	RHC	LAR	Hx	PD	ADP
Hemoglobin								
M < 13.5 g/dl, F < 12.5 g/dl		1.7	1.8					
<10.0 g/dl								1.3
Platelet								
>400,000/µl	2.5							
<150,000/µl								1.5
<120,000/µl				1.9	5.0	1.7		
<80,000/µl		3.1						1.5
<50,000/µl				5.6				
Albumin								
<4.0 g/dl				2.0	3.4			
<3.5 g/dl		1.7	1.5			2.0		
<2.0 g/dl								1.7
Total bilirubin								
>3.0 mg/dl				3.1				1.7
>2.0 mg/dl		2.9						
AST								
>35 U/l		2.3		3.1		2.3		1.4
ALP								
>600 U/l		2.5						1.7
>340 U/l		1.7	2.2					
BUN								
>25 mg/dl		1.9			2.5			1.4
>20 mg/dl								1.8
<8.0 mg/dl							2.3	
Creatinine								
>2.0 mg/dl						3.9		
>1.2 mg/dl			1.8					
Serum Na								
>145 mEq/l								1.7
<138 mEq/l				2.1	3.6			
<135 mEq/l	3.6		2.5					
<130 mEq/l								1.7
CRP								
<10.0 mg/dl								1.5
APTT								
>40 s							3.2	
PT-INR								
>1.25		2.2	2.0					
>1.1	2.0			1.5		1.7		
Non-tumor bearing								0.6
Surgical procedures							#1	
Indication for surgery							#2	

#1 Hepatectomy with S8 (2.2), hepatectomy with revascularization (3.8)

#2 Hilar bile duct carcinoma (2.5), gallbladder cancer (4.1)

ADL, Activities of daily living, PT-INR Prothrombin time-international normalized ratio, *WBC* white blood cells, *ASA* American society of anesthesiologists, *ADL* activities of daily living, *PCI* percutaneous coronary intervention, *COPD* chronic obstructive pulmonary disease, *AST* aspartate amino transferase, *ALP* alkaline phosphatase, *APTT* activated partial thromboplastin time

Table 3 Risk models for operative mortality after 8 gastrointestinal procedures [6–13]

Variables	Eso	TG	DG	RHC	LAR	Hx	PD	ADP
Age category	1.4	1.3	1.3	1.1	1.4	1.4	1.3	1.3
Male sex	2.3				1.9	1.5		
Emergent surgery		1.7	1.9	1.9		2.8		
ADL within 30 days before surgery								
Any assistance	4.7					2.8	2.5	
Total								1.6
ADL immediately before surgery								
Any assistance		2.0		2.5	2.5			1.4
Total			3.0		2.9			
ASA								
Class 3		1.8		1.6				2.3
Class 4								4.7
Class 5								6.5
Class 3, 4, 5			1.9			2.0	2.1	
Class 4, 5		5.2		2.9				
BMI								
>25 kg/m^2							1.9	
>30 kg/m^2					4.6			
Congestive heart failure				2.2				
Angina							2.6	
Previous PVD surgery				3.1	5.8			
Cerebrovascular disease			1.8					
Cerebrovascular accident		1.9						
Respiratory distress								
Any		1.7	2.4		2.9		2.4	
COPD	2.1					2.0		
Preoperative pneumonia						3.8		1.4
Preoperative dialysis		2.6		2.1				
Cancer metastasis/relapse	4.5			1.6				
Disseminated cancer		3.5	2.9	3.1	2.8			2.1
Preoperative transfusion					2.6			1.8
Bleeding disorder without therapy								1.6
Brinkman index							1.6	
Ascites								
Any		1.8		1.6	4.0	1.9		
Without control			2.8					
Chronic steroid use			2.8	2.0				1.9
Weight loss	2.0	1.6	2.2	1.6			2.1	1.4
Sepsis				1.7				
WBC								
>11,000/μl		2.0	2.5				3.1	
>9000/μl				1.6				
<4500/μl	1.8							1.5
<3500/μl		1.6						
Hemoglobin								
M < 13.5 g/dl, F < 12.5 g/dl					2.6			1.3
<10 g/dl						1.8		
Hematocrit								
M > 48 %, F > 42 %					3.6			

Table 3 continued

Variables	Eso	TG	DG	RHC	LAR	Hx	PD	ADP
M < 37 %, F < 32 %			1.4	1.4				
<30 %		1.3						1.2
Platelet								
<120,000/μl	2.0		2.0	1.7	3.4	1.6	2.1	1.4
<80,000/μl				2.6		2.1		
Albumin								
<3.8 g/dl		1.7						
<3.5 g/dl	2.2	1.4				1.6		
<3.0 g/dl		1.4		1.5		1.7		1.4
<2.5 g/dl					2.7			
<2.0 g/dl								1.5
Total bilirubin								
>3.0 mg/dl								2.0
>2.0 mg/dl		2.8	2.6					
>1.0 mg/dl				1.6				
AST								
>40 U/l			1.5	2.7	1.9	1.7		
>35 U/l		1.7						1.4
ALP								
>600 U/l		3.1						1.6
>340 U/l			1.6					
BUN								
>60 mg/dl				2.4				
>25 mg/dl								1.3
>20 mg/dl								1.8
<8 mg/dl	2.6			1.6				
Creatinine								
>2.0 mg/dl								1.5
>1.2 mg/dl			1.8					
Serum Na								
>145 mEq/l				1.9				
<138 mEq/l	2.1	1.4		1.9	2.5			
<135 mEq/l			2.3					
<130 mEq/l								1.8
CRP								
<10.0 mg/dl								1.5
APTT								
>40 s			1.6				2.0	
PT-INR								
>1.25	3.0	1.9						
>1.1			1.5	1.4		1.4	1.5	
Non-tumor bearing								0.5
Surgical procedure		#1				#2		
indication for surgery						#3		

#1 Pancreatico splenectomy (2.2)

#2 Hepatectomy with S1 (1.6), S7 (1.6), S8 (2.0), left tri-segmentectomy with S1 resection (3.9), hepatectomy with revascularization (3.0)

#3 Intrahepatic cholangiocarcinoma (1.8), hilar bile duct carcinoma (2.0), gallbladder cancer (3.2)

Fig. 1 The National Cancer Database feedback system includes a risk calculator for the mortality and morbidity of pre-operative patients (*left schema*) and performance reports of each participating hospital (*right schema*). The latter includes each facility's severity-adjusted clinical performance (*benchmark*) in comparison with the national data (**a**) and the risk-adjusted cumulative expected–observed death (**b**). Better (*right*) or worse (*left*) outcomes can be detected by the monitoring report
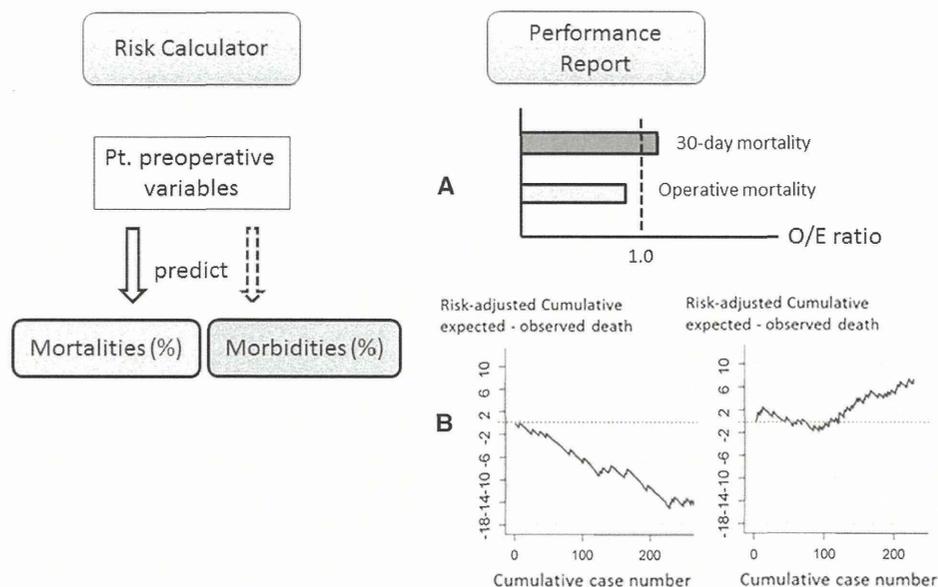
The NCD will soon be able to provide data on each facility's severity-adjusted clinical performance (benchmark), which can be compared with national data (Fig. 1a). Cumulative observed–expected mortality can be traced periodically after each operation and used to detect special cause variations showing better (right) and worse (left) outcomes (Fig. 1b).

Future evolution of NCD

A complete data acquisition system link to board certification

More than 4,000,000 cases were retrieved from the NCD during the 3 years before April 2013. The number of esophagectomy and pneumonectomy cases registered in the NCD accounted for approximately 95 % of all cases registered in the Regional Bureau of Health and Welfare. Thus, most cases in Japan appear to be captured by the NCD system. This NCD project started with support from Health and Labor Sciences Research Grants by the Ministry of Health Labour and Welfare (Principal Investigators; MG, T.I.) and considerable funding from the JSGS and JSS. Participating institutions can now use the database system at no cost; however, it is mandatory for the institutions to participate in the benchmarking project when applying for the board certification system. Currently, the board certification system is operating adequately on the web for surgical society members and allows members to obtain information on their cases being used to assess a member's qualifications for certification during a certain period. Any applicant who has a sufficient number of cases for application no longer needs to write case reports. All participating healthcare professionals use information acquired from the NCD. Moreover, the board certification system itself can be revalidated using the surgical improvement program of the NCD.

Share benefits and costs of the NCD with relevant stakeholders

A previous study by Hall et al. [5] showed that participation in the benchmark reporting system of the ACS-NSQIP improved surgical outcomes across all participating hospitals in the private sector. Improvement is reflected for both poor- and well-performing facilities. They speculated in the model using 183 participating hospitals that each institution may have avoided 200–500 complications and 12–36 deaths. Participation in the ACS-NSQIP benefits patients, surgeons, and hospitals and costs 10,000–29,000 (US$) depending on the ACS-NSQIP options [15.]

In the gastroenterological section, risk models of mortality for the eight procedures were created to enable feedback. Simultaneously, risk models of morbidities for the eight procedures are being created to enable feedback for the next year. Currently, the database system is built up to enable efficient provision of benchmark reports to each institute. The benefits and costs can now be shared with the relevant stakeholders. A participation fee depending on the number of cases for retrieval is expected to be charged by the NCD to each hospital. Research grants from various sources are also expected to support clinical investigations using the NCD data.

Eliminating burden on physicians and maintaining data accuracy

To avoid burdening physicians, the NCD allows data entry by other medical staff members. The NCD data entry privileges allow people other than physicians to enter the data. An appropriate educational system for data managers would be mandatory to maintain the accuracy of data and reduce the burden on physicians. This could be achieved by holding an annual data manager educational meeting and eventually introducing an e-learning system. The JSGS is planning to create an audit committee separately from the NCD, with the goal of achieving accurate data inputs and of educating data managers.

Quality improvement of surgical care for cancer patients

The NCD generalizes site-specific cancer registries by taking advantage of their excellent organizing ability. Some site-specific cancer registries have already been combined with the NCD [16]. Cooperation between the NCD and site-specific cancer registries can establish a valuable platform upon which a cancer care plan can be developed in Japan. Furthermore, information on the prognosis of cancer patients gathered using population- and hospital-based cancer registries can enable efficient data accumulation into the NCD.

Currently, quality assessment of hospitals is being carried out using the Diagnosis Procedure Combination (DPC) data from the participating hospitals [17, 18]. The DPC data include variables for preoperative morbidities, cancer variables, and postoperative complications, but they are based mainly on administrative claim data. A low participation rate by very small hospitals in the DPC system covers 50% of institutions conducting surgical services [17] and hampers complete enumeration. The NCD is a quality assessment and improvement program in which clinical data are used with a high collection rate (95 %). Site-specific cancer registries in the NCD would not only be more accurate and suitable for perioperative assessment, but also for long-term outcomes of cancer patients.

Further improvements through transparency

Public reporting and transparency are being demanded by multiple stakeholders [19, 20]. Although it has been shown that performance data released to the public promote quality improvement activity at the hospital level [21, 22], opponents counter that public reporting induces gaming and other unintended consequences such as "cherry picking" (hospitals selecting lower-risk patients to avoid poorer outcomes) or losing patients to better-performing hospitals [23]. With the consent of participating surgical societies, the NCD stated that the performance of each institute would be fed back only to respective institutes but not to the general public. This practice is similar to that of the ACS-NSQIP, from which a report is prepared for administrators and surgical services staff to compare their risk-adjusted surgical outcomes with those of participating sites that are blinded to data other than their own.

In 2012, the ACS-NSQIP partnered with the Centers for Medicare and Medicaid Services (CMS) to promote public reporting and transparency of surgical outcomes [24]. Although there were few measurable differences between CMS-NSQIP-participating and CMS-NSQIP-nonparticipating hospitals, it was found that of all possible hospital structural characteristics, only the teaching hospital status predicted participation in the CMS-NSQIP public reporting initiative. It may be a challenge for participating hospitals to show their performance to the general public. There is an interesting study by Sherman et al. [25, who investigated surgeons' perceptions of public reporting of hospital and individual surgeon quality. They stated that surgeons recommended patient education, simplified data presentation, and continued risk-adjustment refinement, and conducted an internal review before public reporting to make public reporting more acceptable for them. Linkage between hospital information systems and the NCD registry system may improve data accuracy and save costs. Presentation of care quality is increasingly regarded as imperative to support patients' choice and efficiency of care provision. We want medical professionals to realize that good to great performance can be achieved only through transparency for providers and patients.

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REVIEW ARTICLE

Cancer registries in Japan: National Clinical Database and site-specific cancer registries

Takayuki Anazawa · Hiroaki Miyata · Mitsukazu Gotoh

Abstract The cancer registry is an essential part of any rational program of evidence-based cancer control. The cancer control program is required to strategize in a systematic and impartial manner and efficiently utilize limited resources. In Japan, the National Clinical Database (NCD) was launched in 2010. It is a nationwide prospective registry linked to various types of board certification systems regarding surgery. The NCD is a nationally validated database using web-based data collection software; it is risk adjusted and outcome based to improve the quality of surgical care. The NCD generalizes site-specific cancer registries by taking advantage of their excellent organizing ability. Some site-specific cancer registries, including pancreatic, breast, and liver cancer registries have already been combined with the NCD. Cooperation between the NCD and site-specific cancer registries can establish a valuable platform to develop a cancer care plan in Japan. Furthermore, the prognosis information of cancer patients arranged using population-based and hospital-based cancer registries can help in efficient data accumulation on the NCD. International collaboration between Japan and the USA has recently started and is expected to provide global benchmarking and to allow a valuable comparison of cancer treatment practices between countries using nationwide cancer registries in the future. Clinical research and evidence-based policy recommendation based on accurate data from the nationwide database may positively impact the public.

Keywords Cancer registry · Nationwide database · Risk factor · Risk model

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Introduction

The cancer registry is an essential part of any rational program of evidence-based cancer control [1, 2]. This information can be used to monitor cancer patterns in certain regions and to formulate an effective cancer control plan [2]. In Japan, the government started promoting and supporting a cancer control plan based on the Cancer Control Act of 2006. Cancer registries in Japan are classified into three types—population-based, hospital-based, and site-specific cancer registries. Each registry plays an important role in the epidemiology, evaluation of patient care quality, and in providing clinically detailed information (Table 1); however, all three types have problems with poor standardization or incomplete follow-up [2].

The cancer control program is required to strategize in a systematic and impartial manner and efficiently utilize limited resources. The National Clinical Database (NCD) in Japan, which was launched in 2010 and commenced patient registration in January 2011, is a nationwide prospective registry linked to the surgical board certification system. The NCD systematically collects accurate data to develop a standardized surgery database for quality improvement and healthcare quality evaluation, considering the structure, process, and outcome [3]. Moreover, submitting cases to the NCD is a prerequisite for all member institutions of the surgical society, and only registered cases can be used for board certification. The NCD contains >1,200,000 surgical

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Table 1 Types of cancer registries in Japan

	Organization	Primary purpose	End point
Population-based cancer registries	Prefecture	Cancer surveillance at population level	Morbidity rate Survival rate
Hospital-based cancer registries	Hospital	Evaluation of cancer care quality	Survival rate
Site-specific cancer registries	Academic society	Collecting in-depth information	Survival rate

Epidemiological ↕ *Clinical*

cases collected in 2011, and approximately 4,000 institutions were participating at the end of 2013. Detailed information on cancer, such as gastrointestinal, liver, pancreas, thyroid, and breast cancer is also collected in the NCD. The NCD generalizes site-specific cancer registries by taking advantage of their excellent organizing ability [4]. Some site-specific cancer registries, including pancreatic, breast, and liver cancer registries have already been combined with the NCD. Furthermore, it has also been promoted to cooperate with non-surgical fields.

Here, we summarize the current status of the NCD and site-specific cancer registries in conjunction with future perspectives for developing a cancer registration system.

Current status of the NCD

There was no nationwide clinical database for gastroenterological surgery for cancer treatment in Japan before 2006. The Japanese Society of Gastroenterological Surgery organized preliminary nationwide surveys in gastroenterological surgery in 2006 and 2007. These surveys, without using risk-adjustment techniques, indicated that hospital volume may influence the mortality rate after major gastroenterological surgery [5]. However, it was considered that upgraded analysis using risk-adjustment techniques should have been conducted to reveal the specific contribution of the variables. The NCD was established in 2010 as a general incorporated association in partnership with several clinical societies. The activities of the NCD primarily focus on providing the highest quality healthcare possible to patients and to the general public with the clinical setting serving as the driving force behind improvements [3, 4]. The NCD was developed in collaboration with the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP). The ACS-NSQIP is the first nationally validated database using web-based data

collection software. It is risk adjusted and outcome based to improve the quality of surgical care [6]. Development of the NCD allows risk-adjusted analysis in Japan.

The NCD continuously recruits individuals to approve the input data from members of several departments in charge of annual cases as well as data entry officers, through a web-based data management system to assure the traceability of the data. Furthermore, the project managers consecutively and consistently validate the data by inspecting randomly chosen institutions. All variables, definitions, and inclusion criteria regarding the NCD are accessible to all the participating institutions from the website (http://www.ncd.or.jp/) and are also intended to support an e-learning system in order for participants to input consistent data. The NCD also provides answers to all queries regarding data entry (approximately 80,000 inquiries in 2011) and regularly includes some of the queries as frequently asked questions on the website.

In the gastrointestinal surgery section, all surgical cases are registered and require detailed input items for eight procedures representing the performance of surgery in each specialty (low anterior resection, right hemicolectomy, hepatectomy, total gastrectomy, partial gastrectomy, pancreatoduodenectomy, esophagectomy, and surgery for acute diffuse peritonitis). Risk models for predicting surgical outcome have been created for the mortality of each procedure [7–13]. A total of 120,000 cases collected from the eight procedures in 2011 were then analyzed in each procedure. Data were randomly assigned into two subsets that were split as follows—80 % for model development and 20 % for validation. The two sets of logistic models (30-day mortality and operative mortality) were constructed for dataset development using a step-wise selection of predictors. Potential independent variables included patient demographics, pre-existing comorbidities, preoperative laboratory values, and operative data. Furthermore, multiple significant risk factors were identified in each