



**Universiteit  
Leiden**  
The Netherlands

## **Nationwide prospective audit of pancreatic surgery: design, accuracy, and outcomes of the Dutch Pancreatic Cancer Audit**

Rijssen, L.B. van; Koerkamp, B.G.; Zwart, M.J.; Bonsing, B.A.; Bosscha, K.; Dam, R.M. van; ... ; Dutch Pancreatic Canc Grp

### **Citation**

Rijssen, L. B. van, Koerkamp, B. G., Zwart, M. J., Bonsing, B. A., Bosscha, K., Dam, R. M. van, ... Besselink, M. G. (2017). Nationwide prospective audit of pancreatic surgery: design, accuracy, and outcomes of the Dutch Pancreatic Cancer Audit. *Hpb*, 19(10), 919-926. doi:10.1016/j.hpb.2017.06.010

Version: Not Applicable (or Unknown)

License: [Leiden University Non-exclusive license](#)

Downloaded from: <https://hdl.handle.net/1887/95336>

**Note:** To cite this publication please use the final published version (if applicable).

ORIGINAL ARTICLE

# Nationwide prospective audit of pancreatic surgery: design, accuracy, and outcomes of the Dutch Pancreatic Cancer Audit

L. Bengt van Rijssen<sup>1</sup>, Bas G. Koerkamp<sup>2</sup>, Maurice J. Zwart<sup>1</sup>, Bert A. Bonsing<sup>3</sup>, Koop Bosscha<sup>4</sup>, Ronald M. van Dam<sup>5</sup>, Casper H. van Eijck<sup>2</sup>, Michael F. Gerhards<sup>6</sup>, Erwin van der Harst<sup>7</sup>, Ignace H. de Hingh<sup>8</sup>, Koert P. de Jong<sup>9</sup>, Geert Kazemier<sup>10</sup>, Joost Klaase<sup>11</sup>, Cornelis J. van Laarhoven<sup>12</sup>, I. Quintus Molenaar<sup>13</sup>, Gijs A. Patijn<sup>14</sup>, Coen G. Rupert<sup>15</sup>, Hjalmar C. van Santvoort<sup>16</sup>, Joris J. Scheepers<sup>17</sup>, George P. van der Schelling<sup>18</sup>, Olivier R. Busch<sup>1</sup>, Marc G. Besselink<sup>1</sup> & for the Dutch Pancreatic Cancer Group

<sup>1</sup>Department of Surgery, Academic Medical Center, Cancer Center Amsterdam, Amsterdam, <sup>2</sup>Department of Surgery, Erasmus Medical Center, Rotterdam, <sup>3</sup>Department of Surgery, Leiden University Medical Center, Leiden, <sup>4</sup>Department of Surgery, Jeroen Bosch Hospital, 's Hertogenbosch, <sup>5</sup>Department of Surgery, Maastricht University Medical Center, Maastricht, <sup>6</sup>Department of Surgery, Onze Lieve Vrouwe Gasthuis, Amsterdam, <sup>7</sup>Department of Surgery, Maastad Hospital, Rotterdam, <sup>8</sup>Department of Surgery, Catharina Hospital, Eindhoven, <sup>9</sup>Department of Surgery, University Medical Center Groningen, Groningen, <sup>10</sup>Department of Surgery, VU University Medical Center, Amsterdam, <sup>11</sup>Department of Surgery, Medisch Spectrum Twente, Enschede, <sup>12</sup>Department of Surgery, Radboud University Medical Center, <sup>13</sup>Department of Surgery, University Medical Center Utrecht, Utrecht, <sup>14</sup>Department of Surgery, Isala Clinics, Zwolle, <sup>15</sup>Department of Surgery, Tjongerschans Hospital, Heerenveen, <sup>16</sup>Department of Surgery, St Antonius Hospital, Nieuwegein, <sup>17</sup>Department of Surgery, Reinier de Graaf Gasthuis, Delft, and <sup>18</sup>Department of Surgery, Amphia Hospital, Breda, The Netherlands

## Abstract

**Background:** Auditing is an important tool to identify practice variation and 'best practices'. The Dutch Pancreatic Cancer Audit is mandatory in all 18 Dutch centers for pancreatic surgery.

**Methods:** Performance indicators and case-mix factors were identified by a PubMed search for randomized controlled trials (RCT's) and large series in pancreatic surgery. In addition, data dictionaries of two national audits, three institutional databases, and the Dutch national cancer registry were evaluated. Morbidity, mortality, and length of stay were analyzed of all pancreatic resections registered during the first two audit years. Case ascertainment was cross-checked with the Dutch healthcare inspectorate and key-variables validated in all centers.

**Results:** Sixteen RCT's and three large series were found. Sixteen indicators and 20 case-mix factors were included in the audit. During 2014–2015, 1785 pancreatic resections were registered including 1345 pancreatoduodenectomies. Overall in-hospital mortality was 3.6%. Following pancreatoduodenectomy, mortality was 4.1%, Clavien–Dindo grade  $\geq$  III morbidity was 29.9%, median (IQR) length of stay 12 (9–18) days, and readmission rate 16.0%. In total 97.2% of >40,000 variables validated were consistent with the medical charts.

**Conclusions:** The Dutch Pancreatic Cancer Audit, with high quality data, reports good outcomes of pancreatic surgery on a national level.

Received 28 March 2017; accepted 22 June 2017

## Correspondence

Marc G. Besselink, Dutch Pancreatic Cancer Group, Academic Medical Center, Cancer Center Amsterdam, Department of Surgery, Office G4-196, Meiberdreef 9, 1105 AZ, Amsterdam, The Netherlands. E-mail: [m.g.besselink@amc.nl](mailto:m.g.besselink@amc.nl)

## Introduction

Monitoring quality of care has a long history in surgical practice.<sup>1,2</sup> The goal of measuring outcomes is usually to determine the optimal treatment by comparing interventions. Clinical auditing, however, aims at measuring and comparing outcomes of doctors or hospitals for a specific patient population. These results can then be used to improve current practice and increase transparency, which is increasingly demanded by society. Clinical auditing is increasingly being implemented throughout surgery, and prominent initiatives such as the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) have already improved outcomes for patients.<sup>3,4</sup> Auditing is relevant especially to areas of surgery where there is much inter-hospital variation: in pancreatic surgery, differences in mortality between hospitals are among the highest.<sup>5</sup>

Performance indicators measure various aspects of the quality of care. Indicators are subdivided in structural, process, and patient outcome indicators. An example of a structural performance indicator is hospital volume. Process indicators are typically certain guideline recommendations. Patient outcomes may be divided into short-term (e.g. in-hospital mortality) or long-term (e.g. survival), subjective (e.g. quality of life), and intermediate (e.g. intra-operative blood loss) outcomes. Identifying the most important performance indicators is the main challenge of setting up an audit. Performance indicators should be relevant for the patient, have unambiguous definitions, and data collection should be straightforward. Fair comparison of performance indicators across hospitals (i.e. benchmarking) requires adjustment for differences in baseline characteristics. Therefore, baseline characteristics associated with performance indicators (e.g., tumor stage when comparing survival) should also be collected in the audit.<sup>6,7</sup>

Data collection for the mandatory Dutch Pancreatic Cancer Audit (DPCA) started in 2013. All patients undergoing surgical exploration for a suspected pancreatic or periampullary tumor in the Netherlands are included, as imposed by the Dutch Healthcare Inspectorate.<sup>8</sup> The DPCA aims to improve patient outcomes after pancreatic surgery by reducing practice variation and stimulating 'best practices'. In this study we describe the design, results, and validation of a nationwide evidence-based surgical audit in pancreatic cancer surgery.

## Methods

### Design of the audit

To identify relevant performance indicators and case-mix factors, a systematic literature search was conducted in PubMed in July 2011. Performance indicators and independent case-mix factors in pancreatic cancer surgery were identified by analyzing all randomized controlled trials (RCT's) and large case series ( $n > 1000$ ) in pancreatic surgery published between 2000 and 2011 in core clinical journals. It was assumed that key

performance indicators and case-mix factors are frequently reported by experts.

Performance indicators and case-mix factors found in these studies were cross-checked with existing registries. Data dictionaries of two foreign national audits (United Kingdom HPB audit, Swedish HPB registry), and the Dutch national cancer registry (NCR) were also scrutinized, as well as the prospective registries of three pancreatic centers: the Heidelberg University Hospital in Heidelberg (Germany), the Academic Medical Center in Amsterdam (the Netherlands), and Utrecht Medical Center in Utrecht (the Netherlands).

Next, the selection of the most frequently identified performance indicators and independent case-mix factors was based on a consensus process. The identified performance indicators and case-mix factors were first discussed with (inter)national field experts (see acknowledgements). The data model was developed hereafter in a plenary consensus with all members of the Dutch Pancreatic Cancer Group; the national multidisciplinary working group on pancreatic tumors with active members from all involved medical specialties including surgical oncology, medical-oncology, pathology, gastroenterology, radiology, dietary specialist, and nursing specialist. Formalized definitions were established and provided to the data collectors.

The DPCA includes all patients who are eligible for pancreatic surgery because of a (suspected) pancreatic- or periampullary tumor, or pancreatic cysts. Excluded are pancreatic resections for chronic pancreatitis, and pancreatic resections for tumors arising outside the pancreas. Patients discussed within a multidisciplinary team meeting, but not undergoing surgical exploration can be registered on a voluntary basis.

### Governance

The DPCA is a collaboration of the Dutch Pancreatic Cancer Group (DPCG) and the Dutch Institute of Clinical Auditing (DICA) and endorsed by the Association of Surgeons of The Netherlands (Nederlandse Vereniging voor Heelkunde, NVvH).<sup>9</sup> The Dutch Pancreatic Cancer Audit has been implemented in all 18 centers performing pancreatic surgery in the Netherlands. The minimum requirement in the Netherlands is to perform at least 20 pancreatoduodenectomies annually per center. Each center is responsible for entering their own data. This is typically performed by a research fellow, study nurse, or surgeon. Ownership of the data remains with each individual center, each with a contract with the data processing agency (Medical Research Data Management; MRDM, Deventer, the Netherlands). The DPCG scientific committee supervises the data analysis and writes annual auditing reports. The data collected for auditing is also available for scientific research to all DPCA participants.

### Results of the audit

Morbidity, mortality, length of stay, and readmission rate was examined in all patients undergoing pancreatic surgery in 2014

and 2015, and registered in the DPCA. Mortality was defined as in-hospital mortality. Overall morbidity consisted of all surgical and non-surgical morbidity. Major morbidity was defined as any Clavien–Dindo grade III or more morbidity.<sup>10</sup> Procedure specific complications were recorded according to the International Study Group on Pancreatic Surgery (ISGPS) definitions for postoperative pancreatic fistula (POPF), delayed gastric emptying (DGE), and post-pancreatectomy hemorrhage (PPH), respectively.<sup>11–13</sup> Clinically relevant (CR) complications were defined as grade B or grade C procedure specific complications. Length of stay was defined as the number of days between surgery, and initial discharge from the hospital. Readmissions were registered up to 30 days postoperatively. Additionally, assessment of a patient within a multidisciplinary team (MDT) meeting was noted. The influence of sex, age, procedure type and diagnosis on morbidity, mortality, length of stay, and readmission rate was analyzed. The number of surgical explorations was noted, which did not include diagnostic laparoscopy.

### Data verification

Two trained auditors (MJZ and LBR) verified data entered for each pancreatoduodenectomy registered in 2014 and 2015. All participating centers were visited and all relevant medical charts were cross-checked with the audit data. Cross-checked baseline variables included length, weight, WHO performance status, neoadjuvant therapy, and comorbidities. Intra-operative variables included the use of minimally invasive surgery, vascular resection, additional resection(s), and drain placement. Complications included: mortality, morbidity, grading of morbidity as described by the International Study Group of Pancreatic Surgery (ISGPS) for postoperative pancreatic fistula,<sup>11</sup> post-pancreatectomy hemorrhage,<sup>12</sup> and delayed gastric emptying,<sup>13</sup> or by the International Study Group on Liver Surgery (ISGLS) for bile leakage.<sup>14</sup> Re-interventions (radiologic, surgical or endoscopic), ICU admission, and single- or multi-organ failure were also verified.

Each year, the Dutch Healthcare Inspectorate requests the number of performed pancreatoduodenectomies from each Dutch center regardless of indication (including benign disease, which is excluded from the DPCA). These data are published publicly online and were crosschecked to the number of pancreatoduodenectomies in the audit in 2014 and 2015.<sup>15</sup>

### Statistical analysis

Dichotomous data were presented as proportions. Continuous data were presented as medians with interquartile range (IQR). Differences in binary postoperative outcomes were analyzed using Chi-square test. Unpaired t-test and one-way ANOVA were used in the comparison of postoperative length of stay between two groups, or more than two groups, respectively. P values of less than 5% were considered significant. Statistical analysis was performed using SPSS Statistics for Windows (Version 20.0; IBM, Armonk, NY).

## Results

### Performance indicators and case-mix factors

The literature search retrieved 16 RCT's,<sup>16–31</sup> and three large case series of pancreatic surgery.<sup>6,7,32</sup> A total of 112 individual performance indicators and 111 independent case-mix factors were identified from RCT's, case series and (inter)national registries. After multidisciplinary comments and international advice, 16 indicators and 20 case-mix factors were selected. The final selection of variables was implemented in June 2013 in all 18 pancreatic centers in The Netherlands. Performance indicators and case-mix factors in the audit are shown in Table 1. Performance indicators were categorized into morbidity, severity of morbidity, and clinical consequences. Morbidity was graded with

**Table 1** Variables in the Dutch Pancreatic Cancer Audit: Performance indicators (A) and Case-mix factors (B)

A. Performance indicators	
Morbidity <sup>a</sup>	Postoperative pancreatic fistula (POPF), <sup>b</sup> delayed gastric emptying (DGE), <sup>b</sup> post-pancreatectomy hemorrhage (PPH), <sup>b</sup> bile leakage (BL) <sup>c</sup>
Clinical consequence	Mortality (in-hospital), re-interventions (radiologic, surgical, endoscopic), ICU admission, length of stay, 30-day readmission
Process indicators	Structured imaging (CT/MRI) report, structured pathology report, EUS for unexplained bile duct obstruction, <sup>d</sup> surgery within 3 weeks after final MDT meeting
B. Case-mix factors	
Patient history	Age, sex, BMI, ASA, ECOG/WHO performance status, comorbidity, other malignancy
Laboratory and imaging	CA 19-9, cTNM, MPD diameter, venous involvement on CT, arterial involvement on CT
Surgery and pathology	Margin status (R stage), tumor location, pancreatic texture, tumor diameter, pTNM, tumor histology, number of evaluated lymph nodes, number of positive lymph nodes, tumor grade

BMI, body mass index; ASA, American Society of Anesthesiologists; ECOG, Eastern Cooperative Oncology Group; WHO, World Health Organization; CA, carbohydrate antigen; CTNM, clinical TNM; MPD, main pancreatic duct; VPMS, vena porta mesenteric vein; CT, computed tomography; pTNM, pathology TNM; ICU, intensive care unit; ISGPS, International Study Group on Pancreatic Surgery; ISGLS, International Study Group on Liver Surgery.

<sup>a</sup> Graded by Clavien–Dindo.

<sup>b</sup> Graded by International Study Group on Pancreatic Surgery (ISGPS).

<sup>c</sup> Graded by International Study Group on Liver Surgery (ISGLS).

<sup>d</sup> If CT/MRI shows no tumor, as recommended by the Dutch guideline on pancreatic carcinoma.

the Clavien–Dindo scale, International Study Group of Pancreatic Surgery (ISGPS), and International Study Group on Liver Surgery (ISGLS).<sup>10–14</sup> Independent case-mix factors were categorized into patient history, laboratory and imaging, and surgery and pathology.

## Results of the audit

A total of 2107 patients underwent a surgical exploration. Of all patients, 2016 (95.7%) patients had been discussed within a MDT meeting preoperatively. Of 2107 patients, 84.7% (1785 patients) underwent a pancreatic resection. Of these 1785 patients, 45.8% were female. The proportion of elderly ( $\geq 75$  years) patients was 20.8%. Of patients undergoing pancreatic resection 75.5% (1347 patients) underwent pancreatoduodenectomy. Most patients (39.1%) were diagnosed with pancreatic adenocarcinoma, 24.6% were diagnosed with periampullary (distal bile duct, duodenum, ampulla) adenocarcinoma (Table 2). Other histopathologic diagnosis included mainly pancreatic neuroendocrine tumor (8.9%), intraductal papillary mucinous neoplasma (8.1%), and chronic pancreatitis (3.3%).

Postoperative outcomes following pancreatic resection for suspected malignancy are shown in Table 2 as well. In-hospital mortality following pancreatic resection was 3.6%. There was a significantly higher mortality among males (4.6%) compared to females (2.4%,  $p = 0.04$ ). There was a significantly higher mortality with increasing age categories: 1.7% in patients aged  $< 65$  years, 4.0% in patients aged 65–74 years, and 6.5% in

patients aged  $\geq 75$  years ( $p < 0.001$ ). Mortality was significantly higher in patients with periampullary carcinoma (6.2%) compared to patients with pancreatic adenocarcinoma (3.2%), or another diagnosis (2.3%,  $p = 0.02$ ).

Overall morbidity rate was 57.6% and the rate of Clavien–Dindo grade  $\geq III$  morbidity was 27.3%. Major morbidity rate was higher in patients with periampullary carcinoma (36.5%), compared to patients with another diagnosis (25.8%) or patients with pancreatic adenocarcinoma (22.9%,  $p < 0.001$ ). Pancreatoduodenectomy was the procedure type with highest rate of major morbidity (29.9%,  $p < 0.001$ ) compared to distal pancreatectomy (17.2%) or other types of pancreatic resection (24.4%). A diagnosis of periampullary carcinoma was more often associated with major morbidity (36.5%) compared to pancreatic carcinoma (22.9%), or other diagnosis (25.8%,  $p < 0.001$ ). In total, 231 (12.9%) patients had a grade B/C POPF, 114 (6.4%) a grade B/C PPH, and 250 (14.0%) patients a grade B/C DGE. These numbers were 175 (13.0%), 100 (7.4%), and 223 (16.6%) after pancreatoduodenectomy, respectively.

Median length of postoperative stay following pancreatic resection was 11 (IQR: 8–17) days. After PD median length of postoperative stay was 12 (IQR: 9–18) days and this was 8 (IQR: 6–11) days after distal pancreatectomy. Only type of procedure, but not sex, age category, or diagnosis predicted length of stay.

Readmission rate was 15.7% after pancreatic resection. Readmission rate was slightly higher following pancreatoduodenectomy (16.0%). Sex, age category, procedure type or diagnosis did not predict readmission rate.

**Table 2** Postoperative outcomes after pancreatic resection for malignant and pre-malignant disease in the Netherlands, 2014–2015

	N	Mortality	P value	Overall morbidity	P value	Major morbidity <sup>b</sup>	P value	Length of stay (median days (IQR))	P value	Readmission	P value
All pancreatic resections	1785	64 (3.6%)		1028 (57.6%)		487 (27.3%)		11 (8–17)		281 (15.7%)	
Sex			0.04		0.13		0.003		0.11		0.30
Male	966	44 (4.6%)		575 (59.7%)		292 (30.2%)		11 (8–18)		162 (16.8%)	
Female	818	20 (2.4%)		453 (55.5%)		195 (23.8%)		11 (8–16)		119 (14.5%)	
Age			<0.001		0.22		0.91		0.16		0.15
<65 years	746	13 (1.7%)		420 (56.3%)		206 (27.6%)		10 (8–16)		124 (16.6%)	
65–74 years	667	27 (4.0%)		384 (57.8%)		178 (26.7%)		11 (8–18)		109 (16.3%)	
$\geq 75$ years	372	24 (6.5%)		224 (60.5%)		103 (27.7%)		13 (9–19)		48 (12.9%)	
Procedures			0.11		<0.001		<0.001		0.004		0.64
Pancreatoduodenectomy <sup>a</sup>	1347	55 (4.1%)		830 (61.9%)		403 (29.9%)		12 (9–18)		216 (16.0%)	
Distal pancreatectomy	319	5 (1.6%)		139 (43.6%)		55 (17.2%)		8 (6–11)		49 (15.4%)	
Other	119	4 (3.4%)		59 (49.6%)		29 (24.4%)		13 (8–19)		16 (13.5%)	
Diagnosis			0.02		<0.001		<0.001		0.15		0.45
Pancreatic adenoc.	698	22 (3.2%)		375 (53.7%)		160 (22.9%)		11 (8–16)		110 (15.8%)	
Periampullary adenoc.	439	27 (6.2%)		295 (67.2%)		160 (36.5%)		13 (9–20)		68 (15.5%)	
Other	648	15 (2.3%)		358 (55.7%)		167 (25.8%)		10 (7–16)		103 (15.9%)	

<sup>a</sup> Either classic Whipple or pylorus-preserving procedure.

<sup>b</sup> Defined as Clavien–Dindo grade  $\geq III$ .

## Data verification

In total, 42 179 variables were cross-checked with medical charts. A total of 1162 (2.8%) variables recorded in the audit was missing or different than recorded in the medical charts (Table 3). Type of procedure was incorrectly registered in 9.5% of cases, involving mainly whether or not the pylorus was preserved. In-hospital mortality was correctly registered in all patients.

Crosscheck with the inspectorate data revealed that >90% of performed pancreatoduodenectomies (1347 registered in the audit, compared to 1448 reported to the inspectorate) were included in the first two registration years.

## Discussion

This study demonstrates the evidence-based design, outcomes and validation of the Dutch Pancreatic Cancer Audit as well as its governance structure. Accuracy, as determined by an internal audit was very high (97.2% variables correct), as well as case ascertainment with the Dutch healthcare inspectorate (>90% of all procedures registered). The outcomes of the first two full audit years reveal low in-hospital mortality, especially considering the nationwide level of these data: 3.6% for all pancreatic resection, 4.1% for PD, and 1.6% for distal pancreatectomy. Following pancreatic resection, major morbidity rate was 27.3% and median postoperative length of stay was 11 days.

The DPCA includes all 18 hospitals performing pancreatic surgery in the Netherlands, each performing a minimum of 20 PDs annually. It is a unique nationwide audit because it covers 100% of the population of 17 million. Other noticeable population based registries originate mainly from the U.S. including the Surveillance, Epidemiology, and End Results (SEER), Medicare, and NSQIP programs. While each includes a greater absolute number of patients and hospitals, coverage is far below

100%. For example, the SEER program includes only 28% of the total population and the Medicare database contains only patients aged over 65 years.<sup>33,34</sup>

The nationwide in-hospital mortality rate after PD was 4.1%. Few other studies report population-based outcomes after pancreatic surgery. A NSQIP study reported 30-day mortality of 2.9% for PD.<sup>33</sup> Two notable other large population based reports from the U.S. reported in-hospital mortality rates of 6.6% and 7.9% for PD.<sup>35,36</sup> A recent study from Germany (n = 31 293, 2009–2013) reported a 7.7% in-hospital mortality rate after PD.<sup>37</sup> Other nationwide European reports are more than 10 years old, with reports from Belgium (n = 1794, 2000–2004), England (n = 1905, 2002–2005) and Italy (n = 1576, 2003) describing in-hospital mortality rates after PD of 8.4%, 5.7%, and 8.1% respectively.<sup>38–40</sup> Low mortality rates are reported from Asian countries. Nationwide reports from South-Korea (n = 4975, 2005–2008) and Japan (n = 10 652, 2007–2010) have reported in-hospital mortality rates after PD of 2.1% and 3.3%, respectively.<sup>41,42</sup> The relatively low mortality rate in the Netherlands, as compared to for example Germany, may be explained by the centralization of pancreatic surgery in the Netherlands which has lowered mortality.<sup>43</sup>

The rate of major morbidity (Clavien–Dindo score above III) in this study was 27.3%. Other registries show similar rates although different definitions were used. NSQIP has reported major morbidity rate of 24%.<sup>44</sup> Defined as Modified Accordion severity grade  $\geq 3$ , in another study this was 27.8%.<sup>45</sup> Besides the obvious implications, postoperative morbidity also dominates costs.<sup>46</sup> The nationwide rate of grade B/C POPF was 12.9% (13.0% after pancreatoduodenectomy), comparable to other studies.<sup>47,48</sup> As of 2017, the DPCA will register the new definition and grading system of POPF.<sup>48</sup>

Median length of postoperative stay was 11 days. While high-volume centers are reporting a LOS in the 8-day range now,<sup>49</sup> previous population-based studies from the U.S. have reported a median postoperative length of stay of 13 days, compared to (older studies reporting) 18–23 days in Europe, or 30–40 days in Asia.<sup>38,40,42,50,51</sup> Enhanced recovery after surgery (ERAS) programs are rapidly being implemented worldwide.<sup>52</sup> Implementation of ERAS did not appear to be related to increased readmission rates; 16% in this study versus 20% in previous database studies.<sup>36,49</sup> Length of postoperative stay depends not only on the quality of care but also on local, cultural, and regional aspects.

In the current study, data on mortality was 100% correctly registered. Data accuracy was 97.2% for other indicators and covariates. These results compare favorably to other equivalents.<sup>53,54</sup> The high accuracy at validation is important because of potential criticism that data are entered in the DPCA by health care providers rather than by independent data managers. To guarantee high quality data in the future a formal data validation program will be launched involving trained independent data managers.

The DPCA will be further improved in the coming years. Patients will be involved in the selection of indicators,

**Table 3** Data validation of all pancreatoduodenectomies registered in the Dutch Pancreatic Cancer Audit during 2014–2015

Variables verified	No. discordant values/no. values verified	Percentage discordant <sup>b</sup>
Baseline variables	514/25 593	2.0%
Comorbidities	307/20 205	1.5%
Intraoperative variables	332/8082	4.1%
Procedure type	123/1 298 <sup>a</sup>	9.5%
Postoperative variables	316/8504	3.7%
Complication grading	134/3320	4.0%
Re-intervention scoring	71/830	8.6%
Mortality	0/1347	0.0%
<b>TOTAL</b>	<b>1162/42 179</b>	<b>2.8%</b>

<sup>a</sup> Operative notes were not retrievable in 49 (3.6%) cases.

<sup>b</sup> Discordant variables defined as missing or different than recorded in medical charts.

comparable to the initiatives of the International Consortium for Health Outcomes Measurement (ICHOM).<sup>55</sup> Registration burden will be reduced by implementation of synoptic reports which we have developed for operation note, discharge letter, and pathology and radiology reports.<sup>9</sup> Real-time feedback to individual health care providers of their outcomes in will be introduced. Data sharing initiatives will allow the DPCA to be merged with the National Cancer Registry, hosted by the Netherlands Comprehensive Cancer Organization. This will establish extensive follow-up data, e.g. adjuvant chemotherapy.

Auditing may be seen as a PDCA (plan-do-check-act) cycle. First, quality of care is defined, for example an evidence-based guideline. Second, care is evaluated, i.e. is there compliance to various guideline recommendations and what are the patient related outcomes. Third, areas of lagging compliance are identified and changes are implemented to increase compliance. Furthermore, feedback on results is essential to the effect of auditing.<sup>56</sup> The main objective of the DPCA is not ranking hospitals based on performance indicators, but facilitate PDCA cycles in which best practices are identified and hospitals can learn from each other. The first transparent outcome indicators (mortality and serious complications) for the DPCA will be released in 2018, after appropriate case-mix adjustment.

This study presents the design, completeness, accuracy, and outcomes of an evidence-based nationwide surgical audit in Europe. Case ascertainment and accuracy of the audit was very high. Outcomes were good compared to other nationwide registries, but additional room for improvement remains. Future focus is on independent quality control and feedback systems to individual centers.

## Collaborators

The Dutch Pancreatic Cancer Group is grateful for all multidisciplinary collaborators who supported the development of the Dutch Pancreatic Cancer Audit, including Thomas L. Bollen, MD PhD (department of Radiology, St. Antonius Hospital, Nieuwegein, The Netherlands); Marco J. Bruno, MD PhD (department of Gastroenterology, Erasmus Medical Center, Rotterdam, The Netherlands); G. van Tienhoven, MD PhD (department of Radiotherapy, Academic Medical Center, Amsterdam); A. Norduyn, MD PhD (pathologist, Dordrecht, The Netherlands). The Dutch Pancreatic Cancer Group is deeply indebted to our international collaborators and advisors D.P. Berry, MD PhD (Leicester General Hospital, Leicester, UK); B. Tingstedt, MD PhD (Skåne University Hospital, Lund, Sweden); J.F. Tseng, MD PhD (Beth Israel Deaconess Medical Center, Boston, MA); and C.L. Wolfgang, MD PhD (The Johns Hopkins School of Medicine, Baltimore, MD)

## Acknowledgements

The Dutch Pancreatic Cancer Group wishes to thank the Dutch Institute for Clinical Auditing and the Netherlands Comprehensive Cancer Organisation for the collaboration.

## Conflicts of interest and source of funding

No conflicts of interest. This research was partially funded by a grant from the Dutch Cancer Society (grant number UVA2013-5842)

## References

- Loehrer AP, Chang DC, Hutter MM, Warshaw AL. (2016) Surgical quality and equity: revisiting the class of 1895. *Ann Surg* 264:235–236.
- Gill CJ, Gill GC. (2005) Nightingale in Scutari: her legacy reexamined. *Clin Infect Dis* 40:1799–1805.
- Hall BL, Hamilton BH, Richards K, Bilimoria KY, Cohen ME, Ko CY. (2009) Does surgical quality improve in the American College of Surgeons National Surgical Quality Improvement Program: an evaluation of all participating hospitals. *Ann Surg* 250:363–376.
- Scrivener R, Morrell C, Baker R, Redsell S, Shaw E, Stevenson K *et al.* (2002) *Principles for best practices in clinical audit*. Abingdon: Radcliffe Medical Press Ltd.
- Birkmeyer JD, Siewers AE, Finlayson EV, Stukel TA, Lucas FL, Batista I *et al.* (2002) Hospital volume and surgical mortality in the United States. *N Engl J Med* 346:1128–1137.
- Greenblatt DY, Kelly KJ, Rajamanickam V, Wan Y, Hanson T, Rettammel R *et al.* (2011) Preoperative factors predict perioperative morbidity and mortality after pancreaticoduodenectomy. *Ann Surg Oncol* 18:2126–2135.
- Hartwig W, Hackert T, Hinz U, Gluth A, Bergmann F, Strobel O *et al.* (2011) Pancreatic cancer surgery in the new millennium: better prediction of outcome. *Ann Surg* 254:311–319.
- Dutch Pancreatic Cancer Audit. The Netherlands. Available at: <http://dpca.clinicalaudit.nl> (last accessed 15 July 2017).
- The Dutch Pancreatic Cancer Group (DPCG). The Netherlands. Available at: [www.dpcg.nl](http://www.dpcg.nl) (last accessed 15 July 2017).
- Dindo D, Demartines N, Clavien PA. (2004) Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 240:205–213.
- Bassi C, Dervenis C, Butturini G, Fingerhut A, Yeo C, Izbicki J *et al.* (2005) Postoperative pancreatic fistula: an international study group (ISGPF) definition. *Surgery* 138:8–13.
- Wente MN, Veit JA, Bassi C, Dervenis C, Fingerhut A, Gouma DJ *et al.* (2007) Postpancreatectomy hemorrhage (PPH): an International Study Group of Pancreatic Surgery (ISGPS) definition. *Surgery* 142:20–25.
- Wente MN, Bassi C, Dervenis C, Fingerhut A, Gouma DJ, Izbicki JR *et al.* (2007) Delayed gastric emptying (DGE) after pancreatic surgery: a suggested definition by the International Study Group of Pancreatic Surgery (ISGPS). *Surgery* 142:761–768.
- Koch M, Garden OJ, Padbury R, Rahbari NN, Adam R, Capussotti L *et al.* (2011) Bile leakage after hepatobiliary and pancreatic surgery: a definition and grading of severity by the International Study Group of Liver Surgery. *Surgery* 149:680–688.
- Dutch Hospital Data (DHD). Available at: [www.dhd.nl](http://www.dhd.nl) (last accessed 15 July 2017).
- Yeo CJ, Cameron JL, Lillemoe KD, Sohn TA, Campbell KA, Sauter PK *et al.* (2002) Pancreaticoduodenectomy with or without distal gastrectomy and extended retroperitoneal lymphadenectomy for periampullary adenocarcinoma, part 2: randomized controlled trial evaluating survival, morbidity, and mortality. *Ann Surg* 236:355–366. discussion 66–68.
- Tran KT, Smeenk HG, van Eijck CH, Kazemier G, Hop WC, Greve JW *et al.* (2004) Pylorus preserving pancreaticoduodenectomy versus standard Whipple procedure: a prospective, randomized, multicenter

- analysis of 170 patients with pancreatic and periampullary tumors. *Ann Surg* 240:738–745.
18. Bassi C, Falconi M, Molinari E, Salvia R, Butturini G, Sartori N *et al.* (2005) Reconstruction by pancreaticojejunostomy versus pancreaticogastrostomy following pancreatectomy: results of a comparative study. *Ann Surg* 242:767–771. discussion 71–73.
  19. Bassi C, Molinari E, Malleo G, Crippa S, Butturini G, Salvia R *et al.* (2010) Early versus late drain removal after standard pancreatic resections: results of a prospective randomized trial. *Ann Surg* 252:207–214.
  20. Berger AC, Howard TJ, Kennedy EP, Sauter PK, Bower-Cherry M, Dutkevitch S *et al.* (2009) Does type of pancreaticojejunostomy after pancreaticoduodenectomy decrease rate of pancreatic fistula? A randomized, prospective, dual-institution trial. *J Am Coll Surg* 208: 738–747. discussion 47–49.
  21. Conlon KC, Labow D, Leung D, Smith A, Jarnagin W, Coit DG *et al.* (2001) Prospective randomized clinical trial of the value of intraperitoneal drainage after pancreatic resection. *Ann Surg* 234:487–493. discussion 93–94.
  22. Farnell MB, Pearson RK, Sarr MG, DiMaggio EP, Burgart LJ, Dahl TR *et al.* (2005) A prospective randomized trial comparing standard pancreaticoduodenectomy with pancreaticoduodenectomy with extended lymphadenectomy in resectable pancreatic head adenocarcinoma. *Surgery* 138:618–628. discussion 28–30.
  23. Fischer M, Matsuo K, Gonen M, Grant F, Dematteo RP, D'Angelica MI *et al.* (2010) Relationship between intraoperative fluid administration and perioperative outcome after pancreaticoduodenectomy: results of a prospective randomized trial of acute normovolemic hemodilution compared with standard intraoperative management. *Ann Surg* 252: 952–958.
  24. van der Gaag NA, Rauws EA, van Eijck CH, Bruno MJ, van der Harst E, Kubben FJ *et al.* (2010) Preoperative biliary drainage for cancer of the head of the pancreas. *N Engl J Med* 362:129–137.
  25. Gouillat C, Chipponi J, Baulieux J, Partensky C, Saric J, Gayet B. (2001) Randomized controlled multicentre trial of somatostatin infusion after pancreaticoduodenectomy. *Br J Surg* 88:1456–1462.
  26. Peng SY, Wang JW, Lau WY, Cai XJ, Mou YP, Liu YB *et al.* (2007) Conventional versus binding pancreaticojejunostomy after pancreaticoduodenectomy: a prospective randomized trial. *Ann Surg* 245:692–698.
  27. Pessaux P, Sauvanet A, Mariette C, Paye F, Muscari F, Cunha AS *et al.* (2011) External pancreatic duct stent decreases pancreatic fistula rate after pancreaticoduodenectomy: prospective multicenter randomized trial. *Ann Surg* 253:879–885.
  28. Seiler CA, Wagner M, Bachmann T, Redaelli CA, Schmied B, Uhl W *et al.* (2005) Randomized clinical trial of pylorus-preserving duodeno-pancreatectomy versus classical Whipple resection-long term results. *Br J Surg* 92:547–556.
  29. Suc B, Msika S, Fingerhut A, Fourtanier G, Hay JM, Holmieres F *et al.* (2003) Temporary fibrin glue occlusion of the main pancreatic duct in the prevention of intra-abdominal complications after pancreatic resection: prospective randomized trial. *Ann Surg* 237:57–65.
  30. Tran K, Van Eijck C, Di Carlo V, Hop WC, Zerbi A, Balzano G *et al.* (2002) Occlusion of the pancreatic duct versus pancreaticojejunostomy: a prospective randomized trial. *Ann Surg* 236:422–428. discussion 8.
  31. Diener MK, Seiler CM, Rosson I, Kleeff J, Glanemann M, Butturini G *et al.* (2011) Efficacy of stapler versus hand-sewn closure after distal pancreatectomy (DISPACT): a randomised, controlled multicentre trial. *Lancet* 377:1514–1522.
  32. de Jong MC, Li F, Cameron JL, Wolfgang CL, Edil BH, Herman JM *et al.* (2011) Re-evaluating the impact of tumor size on survival following pancreaticoduodenectomy for pancreatic adenocarcinoma. *J Surg Oncol* 103:656–662.
  33. Parikh P, Shiloach M, Cohen ME, Bilimoria KY, Ko CY, Hall BL *et al.* (2010) Pancreatectomy risk calculator: an ACS-NSQIP resource. *HPB Oxf* 12:488–497.
  34. Surveillance, Epidemiology, and End Results (SEER) Program. Available at: [seer.cancer.gov](http://seer.cancer.gov) (last accessed 15 July 2017).
  35. McPhee JT, Hill JS, Whalen GF, Zayaruzny M, Litwin DE, Sullivan ME *et al.* (2007) Perioperative mortality for pancreatectomy: a national perspective. *Ann Surg* 246:246–253.
  36. Hyder O, Dodson RM, Nathan H, Schneider EB, Weiss MJ, Cameron JL *et al.* (2013) Influence of patient, physician, and hospital factors on 30-day readmission following pancreatoduodenectomy in the United States. *JAMA Surg* 148:1095–1102.
  37. Nimptsch U, Krautz C, Weber GF, Mansky T, Grutzmann R. (2016) Nationwide in-hospital mortality following pancreatic surgery in Germany is higher than anticipated. *Ann Surg* 264:1082–1090.
  38. Topal B, Van de Sande S, Fieuw S, Penninckx F. (2007) Effect of centralization of pancreaticoduodenectomy on nationwide hospital mortality and length of stay. *Br J Surg* 94:1377–1381.
  39. Pal N, Axisa B, Yusuf S, Newcombe RG, Wemyss-Holden S, Rhodes M *et al.* (2008) Volume and outcome for major upper GI surgery in England. *J Gastrointest Surg* 12:353–357.
  40. Balzano G, Zerbi A, Capretti G, Rocchetti S, Capitanio V, Di Carlo V. (2008) Effect of hospital volume on outcome of pancreaticoduodenectomy in Italy. *Br J Surg* 95:357–362.
  41. Kim CG, Jo S, Kim JS. (2012) Impact of surgical volume on nationwide hospital mortality after pancreaticoduodenectomy. *World J Gastroenterol* 18:4175–4181.
  42. Yoshioka R, Yasunaga H, Hasegawa K, Horiguchi H, Fushimi K, Aoki T *et al.* (2014) Impact of hospital volume on hospital mortality, length of stay and total costs after pancreaticoduodenectomy. *Br J Surg* 101: 523–529.
  43. de Wilde RF, Besselink MG, van der Tweel I, de Hingh IH, van Eijck CH, Dejong CH *et al.* (2012) Impact of nationwide centralization of pancreaticoduodenectomy on hospital mortality. *Br J Surg* 99:404–410.
  44. Hallet J, Mahar AL, Tsang ME, Lin Y, Callum J, Coburn NG *et al.* (2015) The impact of peri-operative blood transfusions on post-pancreatectomy short-term outcomes: an analysis from the American College of Surgeons National Surgical Quality Improvement Program. *HPB Oxf* 17: 975–982.
  45. McMillan MT, Allegrini V, Asbun HJ, Ball CG, Bassi C, Beane JD *et al.* (2017) Incorporation of procedure-specific risk into the ACS-NSQIP surgical risk calculator improves the prediction of morbidity and mortality after pancreatoduodenectomy. *Ann Surg* 265:978–986.
  46. Govaert JA, van Dijk WA, Fiocco M, Scheffer AC, Gietelink L, Wouters MW *et al.* (2016) Nationwide outcomes measurement in colorectal cancer surgery: improving quality and reducing costs. *J Am Coll Surg* 222:19–29 e2.
  47. McMillan MT, Soi S, Asbun HJ, Ball CG, Bassi C, Beane JD *et al.* (2016) Risk-adjusted outcomes of clinically relevant pancreatic fistula following pancreatoduodenectomy: a model for performance evaluation. *Ann Surg* 264:344–352.
  48. Bassi C, Marchegiani G, Dervenis C, Sarr M, Abu Hilal M, Adham M *et al.* (2017) The 2016 update of the International Study Group (ISGPS)

definition and grading of postoperative pancreatic fistula: 11 years after. *Surgery* 161:584–591.

49. Sutton JM, Wilson GC, Wima K, Hoehn RS, Cutler Quillin, R, 3rd, Hanseman DJ *et al.* (2015) Readmission after pancreaticoduodenectomy: the influence of the volume effect beyond mortality. *Ann Surg Oncol* 22:3785–3792.
50. Schneider EB, Hyder O, Wolfgang CL, Dodson RM, Haider AH, Herman JM *et al.* (2013) Provider versus patient factors impacting hospital length of stay after pancreaticoduodenectomy. *Surgery* 154: 152–161.
51. Shi HY, Wang SN, Lee KT. (2014) Temporal trends and volume-outcome associations in periampullary cancer patients: a propensity score-adjusted nationwide population-based study. *Am J Surg* 207:512–519.
52. Coolsen MM, van Dam RM, van der Wilt AA, Slim K, Lassen K, Dejong CH. (2013) Systematic review and meta-analysis of enhanced recovery after pancreatic surgery with particular emphasis on pancreaticoduodenectomies. *World J Surg* 37:1909–1918.
53. Pitt HA, Kilbane M, Strasberg SM, Pawlik TM, Dixon E, Zyromski NJ *et al.* (2009) ACS-NSQIP has the potential to create an HPB-NSQIP option. *HPB Oxf* 11:405–413.
54. Epelboym I, Gawlas I, Lee JA, Schrope B, Chabot JA, Allendorf JD. (2014) Limitations of ACS-NSQIP in reporting complications for patients undergoing pancreatectomy: underscoring the need for a pancreas-specific module. *World J Surg* 38:1461–1467.
55. The International Consortium for Health Outcomes Measurement (ICHOM). Available at: [www.ICHOM.org](http://www.ICHOM.org) (last accessed 15 July 2017).
56. Simunovic M, Urbach D, Major D, Sutradhar R, Baxter N, To T *et al.* (2010) Assessing the volume-outcome hypothesis and region-level quality improvement interventions: pancreas cancer surgery in two Canadian Provinces. *Ann Surg Oncol* 17:2537–2544.