# Pancreatic Disease Register of the German Society of General and Visceral Surgery

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**Key words:** pancreatic disease, register, German Society of General and Visceral Surgery, data analysis, confidentiality of personal information

The modern medical community is on the path to improving the efficiency and safety of treatment, standardizing the services provided and the health systems in general. Keeping registers of patients with different nosologies can be a tool to solve these problems. Registers provide such data on the use of medical technologies as their efficacy, safety and monitoring of treatment results in real clinical practice [1].

A patient register is an organized system that uses observational research methods to collect homogeneous data used to evaluate the results of applied medical technologies and serves a specific scientific, clinical, or organizational goal. The data obtained from the correctly developed and filled registers provide an idea of the actual clinical practice of managing patients with various diseases, as well as assessing the clinical and economic effectiveness of using certain types of treatment, their safety and quality [1].

The results of registries in a number of countries are provided only to participating clinics, but the most common form of obtaining the results of register analysis is the publication of articles and reports in scientific journals [1].

Pancreatic Disease Register of the German Society of General and Visceral Surgery (DGAV — Deutschen Gesellschaft für Allgemein- und Viszeralchirurgie) is a database of patients with diseases of the pancreas and surgical interventions performed by it, used to collect, analyze information online. DGAV is created on the basis of «DGAV-StuDoQ» (StuDoQ-Studien-, Dokumentations- und Qualitätszentrum (Center for training, regulatory framework and quality control) Center for training, regulatory framework and quality control.

Launch of the register «DGAV-StuDoQ», which took place in 2008, was initiated by the creation of the largest at the time in the world national registry of NOTES-operations in Germany. That register was called «StuDoQ | NOTES» (NOTES — Natural Orifice Transluminal Endoscopic Surgery — surgical technique through natural openings in the body, such as the mouth, rectum, vagina, etc. using small incisions and endoscopic equipment). n addition to collecting information, the purpose of creating this register was to monitor and increase the security of all NOTES-operations conducted in Germany. All medical institutions and surgeons practicing such operations were invited to participate in the collection of information [8, 13]. Within the framework of this project, its own infrastructure was created, in particular, software was introduced — «StuDoQ-Software», which is currently used to enter data, search and analyze information in all the registers of «StuDoQ» [13, 15].

In 2011, a register similar to the NOTES registry was created for patients with peritoneal carcinomatosis who used to be treated by HIPEC (hyperthermic intraperitoneal chemotherapy) — «StuDoQ | HIPEC» [4].

On September 1, 2013 the register «StuDoQ | Pancreas» was opened for the search and analysis of clinical data of patients with diseases of the pancreas [9]. This registry was developed as a tool to assess the operational risk, results of operations and outcomes of the surgical treatment of all diseases of the pancreas. Results and indicators of the quality of surgical care provided to patients with pancreatic pathology were used in accordance with the recommendations of expert consensus, current data from controlled randomized studies, clinical recommendations for certification of the Pancreatic Cancer Treatment Centers of the German Cancer Society [9].

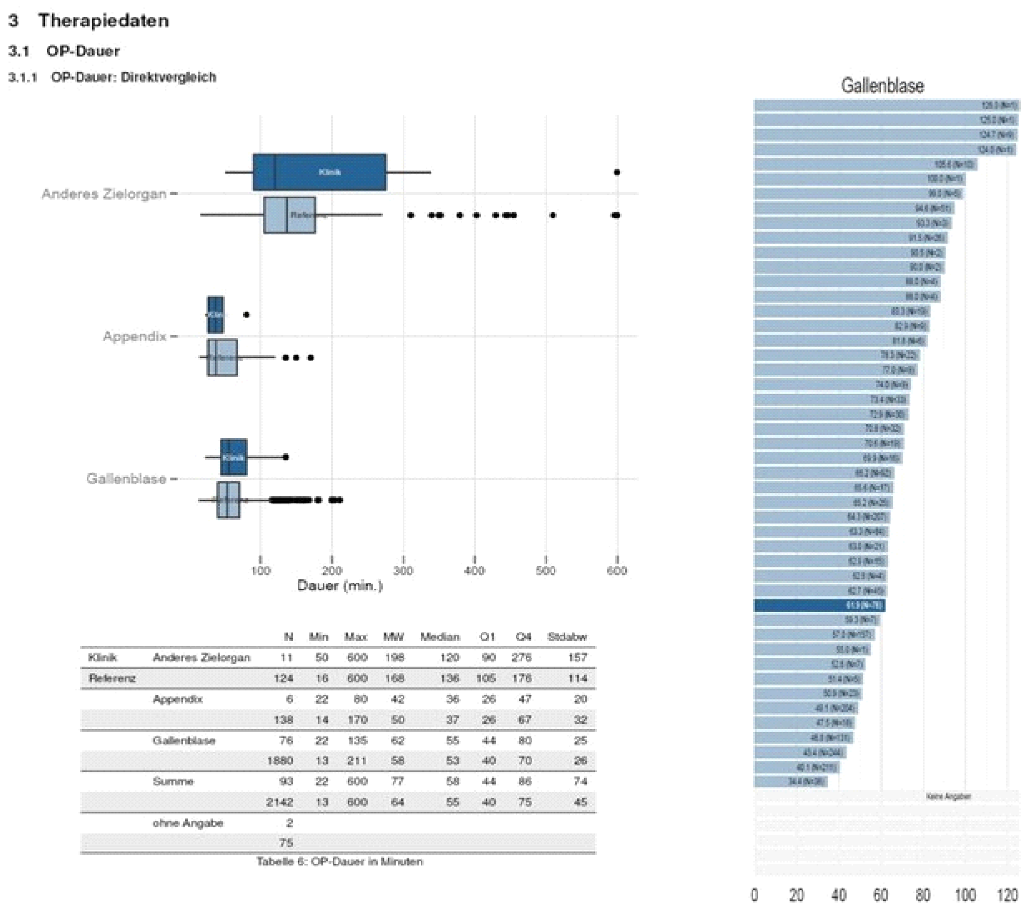
Currently “StuDoQ | Pancreas ”is a common center for collecting information on surgical diseases of the pancreas, bringing together participants not only in Germany, but also in other German-speaking countries, such as Switzerland and Austria. Methodical and organizational support, material and technical support is carried out directly by the German Society of Visceral and

General Surgery. The management of the register does not depend on external sources, either from the state or from private organizations [9].

The creation of a DGAV has several objectives: 1) the register is a tool for determining the quality of surgical care, adapted to the risks and outcomes of surgical interventions on the pancreas; 2) the register allows to assess compliance with clinical guidelines in the treatment of cancer and other diseases of the pancreas; 3) the registry is an information platform for retrospective studies of the results of surgical treatment of diseases of the pancreas; 4) the register can be used as an information platform for prospective randomized studies and additional study of histological material obtained during surgery [9].

To increase the relevance and validity of the information collected, “DGAV-StuDoQ” is authorized to issue a standard certificate for a period of 3 years. The certificate is issued to both a private practitioner and a medical institution and provides an opportunity to participate in the collection of clinical data, as well as provides access to the information already collected. Upon expiration of the certificate is issued by the relevant authority again only if the information provided by the project participant meets the established criteria. In this case, the participant can continue to work with the registry database “DGAV-StuDoQ” [9, 15]. The data collected in this way is further used to develop and test new high-quality standards for the diagnosis and surgical treatment of diseases of the pancreas.

The process of collecting information is organized in such a way that access to the register is carried out online using the software “StuDoQ-Software” [13]. User and patient data are entered anonymously in a standardized input mask with customizable parameters. Each patient is assigned an individual serial number. The automatic error correction built into the program is responsible for the optimal quality of the input data. Users are able to compare their data online with other participants (Fig. 1).



## 3 Therapiedaten

### 3.1 OP-Dauer

#### 3.1.1 OP-Dauer: Direktvergleich

| | | N | Min | Max | MW | Median | Q1 | Q4 | Stdabw |
|---|---|---|---|---|---|---|---|---|---|
| Klinik | Anderes Zielorgan | 11 | 50 | 600 | 198 | 120 | 90 | 276 | 157 |
| Referenz | | 124 | 16 | 600 | 168 | 136 | 105 | 176 | 114 |
| | Appendix | 6 | 22 | 80 | 42 | 36 | 26 | 47 | 20 |
| | | 138 | 14 | 170 | 50 | 37 | 26 | 67 | 32 |
| | Gallenblase | 76 | 22 | 135 | 62 | 55 | 44 | 80 | 25 |
| | | 1880 | 13 | 211 | 58 | 53 | 40 | 70 | 26 |
| | Summe | 93 | 22 | 600 | 77 | 58 | 44 | 86 | 74 |
| | | 2142 | 13 | 600 | 64 | 55 | 40 | 75 | 45 |
| | ohne Angabe | 2 | | | | | | | |
| | | 75 | | | | | | | |

Tabelle 6: OP-Dauer in Minuten

Fig. 1. Automatically generated online statistics («benchmarking»).

The program offers a wide range of settings for searching and sorting statistical data using a variety of customizable parameters. In addition, participants can export their data at any time in formats such as Excel, SPSS, CSV. The main researchers, in turn, have the ability to export the entire volume of data. In addition, participants are notified via e-mail of all important events and changes, and also have the opportunity to contact DGAV through the contact forms embedded in the software [13].

Validation of input data is performed by cross-checking using data from medical monitoring and is part of the annual certification process of the Pancreatic Cancer Treatment Centers. The concept of informed consent and data security was approved by the Society of Technologies, Methods and Infrastructure for Network Medical Research (http://www.tmf-ev.de), and the clinical guidelines were approved by the German Society for General and Visceral Surgery [9, 15].

Currently besides “StuDoQ | Pancreas "collection and comparative analysis of information is carried out in the following fields:

«StuDoQ | Kolonkarzinom» — cancer of the colon [5];

«StuDoQ | LapSigma» — laparoscopic surgery on the sigmoid colon with its diverticulosis [6];

«StuDoQ | LiveDoQ» — register of real-time transactions with online video broadcasting [12];

«StuDoQ | MBE» — Metabolische und bariatrische Erkrankungen (metabolic and bariatric diseases); register of patients with surgically significant metabolic disorders and undergoing bariatric surgery [7];

«StuDoQ | Rektumkarzinom» — colorectal cancer registry [12];

«StuDoQ | Robotik» — register of patients operated with the using robot-assisted technology [11];

«Pleuratumor-Register der DGT» — register of malignant neoplasms of the pleura of the German Society of Thoracic Surgeons (DGT) [3];

In addition to the above-mentioned database “StuDoQ | DGAV” includes «Nationales Register laparoskopische Leberchirurgie» — National Registry of Laparoscopic Liver Surgery and «Laparoskopisches Pankreasregister der DGAV» — Registry of Laparoscopic Pancreatic Surgery. However, for data of registries today it is still impossible to collect data “online” using “StuDoQ-Software” [14].

Therefore, register «DGAV StuDoQ | Pancreas» It is a good platform to evaluate the results and quality of the surgical treatment of pancreatic diseases, as well as prospective randomized studies in the field of pancreatic surgery.

DGAV is an optimal set of options for correct and complete data entry and analysis. Directly managing DGAV without interference from external sources ensures the independence of the registry. Own material and technical base provides autonomous functioning of the system. A good combination of transparency of exported data and certification control by the German Society of

General and Visceral Surgery makes, on the one hand, data collection is controlled, and on the other, it does not impose unnecessary restrictions on the work of participants and responsible authorities. Strict data privacy protections prevent disclosure of information and protect the interests of patients and specialists. The data export mode at any time and automatic comparative statistics speed up the process of analyzing clinical data.

At present, participation in the work of the DGAV is possible for clinics in other countries that are treating pancreatic diseases at the present level, after obtaining the appropriate permission “DGAV | StuDoQ”. At the same time, in our opinion, there is a need to create an international Pancreatic Disease Register under the auspices of the International Association of Pancreatology (IAP) / European Pancreatic Club (EPC). This should lead to a further improvement in the quality of surgical care provided to patients with diseases of the pancreas.

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Modern standards of registering the medical information involve a creation of registers of patients with various nosologies, which allows to standardize the services provided by the health care system, as well as to increase the efficiency and safety of treatment in actual clinical practice. The Pancreatic Disease Register of the German Society of General and Visceral Surgery, which is a database of patients with pancreatic diseases and their surgeries, has become very popular in the medical field. The register is a multidisciplinary database with its own infrastructure, coordination center and it contains information on surgical diseases and surgical interventions performed on the pancreas. The register is used to collect and analyze information online and integrates clinics of German-speaking countries (Germany, Switzerland, Austria), as well as doctors from other countries after receiving the relevant permission. The review analyzes the features of information collection and the creation of own register infrastructure, aspects of the implementation of methodological and organizational support, as well as the nuances of its logistics. The ways of statistical processing and validation of the collected information are listed, the possibility of autonomous functioning of the system and the presence of strict measures to protect the confidentiality of data are emphasized. The register is an optimal set of possibilities for correct, full-fledged introduction and analysis of extensive medical data, which is a prerequisite for conducting the prospective randomized studies in the field of pancreatic surgery.