

Accepted Manuscript

Common data items in seven European oesophagogastric cancer surgery registries:
Towards a European Upper GI Cancer Audit (EURECCA Upper GI)

W.O. de Steur, D. Henneman, W.H. Allum, J.L. Dikken, J.W. van Sandick, J. Reynolds, C. Mariette, L. Jensen, J. Johansson, P. Kolodziejczyk, R.H. Hardwick, C.J.H. van de Velde

PII: S0748-7983(13)00931-1

DOI: [10.1016/j.ejso.2013.11.021](https://doi.org/10.1016/j.ejso.2013.11.021)

Reference: YEJSO 3695

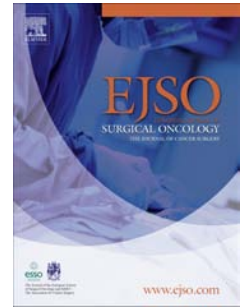
To appear in: *European Journal of Surgical Oncology*

Received Date: 22 November 2013

Accepted Date: 22 November 2013

Please cite this article as: de Steur WO, Henneman D, Allum WH, Dikken JL, van Sandick JW, Reynolds J, Mariette C, Jensen L, Johansson J, Kolodziejczyk P, Hardwick RH, van de Velde CJH, , Common data items in seven European oesophagogastric cancer surgery registries: Towards a European Upper GI Cancer Audit (EURECCA Upper GI), *European Journal of Surgical Oncology* (2014), doi: 10.1016/j.ejso.2013.11.021.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.



Common data items in seven European oesophagogastric cancer registries: Towards a European Upper GI Cancer Audit (EURECCA Upper GI)

W.O. de Steur¹, D. Henneman^{1*}, W.H. Allum², J.L. Dikken³, J.W. van Sandick⁴, J. Reynolds⁵, C. Mariette⁶, L.

Jensen⁷, J. Johansson⁸, P. Kolodziejczyk⁹, R.H. Hardwick¹⁰, C.J.H. van de Velde¹ (the EURECCA Upper GI group)

*both authors contributed equally to this manuscript

¹ Department of Surgery, Leiden University Medical Center, Leiden the Netherlands

² Department of Surgery, the Royal Marsden Hospital, London, United Kingdom, Chair EURECCA Upper GI

³ Department of surgery, Medical Center Haaglanden, The Hague, the Netherlands

⁴ Department of Surgery, Antoni van Leeuwenhoek Ziekenhuis, Amsterdam

⁵ Department of Surgery, St James's Hospital and Trinity College, Dublin, Ireland

⁶ Department of Digestive and Oncological Surgery, University Hospital C Huriez, Lille, France

⁷ Department of Surgical Gastroenterology, Aarhus, Denmark

⁸ Department of Surgical Oncology, Lund University Hospital, Sweden

⁹ Department of Surgery I Jagiellonian University, Krakow, Poland

¹⁰ Cambridge Oesophago-Gastric Centre, Addenbrookes Hospital, Cambridge, United Kingdom

Corresponding author

Prof. dr. C.J.H. van de Velde

Dept. of Surgery, K6-50

Leiden University Medical Center

PO Box 9600

2300 RC Leiden

The Netherlands

Telephone +31 71 5262309

Fax +31 71 5266750

Email c.j.h.van_de_velde@lumc.nl

Abstract

Aims: Seven countries (Denmark, France, Ireland, the Netherlands, Poland, Sweden, United Kingdom) collaborated to initiate a EURECCA (European Registration of Cancer Care) Upper GI project. The aim of this study was to identify a core dataset of shared items in the different data registries which can be used for future collaboration between countries.

Methods: Itemlists from all participating Upper GI cancer registries were collected. Items were scored 'present' when included in the registry, or when the items could be deducted from other items in the registry. The definition of a common item was that it was present in at least six of the seven participating countries.

Results: The number of registered items varied between 40 (Poland) and 650 (Ireland). Among the 46 shared items were data on patient characteristics, staging and diagnostics, neo-adjuvant treatment, surgery, postoperative course, pathology, and adjuvant treatment. Information on non-surgical treatment was available in only 4 registries.

Conclusions: A list of 46 shared items from seven participating Upper GI cancer registries was created, providing a basis for future quality assurance and research in Upper GI cancer treatment on a European level.

Introduction

At current times, society, stakeholders and caregivers focus more and more on effectiveness and efficiency in healthcare. Differences in hospital performance and outcomes between different providers and different countries may vary considerably¹⁻⁴. As a result, quality assurance is increasingly acknowledged as a crucial factor in the (oncological) surgical care process^{5,6} and many clinical audit programs have been initiated in recent years⁷. Audits can identify shortcomings in the care process on any level in the health care system (i.e., on a hospital, regional or national level) and can aid clinicians in improving the standard level of care by providing feedback to participating clinics. Many improvements have been achieved by various national surgical audits, as have been described particularly in the field of colorectal cancer surgery^{8,9}.

In 2010, a number of European colorectal cancer surgery audits started an initiative to distil a 'core dataset' from the existing audit data forms, thereby creating a European outcome based registry for preoperative, surgical and postoperative treatment of colorectal cancer¹⁰. The project is known as the European Registration of Cancer Care (EURECCA). Until recently, the colorectal initiative was the only European quality assurance project in oncologic care.

Following the EURECCA colorectal initiative, under the auspices of the European Society for Surgical Oncology (ESSO) and the European Network of Excellence on gastric and oesophagogastric junction cancer (EUNE), a EURECCA Upper GI project was initiated wherein several European national and regional oesophagogastric cancer registries and audits collaborate with the aim to develop a European oesophagogastric cancer audit. The first step in this project was to describe a 'common data item list'. Such a list of shared items on a European level may prove beneficial for existing national audits, because treatment results can then be compared to a wider range of centres in different settings. Moreover, the European Upper GI cancer audit list of data items can serve as an example for new audits, indicating which items were found to be important by most countries and which items may be considered 'optional' in a dataset- only to be included when the extra registration effort can be made. Lastly, the core set of items may give insight into what research can be done in a European setting in the future.

The purpose of the current study was to compare the data sets used by the seven participating European oesophagogastric cancer registries and audits and to identify a list of common items. This core dataset can be used for future collaboration in the EURECCA Upper GI project.

Methods

From the participating registries and audits, item lists were collected. These items were entered in a database and assigned to a main category and a subcategory. Items were scored 'present' if they appeared on an item list or when they could be calculated using other items in the same registration. The type of data (categorical, number, yes/no, free text) was scored. After all the items were entered in the database, a report was sent back to the representatives of each organisation to check for errors or incompleteness. Adjustments were made where appropriate. In the corrected and completed database, shared data items between the registries were identified as well as similarity in data type and categories. Following the colorectal EURECCA initiative¹⁰, the definition of a 'shared data-item' or 'common data item' was that at least six of the seven participating registries scored the item. Definitions of items were compared among the different registries. This way comparability was investigated. Software used for data input and analyses was SPSS 20 (PASW, Chicago).

Results

Seven countries (Denmark, France, Ireland, the Netherlands, Poland, Sweden, United Kingdom, figure 1) supplied complete items lists from an existing registry or audit. In six countries, the registry included both patients with oesophageal cancer and patients with gastric cancer. In one country (Poland), only a gastric cancer database was available. Some audits focused mainly on the surgical care process, other audits also had detailed information on non-surgical treatment. Inclusion criteria also varied.

The number of registered items varied between 40 (Poland) and 650 (Ireland). The items were categorized into the following subgroups: patient administrative/medical condition, staging/diagnostics, neo adjuvant treatment, surgery, postoperative course/complications, pathology, adjuvant treatment and survival/follow up. Only 4 registries had information on non-surgical patients. It was therefore decided that only data-items concerning patients undergoing surgical treatment (including multimodality treatment in the neoadjuvant and adjuvant setting) could be used. A total of 46 items was present in at least six of seven datasets, thereby forming the common data set.

The complete list of common data items is given in Table 1. Postoperative complications were scored in all registries, but there are differences in the definitions (Table 2).

Discussion

By comparing the datasets of the seven participating registries, 46 items were identified as a shared item to enter a core dataset for a surgical outcomes registration of oesophagogastric cancer patients. The most vital variables regarding patient, disease, preoperative staging, operation, pathology and mortality are included. Furthermore, data on the use of pre- and postoperative adjuvant treatment are included.

Outcomes between different providers and different countries may vary considerably. Donabedian has proposed a model to evaluate patient care in terms of structure, process, and outcome measures¹¹, which forms the basis of many clinical audits. A clinical audit is a quality instrument that collects detailed clinical data from different health care providers. Audits have two main goals: firstly, identification of shortcomings in the care process on a hospital, regional or national level, for instance in terms of guideline adherence or in outcomes such as postoperative mortality; and secondly, improving the standard level of care and reducing the variation in outcomes between centres by feeding back benchmark information to participating clinics.

In 2010, the European Cancer Organisation (ECCO) initiated a European colorectal cancer surgical quality assurance program: EURECCA colorectal. Its goal was to provide insight into differences in treatment and outcomes of patients undergoing colorectal cancer resections, in order to reduce unwanted variation in treatment patterns and to spread best practice. By identifying data-items already registered in nine participating European countries, a common European dataset was created. With this collaborative research, more insight is gained in the differences among countries regarding, for example, the use of (neo)adjuvant therapy for rectal cancer. The EURECCA colorectal initiative formed the basis for a successful European multidisciplinary consensus meeting in Perugia, Italy, in December 2012.¹² Consensus was reached on many key diagnostic and treatment issues, thereby defining many core treatment strategies in colorectal cancer treatment. Implementation of the various issues on which consensus was reached will be monitored with the European registry.

Using the European Upper GI core dataset, an inventory of differences in treatment patterns can be made and linked to outcome measures such as morbidity, mortality, and surgical margins. The EURECCA Upper GI core dataset offers enough patient data to perform statistical corrections for patient- and tumour factors, necessary for a fair comparison between different treatment strategies. Moreover, collective data from the core dataset may answer questions concerning the optimal treatment for elderly patients, which are often excluded from randomized trials, but in daily practice form a significant proportion of the patient population with oesophagogastric cancer. The

EURECCA Upper GI project provides (surgical) teams participating in the national projects with the opportunity to benchmark their performance on a European level. This way, EURECCA can stimulate quality improvement projects throughout Europe, on a European, national and local level.

Although the first step has been taken, some challenges remain. Firstly, not all European countries were able to participate because of limited availability of nationwide or regional registries and audits. The objective is to get as many countries to participate in the project as possible. In figure 1, newly participating countries are shown. A second challenge is the data validity. The current participating national audits have different degrees of coverage on a national level. Results from registries in countries with lower case-ascertainment may not be generalizable to the entire country, possibly hampering comparability of data. Moreover, many registries consist of self-reported data and validity of data should be investigated. Thirdly, definitions for postoperative complications differ among countries. In order to compare the data from the different registries, agreement has to be obtained concerning the definition of all complications used in the registries. Lastly, the items that are registered in all but one participating country should be added to the registry in that particular country. Ideally, participating datasets are fully harmonized.

In June 2013, at the 10th International Gastric Cancer Congress in Verona, Italy, a collaborative meeting was held. The setup and results of each registry (figure 1) and audit were presented to share experience and to provide an opportunity for other countries in Europe to start participating in the collaborative project. Already, the project has created a pilot for a clinical registry in the Spanish region of Catalonia which was presented. In addition the Italian Research Group for Gastric Cancer has plans to extract 'core data' from their established regional database.

In conclusion, in this study, a core dataset with patient, tumour, treatment and outcome parameters of oesophagogastric cancer surgery was identified. This dataset can help starting clinical audits or other registries setting up their database. The main goal is to compose a European, widely accepted set of data items, which can be used to compare and improve different treatment modalities. By comparing the registries, it is possible to identify differences in patterns of care. Also, benchmarking of outcomes can be expanded to a European level. This way, differences in outcomes can be identified and specific research questions, for example concerning elderly patients, may be answered using a common dataset.

Acknowledgements

The authors would like to thank all the participating countries and prospective participants of the EURECCA upper GI group for their input and providing the used item list for comparison.

1. the Netherlands: J.W. van Sandick, On behalf of the Dutch Upper GI Cancer Audit
2. Ireland: J. Reynolds, On behalf of the National Upper GI & Gastric Cancer Registry
3. France: C. Mariette, On behalf of the French Eso-Gastric Tumors working group
4. Denmark: L. Jensen, On behalf of the Danish Group of Esophageal, Gastro-esophageal Junction and Gastric Cancer
5. Sweden: J. Johansson, On behalf of the National quality registry of Esophageal and Gastric cancer
6. Poland: P. Kolodziejczyk, On behalf of the Polish gastric cancer registry
7. United Kingdom: R.H. Hardwick, On behalf of the National Oesophago-Gastric Cancer Audit
8. Spain (Catalonia region): M. Pera, Section of Gastrointestinal Surgery, Parc de Salut Mar and Institute de Recerca Hospital del Mar, Universitat Autònoma del Barcelona, Barcelona, Spain.
9. Germany: A. Hölscher, Klinik für visceral- und Gefasschirurgie der universität zu Köln, Cologne, Germany.
10. Italy: F.Roviello, Department of Medical, Surgical and neurological Sciences, Unit of Surgical Oncology, University of Sienna, Italy

Figure caption

Figure 1. Countries participating and involved in the EURECCA Upper GI project

ACCEPTED MANUSCRIPT

Tables

Main category	Item
Patient administrative / medical condition	Date of birth / age Gender ASA score
Staging/diagnostics	Upper GI endoscopy Localization of tumour (ICD 10) GOJ tumours: Siewert classification Histological type of the tumour adeno/SCC (from biopsy) Preoperative CT scan Preoperative endoscopic ultrasound Staging laparoscopy cT classification (TNM7) cN classification (TNM7) cM classification (TNM7)
Neoadjuvant treatment	Neoadjuvant treatment Neoadjuvant treatment; type
Surgery	Resection performed? Oesophageal operation: approach transhiatal / trans thoracic Oesophagectomy: type Gastrectomy: type Reconstruction type Location of anastomosis Nodal dissection Date of surgery
Postoperative course / complications	Postoperative surgical complication Postoperative complications: anastomotic leakage Postoperative complications: chylous leakage Postoperative general complication Postoperative complications: bleeding Postoperative complications: pulmonary complications Postoperative complications: cardiac complications Reoperation Date of discharge
Pathology	Location of bulk of the tumour (stomach or oesophagus) Histological type adenocarcinoma/SCC Involvement of vertical resection margins Involvement of circumferential resection margin Number of lymph nodes examined Number of positive lymph nodes pT classification (TNM6-7) pN classification (TNM6-7) pM classification (TNM6-7) Radicality of resection (R0,R1,R2)

Adjuvant treatment	Adjuvant treatment Adjuvant treatment, type
Mortality	30-day mortality In-hospital mortality

Table 1: main categories with the shared data-items in the EURECCA Upper GI core dataset

ASA = American Society of Anaesthesiologists

ICD = International Classification of Diseases

GOJ = Gastric Oesophageal Junction

SCC = Squamous Cell Carcinoma

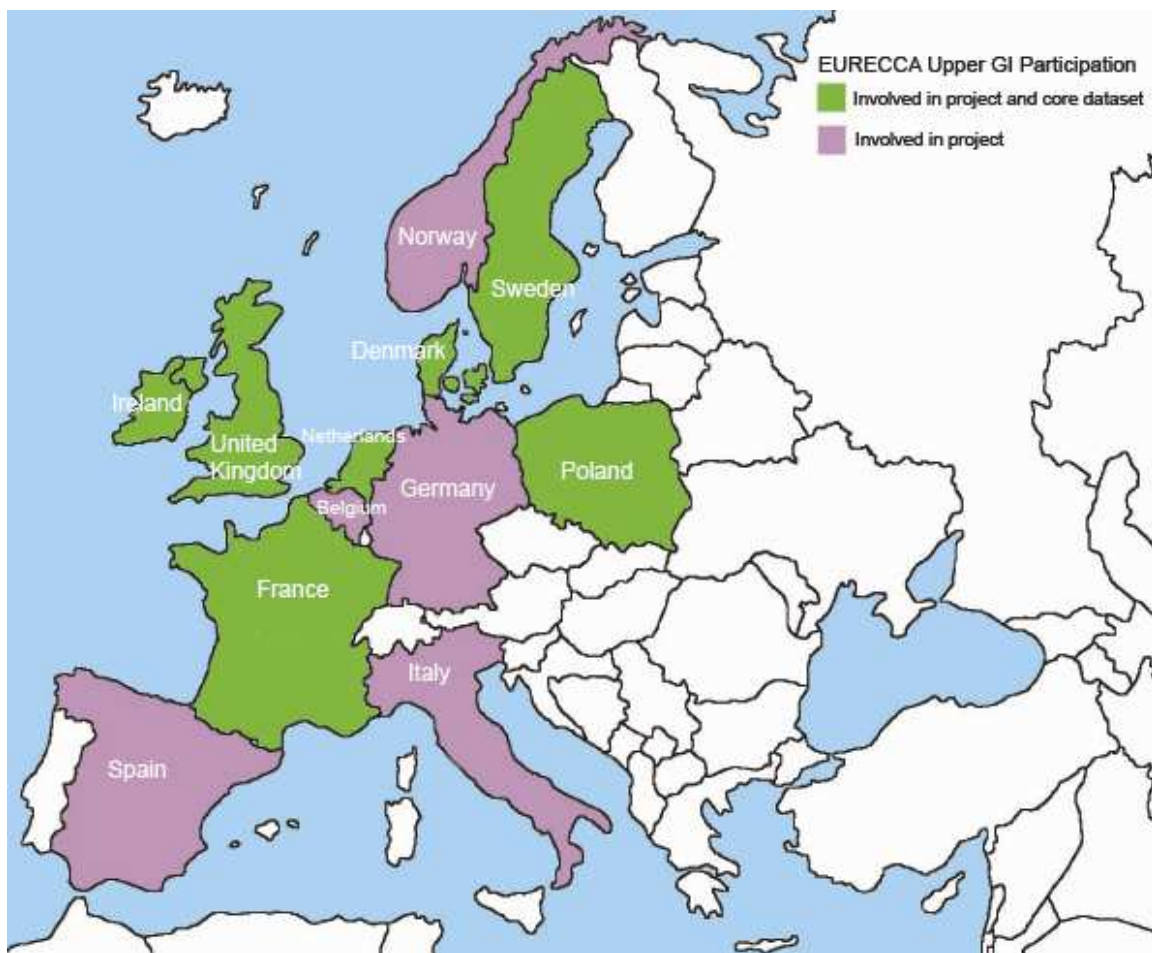
AC = Adenocarcinoma

Table 2: definitions of postoperative complications in the seven participating registries and audits participating in the EURECCA Upper GI project.

	the Netherlands	United Kingdom	France	Ireland	Sweden	Denmark	Poland
Anastomotic leak	Radiological or clinical y/n	Not otherwise specified	Radiological leak y/n	Not otherwise specified	Radiological or clinical y/n	Not otherwise specified	Not otherwise specified
Chylous leak	If special diet/TPN/intervention is required	Not otherwise specified	drainage > 7 days or reintervention	Not otherwise specified	Not otherwise specified	Not otherwise specified	Not otherwise specified
Pulmonary complications	Pneumonia, pleural effusion, ARDS, thoraxempyema reintubation	Pneumonia ARDS pulmonary embolism Pleural effusion y/n	Pneumonia pulmonary embolism y/n	Pneumonia ARDS pulmonary embolism atelectasis pulmonary failure y/n	Pneumonia pulmonary failure (atelectasis or ARDS) pulmonary embolism drainage for pleural effusion y/n	Not otherwise specified	Not otherwise specified
Cardiac complications	Arrhythmia myocardial infarction	Not otherwise specified	myocardial infarction	Arrhythmia myocardial infarction	Arrhythmia myocardial infarction	Not otherwise specified	Not otherwise specified

References

1. Lingsma HF, Steyerberg EW, Eijkemans MJ, Dippel DW, Scholte Op Reimer WJ, Van Houwelingen HC. Comparing and ranking hospitals based on outcome: results from The Netherlands Stroke Survey. *QJM* 2010;103:99-108.
2. Friese CR, Earle CC, Silber JH, Aiken LH. Hospital characteristics, clinical severity, and outcomes for surgical oncology patients. *Surgery* 2010;147:602-9.
3. Kolfschoten NE, Gooiker GA, Bastiaannet E, et al. Combining process indicators to evaluate quality of care for surgical patients with colorectal cancer: are scores consistent with short-term outcome? *BMJ Qual Saf* 2012;21:481-9.
4. Ptok H, Marusch F, Schmidt U, Gastinger I, Wenisch HJ, Lippert H. Risk adjustment as basis for rational benchmarking: the example of colon carcinoma. *World J Surg* 2011;35:196-205.
5. Ingraham AM, Richards KE, Hall BL, Ko CY. Quality improvement in surgery: the American College of Surgeons National Surgical Quality Improvement Program approach. *Adv Surg* 2010;44:251-67.
6. van Gijn W, van de Velde CJ. Improving quality of cancer care through surgical audit. *Eur J Surg Oncol* 2010;36 Suppl 1:S23-6.
7. van Leersum NJ, Kolfschoten NE, Klinkenbijn JH, Tollenaar RA, Wouters MW. ['Clinical auditing', a novel tool for quality assessment in surgical oncology]. *Ned Tijdschr Geneesk* 2011;155:A4136.
8. van Gijn W, Wouters MW, Peeters KC, van de Velde CJ. Nationwide outcome registrations to improve quality of care in rectal surgery. An initiative of the European Society of Surgical Oncology. *J Surg Oncol* 2009;99:491-6.
9. van Leersum NJ, Snijders HS, Henneman D, et al. The Dutch Surgical Colorectal Audit. *Eur J Surg Oncol* 2013;39(10):1063-70.
10. van Gijn W, van den Broek CB, Mroczkowski P, et al. The EURECCA project: Data items scored by European colorectal cancer audit registries. *Eur J Surg Oncol* 2012;38:467-71.
11. Donabedian A. Evaluating the quality of medical care. 1966. *The Milbank quarterly* 2005;83:691-729.
12. van de Velde CJ, Aristei C, Boelens PG, et al. EURECCA colorectal: Multidisciplinary Mission statement on better care for patients with colon and rectal cancer in Europe. *Eur J Cancer* 2013;49:2784-90.



ACCEPTED

Leiden 22/11/2013

Dear Editorial board,

On behalf of C. van de Velde and Bill Allum and other authors, there is no conflict of interest.

Kind regards

Wobbe de Steur

Daniel Henneman

ACCEPTED MANUSCRIPT