

QUALITY INDICATORS FOR THE MANAGEMENT OF UPPER GASTROINTESTINAL CANCER

SYNTHESIS





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Belgian Health Care Knowledge Centre

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QUALITY INDICATORS FOR THE MANAGEMENT OF UPPER GASTROINTESTINAL CANCER SYNTHESIS

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Disclaimer:

The external experts were consulted about a (preliminary) version of the scientific report. Their comments were discussed during meetings. They did not co-author the scientific report and did not necessarily agree with its content.

Subsequently, a (final) version was submitted to the validators. The validation of the report results from a consensus or a voting process between the validators. The validators did not co-author the scientific report and did not necessarily all three agree with its content.

Finally, this report has been approved by common assent by the Executive Board.

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In our recent report on the performance of the Belgian health system, we were able to credit our country for the quality of care, and in particular for the survival after breast cancer. The present report proves that this is not only the case for breast cancer: the chance of surviving oesophageal and gastric cancer in Belgium is clearly higher than the European average. All things considered, survival is a very important, if not the most important indicator.

The first national clinical practice guidelines on oesophageal and gastric cancer date from 2008, and we published an updated version in 2012. From these guidelines it is clear that these patients need a complex and highly specialized management and that some centralisation is definitely warranted. Still, in our country – somehow paradoxically –most centres continue to offer this type of treatment.

As usual, the average results, although very good in this case, hide considerable differences between the centres. Furthermore, also as often is the case, centres with a vast experience score on average better than centres that treat only few of these tumour types per year. Of course, this does not necessarily mean that centres with less patients cannot provide care of excellent quality. In other words, evaluating individual centres solely on the basis of their volume – in terms of number cases per annum – is manifestly short-sighted.

But isn't this exactly where the shoe pinches? The really important issue is not about judging individual hospitals or specialists in the first place; it is about offering patients of today and tomorrow the best possible chances in terms of survival and quality of care. Indicators — of course always based on the past, and never completely free of shortcomings — proved to be useful for the measurement of these chances for quality and survival. Now, no need to have an advanced knowledge of statistics to realize that 3 successes on 3 cannot offer the same guarantees as 30 successes on 30. Inevitably, this is the conclusion that will be drawn by the citizen-patient, whose right for demonstrable quality is no longer disputed in 2013. The hospital sector should enter this reality with an open view and in a constructive way: the necessary specialization, multidisciplinarity and infrastructure simply require a movement towards much more centralization. Volume then becomes a necessary consequence of this strive for quality, not a goal in itself, and certainly not an *a priori* criterion that all too often leads to perverse effects.

This report also clearly shows is that it is not an either/or story. Volume in itself is most likely a necessary, but not a sufficient element. Demonstrable excellence pays attention to all dimensions of care. Thanks to the combination of data from clinicians, pathologists and sickness funds, securely pooled and processed by the Belgian Cancer Registry, we now have a set of validated indicators. As already said: the patients is entitled to this.

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Background: In Belgium during the year 2010, more than 2 300 patients were diagnosed with either an oesophageal or a gastric cancer. Survival is poor for both cancers. In Belgium, the global relative 5-year survival is higher than in neighbouring countries, reaching 21% for oesophageal cancer and 30% for gastric cancer (2004-2008). The care for oesophageal and gastric cancer requires high specialisation, but remains very dispersed in Belgium, and is provided in almost all hospitals.

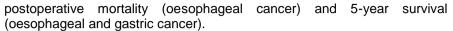
Objectives: The primary objectives of this report were to develop a set of quality indicators for upper gastrointestinal cancer and to evaluate their measurability with available cancer registry and administrative data. Secondary objectives were to calculate these quality indicators in order to evaluate the quality of care on a national and hospital-level with Belgian data covering a period of 5 years. The ultimate goal of this project is to improve the quality of care for upper gastrointestinal cancer.

Quality indicator selection process and measurability: A set of 15 indicators for oesophageal cancer and 14 indicators for gastric cancer covering the entire care pathway has been defined. Patients diagnosed with oesophageal cancer (ICD-10 C15.0-16.0; n= 5 813) or gastric cancer (ICD-10 C16.1-16.9; n= 4 847) between 2004 and 2008 were selected from the Belgian Cancer Registry database. These data were coupled with claims data from the Intermutualistic Agency. Based on these linked data, some indicators cannot be measured. The final set contains 13 indicators that can be reliably measured.

Results of the quality indicators at a national level and by hospital: Five-years survival appears to be higher in Belgium than in neighbouring countries. Conversely, postoperative mortality appears to be worse than in some of the neighbouring countries. For patients treated with oesophageal resection, a 30-day mortality of 4.8% and a 90-day mortality of 9.9% were found.

Some positive trends were found in the management of patients, e.g. for staging CT in gastric cancer. On the contrary, there are indications of underuse of recommended interventions, especially in elderly patients (e.g. palliative combination chemotherapy in metastatic gastric cancer patients).

During the period 2004-2008, (almost) all Belgian acute hospitals delivered care for patients with oesophagogastric cancer. A clear volume-outcome relationship was found for upper gastrointestinal cancer, both for



Finally, the underreporting of the cancer stage to the Belgian Cancer Registry is a major finding of this study. An adequate reporting of cancer stage should be used as a quality indicator in itself and should be mandatory.

Suggestions for quality improvement initiatives: Firstly, Belgian centres and care providers will receive their results from the Belgian Cancer Registry for *individual feedback*. The analysis per centre could allow to benchmark results from one centre against others, and to consider *targeted and corrective actions*.

Secondly, in addition to recurrent evaluations with the complete set of measurable indicators, *in-depth evaluations* could be conducted on

specific indicators. A further refinement of the measurable indicators and the registration of additional data will be probably required. Additional registration of the intention of treatment, co-morbidity, recurrence and some clinical data (resection margins, postoperative complications, lymph node status) would further increase the relevance and comprehensiveness of the indicator set.

Thirdly, *centralization of care* deserves further attention. This report does not allow to provide recommendations on how to organise this centralised care. The discussion about these organisational issues should be done using this report as a starting point.

Finally, all of the above-mentioned actions should be embedded in an integrative quality system.

■ SYNTHESIS

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LIST OF ABBREVIATIONS

ABBREVIATION DEFINITION

95%CI 95% confidence interval

combStage Combined stage cStage Clinical stage

CT Computed tomography

GC Gastric cancer

ICD International Classification of Diseases

IMA InterMutualistic Agency

KCE Belgian Health Care Knowledge Centre
MOC-COM Multidisciplinary Oncological Consultation

OC Oesophageal cancer pStage Pathological stage

TNM Tumour – Node – Metastasis

UK United Kingdom
US United States

WHO World Health Organization



1. BACKGROUND AND OBJECTIVES

In 2011, KCE published a study report in which it recommended to set up an integrative quality system in oncology. Such a system should cover the development and implementation of clinical practice guidelines, monitor quality of care using indicators, provide feedback to health care providers and organisations, and finally target actions to improve the quality if needed ¹. Quality indicator sets have already been developed for rectal cancer ^{2, 3}, breast cancer ⁴ and testicular cancer ⁵. Building on this experience, it was decided to set up a project to evaluate the quality of care of upper gastrointestinal cancer (comprising both oesophageal and gastric cancer) for the following reasons:

Upper gastrointestinal cancer causes an important burden.

In Belgium during the year 2010, 680 men and 242 women were diagnosed with oesophageal cancer (ICD-10 15.0-15.9) and 854 men and 547 women with gastric cancer (ICD-10 16.0-16.9) (www.kankerregister.org). Both cancer types are responsible for a substantial number of cancer deaths ⁶. In 2008, 3.4% and 3.2% of all cancer deaths in men and 1.4% and 2.6% in women were caused by oesophageal cancer and gastric cancer, respectively. According to the most recent data (2004-2008) from the Belgian Cancer Registry, the global relative 5-year survival was 21.7% and 21.6% for men and

women with oesophageal cancer, and 28.4% and 31.4% for men and women with gastric cancer.

 Care for oesophageal and gastric cancer requires high specialisation but is very dispersed in Belgium.

The first national guidelines for the treatment of upper gastrointestinal cancer were developed by the College of Oncology in collaboration with the KCE in 2008 7 and updated in 2012 8 . These guidelines highlight the clinical challenges when dealing with a patient with upper gastrointestinal cancer.

In both versions, centralisation of care was recommended, based on the available scientific literature. We found that during the period 2004-2008, 111 and 114 out of the 115 acute Belgian hospitals delivered medico-surgical treatment for patients with oesophageal or gastric cancer, respectively.

The primary objectives of this report were to develop a set of quality indicators of the care for upper gastrointestinal cancer and to evaluate their measurability with the available cancer registry and administrative data. A secondary objective was to calculate these quality indicators in order to evaluate the quality of care on a national and hospital-level with Belgian data covering a period of 5 years. The ultimate goal of this project is to improve the quality of care of upper gastrointestinal cancer.



2. A COMPREHENSIVE SET OF QUALITY INDICATORS?

2.1. Quality indicator selection process

The updated national guidelines on upper gastrointestinal cancer ⁸ served as a major source for quality indicators (54 potential indicators). The indexed and grey literature added 30 potential indicators. The resulting list of 84 indicators was subjected to a two-step selection process. First, a panel of 14 experts selected quality indicators on the basis of their relevance. Second, the 33 remaining indicators were evaluated by a smaller working panel on their reliability, interpretability and actionability.

This formal selection process eventually resulted in 15 indicators for oesophageal cancer and 14 indicators for gastric cancer (Table 1)

A good balance was found between process and outcome indicators, but no single structure indicator was selected. The following quality dimensions were covered: effectiveness, appropriateness, continuity, safety, timeliness and patient-centeredness. No indicator addressed efficiency or equity.

2.2. Measurability of the selected quality indicators

To calculate the quality indicators for upper gastrointestinal cancer, patients diagnosed with oesophageal cancer (ICD-10 C15.0-16.0) or

gastric cancer (ICD-10 C16.1-16.9) between 2004 and 2008 were selected from the Belgian Cancer Registry database. These data were coupled with claims data from the Intermutualistic Agency. The vital status was retrieved from the Kruispuntbank van de Sociale Zekerheid / Banque Carrefour de la Sécurité Sociale based on the patients' unique social security number (NISS/INSZ). Using this follow-up method, patients were followed up until January 1st 2010.

For each cancer type, only 9 indicators were found to be measurable. The remaining one third of the selected indicators could not be assessed by means of the available data. Important reasons for not being measurable were:

- The absence of clinical information in administrative and cancer registry databases (e.g. on R0 resection [OC5, GC5], number of resected lymph nodes [OC8, GC7], anastomotic leakage [OC9, GC8]);
- The absence of very specific nomenclature codes for some interventions (e.g. en bloc endoscopic mucosal resection [OC3, GC3], transthoracic oesophagectomy with 2-field lymphadenectomy [OC7]);
- The lack of systematically registered information about recurrence at the Belgian Cancer Registry and the absence of a specific nomenclature code to record a treatment administered due to recurrence (OC12 and GC12).

Process

GC7: Mean number of resected/evaluated lymph nodes during Outcome

GC8: Proportion of patients experiencing anastomotic leakage after Outcome

OC7: Proportion of patients with oesophageal cancer or cancer of

the gastro-oesophageal junction who were treated by a radical transthoracic oesophagectomy and two-field lymphadenectomy of

OC8: Mean number of resected/evaluated lymph nodes during

OC9: Proportion of patients experiencing anastomotic leakage after

abdominal and thoracic lymph nodes

oesophagectomy

oesophagectomy



Table 1 – Final selection of quality indicators §					
Oesophageal cancer (OC)	Gastric cancer (GC)	Type of indicator			
Staging					
OC1: Proportion of patients diagnosed with oesophageal cancer discussed at the multidisciplinary team meeting	GC1: Proportion of patients diagnosed with gastric cancer discussed at the multidisciplinary team meeting	Process			
OC2: Proportion of patients diagnosed with oesophageal cancer undergoing a CT neck/thorax/abdomen	GC2: Proportion of patients diagnosed with gastric cancer undergoing a CT thorax/abdomen	Process			
Treatment of mucosal cancer					
OC3: Proportion of patients diagnosed with cT1a oesophageal cancer undergoing endoscopic mucosal resection who had an en bloc resection	GC3: Proportion of patients diagnosed with cT1a gastric cancer undergoing endoscopic mucosal resection/endoscopic submucosal dissection who had an en bloc resection	Outcome			
Neoadjuvant treatment					
OC4: Proportion of patients with oesophageal cancer beyond the mucosa (T_{2-4} N_{Any} M_{0-1a}) who received neoadjuvant treatment	GC4: Proportion of patients with a gastric cancer beyond the mucosa (T_{2-4} N_{Any} M_0) who received neoadjuvant treatment	Process			
Surgery					
OC5: Proportion of surgically treated patients who had a R0 resection	GC5: Proportion of surgically treated patients who had a R0 resection	Process			
OC6: Oesophageal resection mortality rate within 30 days	GC6: Gastric resection mortality rate within 30 days	Outcome			

gastrectomy

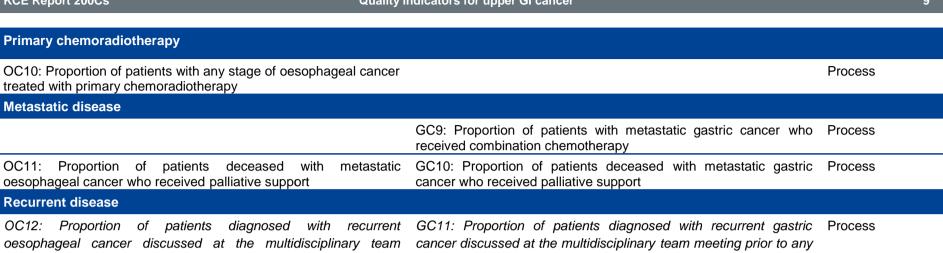
gastrectomy

Metastatic disease

Recurrent disease

Primary chemoradiotherapy

treated with primary chemoradiotherapy



oesophageal	cancer	discussed	at	the	multidisciplinary	team	cancer discussed at the multidisciplinary team meeting prior to any	
meeting prior	to any tre	eatment					treatment	
Generic indic	ators							

OC13: Five-year relative survival by stage	GC12: Five-year relative survival by stage	Outcome
OC14: Five-year overall survival	GC13: Five-year overall survival	Outcome
OC15: Proportion of patients with oesophageal cancer surgically treated in high-volume hospitals	GC14: Proportion of patients with gastric cancer surgically treated in high-volume hospitals	Process

[§] Non-measurable indicators are in italic.



3. WHAT DO THE INDICATORS TELL ABOUT THE QUALITY OF CARE?

3.1. On a national level

The study population included 5 813 patients with oesophageal cancer and 4 847 patients with gastric cancer diagnosed between 2004 and 2008. The most important demographics are summarized in Table 2. The indicator results on a national level are summarized in Table 3 and Table 4 and further discussed in the paragraphs below.

Table 2 – Demographic information of study population and tumour characteristics by cancer type

	Oesophageal cancer (N = 5 813)	Gastric cancer (N = 4 847)
Male/female ratio	3.1 : 1	1.4 : 1
Mean age (range)		
• Men	65 years (23 – 99)	71 years (8 – 99)
• Women	70 years (36 – 101)	73 years (15 – 103)
Adenocarcinoma	56.2%	91.8%
Documented combined § stage I / II / III / IV	16.6% / 24.4% / 26.7% / 32.3%	28.9% / 16.0% / 18.9% / 36.2%

[§] Because the clinical (cStage) and/or pathological stage (pStage) is lacking for many patients, a combined stage (combStage) is calculated for each patient. To determine this combined stage, known pStage prevails over known cStage, except when there is clinical proof of distant metastasis. When only pStage or cStage is known, this is considered as the combined stage. Otherwise, when pStage and cStage are unknown, the combined stage also remains unknown.



Table 3 – Overview of indicator results for oesophageal cancer on a national level

	Definition of indicator	Result 2004-2008	Time trend §
Proces	s indicators		
OC1	Proportion of patients diagnosed with oesophageal cancer discussed at the multidisciplinary team meeting within 1 month after incidence date	44.0%	1
OC2	Proportion of patients diagnosed with oesophageal cancer undergoing a CT neck/thorax/abdomen within 1 month after incidence date	88.3%	=
OC4	Proportion of patients with oesophageal cancer beyond the mucosa (T_{2-4} N_{Any} M_{0-1a}) who received neoadjuvant treatment	43.3%	1
OC10	Proportion of patients with any stage of oesophageal cancer treated with primary chemoradiotherapy	21.1%	=
OC11	Proportion of patients with metastatic oesophageal cancer who received palliative support within 3 months before death	44.0%	~
OC15	Proportion of patients with oesophageal cancer surgically treated in high-volume hospitals (≥ 20 oesophagectomies per year)	34.7%	=
Outcon	ne indicators		
OC6	Oesophageal resection mortality rate within 30 days	4.8%	~
OC13	Relative 5-year survival (all stages combined)		
	Men	21.7%	Not calculated
	Women	21.6%	Not calculated
OC14	Overall 5-year survival (all stages combined)		
	Men	18.9%	Not calculated
	Women	18.9%	Not calculated

^{§ ↑:} increasing trend; =: stable trend; ~: no clear trend.

Table 4 – Overview of indicator results for gastric cancer on a national level

	Definition of indicator	Result 2004-2008	Time trend §
Proces	s indicators		
GC1	Proportion of patients diagnosed with gastric cancer discussed at the multidisciplinary team meeting within 1 month after incidence date	37.1%	1
GC2	Proportion of patients diagnosed with gastric cancer undergoing a CT thorax/abdomen within 1 month after incidence date	84.5%	1
GC4	Proportion of patients with a gastric cancer beyond the mucosa (T_{2-4} N_{Any} M_0) who received neoadjuvant treatment	20.7%	1
GC9	Proportion of patients with metastatic gastric cancer who received combination chemotherapy	42.0%	↑
GC10	Proportion of patients with metastatic gastric cancer who received palliative support within 3 months before death	43.9%	~
GC14	Proportion of patients with gastric cancer surgically treated in high-volume hospitals (≥ 20 gastrectomies per year)	4.7%	=
Outcon	ne indicators		
GC6	Gastric resection mortality rate within 30 days	5.6%	~
GC12	Relative 5-year survival (all stages combined)		
	Men	28.4%	Not calculated
	Women	31.4%	Not calculated
GC13	Overall 5-year survival (all stages combined)		
	• Men	22.3%	Not calculated
	• Women	25.3%	Not calculated

^{§ ↑:} increasing trend; =: stable trend; ~: no clear trend.



Multidisciplinary team meeting underused or not evaluable with administrative data?

On the basis of the available data, 44% and 37% of the patients with oesophageal and gastric cancer respectively, were discussed in a multidisciplinary consultation within 1 month after the incidence date between 2004 and 2008. Within this period the proportion clearly increased for both cancer types (to 49% and 41% in 2008 for oesophageal and gastric cancer respectively). The proportion may seem rather low, certainly compared with other cancer types such as breast cancer 4, but needs to be interpreted with caution. Firstly, the absence of a recorded nomenclature code for a multidisciplinary meeting for a particular patient does not necessarily mean that no multidisciplinary meeting was held. Some centres might not charge multidisciplinary meetings and in turn, they do not appear in the IMA database. Secondly, some centres organize several multidisciplinary meetings for each patient and only charge the last meeting, which is often months after the incidence date (with the first meeting being within 1 month after incidence date). This may have led to an underestimation of the real proportion. In fact, this was confirmed during the validation phase for this indicator. Thirdly, discussion at a multidisciplinary team meeting is not obligatory in Belgium. However, besides the reimbursement of the act, additional financial incentives have been set up in 2009 through the hospital financing. The financing of a data manager, psycho-oncologists, etc. has become dependent upon the number of registered multidisciplinary consultations. It is therefore expected that the proportion of patients discussed at a multidisciplinary consultation will significantly increase. Finally, these administrative data do not provide any information about the quality of the meeting itself: which specialists were involved, which diagnostic strategy was proposed, which treatment was proposed and finally provided? Given all these caveats, the results for this indicator cannot at present be used to judge the quality of care.

Staging CT slightly underused

Of the patients diagnosed with oesophageal or gastric cancer between 2004 and 2008, 88% and 85% respectively received a *staging CT* within 1 month before and 1 month after incidence date. In view of the fact that CT is one of the key diagnostic interventions during the staging phase of patients with oesophagogastric cancer ⁸, this proportion can be considered too low. However, when the time period was extended to 3 months after incidence date, the proportions rose to 92% and 88%, respectively. Proportions of 99% (oesophageal cancer, The Netherlands) ⁹ and 89% (oesophagogastric, UK) ¹⁰ are reported in neighbouring countries. However, it is unclear what the time lag was between incidence date and CT in these countries.

Increasing use of palliative combination chemotherapy, but underuse in older patients

Palliative combination chemotherapy is strongly recommended in patients with metastatic cancer of the stomach with good performance status and this recommendation is based on high-quality evidence ⁸. Of the patients diagnosed with metastatic gastric cancer between 2004 and 2008, 42% received combination chemotherapy within 1 month before and 3 months after incidence date, and this proportion slightly increased between 2004 (40.4%) and 2008 (47.9%). These results appear to be better compared to results from the UK (25%) ¹¹ and the US (22%) ¹². Sadly, information on the performance status and co-morbidity is not available in the administrative databases used for this report and this hampers correct interpretation of this indicator. Nevertheless, a clear decrease was found with age. About two thirds of patients below 70 years received palliative combination chemotherapy compared to only about 8% of patients aged 80 years and above.

Underuse of palliative support, but rates are underestimated

About 44% of the patients diagnosed with metastatic oesophagogastric cancer between 2004 and 2008 benefited from *palliative support* within 3 months before death. No clear time trend was found. However, clear differences were found between the Belgian provinces, differences that were not identical for the 2 tumour types. The highest rates of palliative support for oesophageal cancer were found in Luxembourg (59.3%) and Limburg (52.2%), for gastric cancer the highest rates were found in Namur



(63.2%) and West-Vlaanderen (53.5%). Such differences can be due to the low sample sizes. Importantly, the reported rates are probably an underestimation, since not all relevant nomenclature codes were available for this research project, as for example the nomenclature codes for palliative home visits by a general practitioner. In addition, other palliative care interventions are not recorded in administrative databases, for example interventions of in-hospital palliative care teams. For the latter reason, prospective registration is probably a better option to correctly evaluate this indicator.

Process indicators related to less specific clinical recommendations

Absence of clear definition of locally-advanced cancer

Some of the selected process indicators are related to less specific recommendations explaining variability in practice. A first example is the use of neoadjuvant treatment for patients with T₂₋₄ N_{Anv} M_{0-1a} oesophageal cancer or T₂₋₄ N_{Any} M₀ gastric cancer. The 2012 guidelines state that 'if, after multidisciplinary discussion, neoadjuvant treatment is considered for a locally-advanced oesophageal or junction tumour, neoadjuvant chemoradiotherapy is preferred' (to neoadjuvant chemotherapy alone) 8. Similarly, 'if, after multidisciplinary discussion, neoadiuvant treatment is considered for a locally-advanced gastric tumour, neoadjuvant chemotherapy is recommended. The recommendations leave room for interpretation, in that neoadjuvant treatment is not mandatory for all patients with locally-advanced cancer because no clear definition is given for locally-advanced cancer neither in the literature or by experts. Nevertheless, neoadjuvant chemoradiotherapy for oesophageal cancer and chemotherapy for gastric cancer are increasingly used in Belgium. since nearly 50% and 40% of patients with T₂₋₄ N_{Anv} M_{0-1a} oesophageal cancer or T₂₋₄ N_{any} M₀ gastric cancer, respectively, received this treatment in 2008. It is important to stress that the results presented in this report apply to the period 2004-2008, when inconsistent results were reported in the international literature and when no national guidelines were available. More recent trials support the use of neoadjuvant therapy in locallyadvanced and locoregional oesophageal cancer, prompting some agencies to revise their recommendations 14-16. Given the liberal formulation of the recommendations, this indicator cannot be used to judge

the quality of care as yet but the results can serve as baseline values to compare with future measurements.

Clear indications needed for primary chemoradiotherapy

Similar criticism can be given to the indicator about primary chemoradiotherapy for patients with oesophageal cancer. According to the 2012 guidelines, 'definitive concomitant chemoradiotherapy should be considered in patients with oesophageal cancer of any histological type if the tumour is considered unresectable, if the patient is unfit for surgery or if the patient declines surgery ⁸. Two pivotal studies of definitive chemoradiotherapy (RTOG 85-01 ¹⁷ and RTOG 94-05/INT 0123 trial ¹⁸) were decisive to consider chemoradiotherapy as standard of care for these patients in Western countries. Later, a phase III trial (FFCD 9102) 19 found that patients with squamous cell cancer who respond to primary chemoradiotherapy have similar median survival and quality of life irrespective of resection. These trials led clinicians to adopt different strategies according to the histological type of the oesophageal tumour and the morphologic response after induction treatment ²⁰. For locally advanced adenocarcinomas, neoadiuvant chemotherapy or neoadiuvant chemoradiotherapy was considered as the standard of care. In France for example, primary chemoradiotherapy was considered for locally advanced squamous cell cancer (cStage III) in morphological responders, leading to similar overall survival with less post-treatment morbidity and mortality than neoadjuvant chemoradiotherapy followed by surgery ²¹. In Belgium, about one fifth of patients with oesophageal cancer was treated with primary chemoradiotherapy between 2004 and 2008, and the proportions were higher in squamous cell cancers with advanced stage (cStage III and IV). However, in the absence of a target value, it is impossible to say whether this result is good or bad. In addition, what complicates interpretation is that the intention of treatment is not recorded in administrative databases. Therefore, it is impossible to distinguish a patient who received chemoradiotherapy with the intention of being neoadjuvant but for whom surgery was cancelled because of comorbidity, from a patient who received primary chemoradiotherapy. For these reasons, this indicator cannot be used to judge the quality of care.



Irrespective of which diagnostic modalities and treatment strategies patients with oesophagogastric cancer are receiving, the management of these patients in Belgium appears to be effective in terms of *5-year survival* when compared with other countries. The EUROCARE-4 study reported a European estimate of the 5-year relative survival of 9.8% (95% CI 9.4-10.1%) for oesophageal cancer between 1995 and 1999 ²². Belgium had the highest survival rate in men (17.2%) and the second highest rate in women (20.9%) ²². Our analysis on Belgian data for a more recent period (2004-2008) reported an even higher estimation (around 22% for both sexes). In comparison, for the period 2002-2006, Germany reached a 5-year relative survival as high as 18.3% ²³. Five-year relative survival of patients with gastric cancer in Belgium was 22.3% in men and 25.3% in women. In comparison, the rates ranged from 33% in Germany to 17% in England and Scotland ²⁴.

Conversely, *postoperative mortality* appears to be worse in Belgium than in some of the neighbouring countries. For patients with oesophageal cancer diagnosed between 2004 and 2008 and treated with oesophageal resection, a 30-day mortality of 4.8% and a 90-day mortality of 9.9% were found. In the Netherlands, for example, a 30-day mortality of 1.4% was reported in 2011 ⁹. Importantly, these results were measured after the instauration of a volume criterion for the treatment of patients with oesophageal cancer. In the Belgian cohort, 30-day and 90-day mortality for patients treated in high-volume centres (defined as treating at least 20 patients per year) was 1.7% and 5.0% compared to 7.4% and 12.6% for patients treated in low-volume centres (defined as treating 5 or less patients per year).

High-volume centres

Finally, *centralisation of care* for patients with oesophagogastric cancer was recommended in the 2012 guidelines ⁸. In the period 2004-2008, 111 and 114 out of 115 acute Belgian hospitals delivered medico-surgical treatment for patients with oesophageal and gastric cancer respectively. During this period, only about one third of patients with oesophageal cancer was treated in a high-volume hospital (defined as surgically treating at least 20 patients with oesophageal cancer per year). The proportion of patients with gastric cancer that was treated in a high-volume hospital

(defined as surgically treating at least 20 patients with gastric cancer per year) was only about 5% for that same period. The need for centralisation is further discussed in chapter 5.

3.2. On a centre level

In order to evaluate the results of the quality indicators at a centre level and to compare them between different centres, a patient needs to be attributed to one single centre where the care is coordinated. This is not straightforward, since some patients are diagnosed in one centre, surgically treated in another one and may receive radiotherapy in a third centre. To solve this problem, a pre-specified algorithm was used that allowed the allocation of 96.8% of patients to one single centre.

For the outcome indicators (postoperative mortality, 5-year survival), large variability between centres was observed, even after adjustment for known confounding factors (Figure 1 and Figure 2). Some of this variability could be explained by a volume-outcome relationship, which is further discussed in chapter 5. Striking is the high 5-year survival of the patients who could not be assigned to a centre (i.e. unknown centre; N=140 for oesophageal cancer). A possible explanation is that many of these patients had T1a cancer that was treated with endoscopic mucosal resection (or endoscopic submucosal dissection in the case of gastric cancer), a treatment that had no nomenclature code before June 2009.

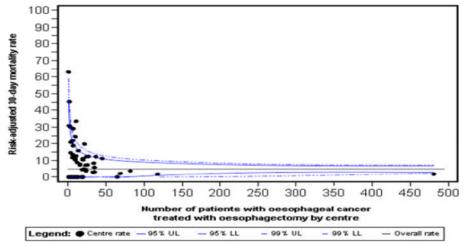
To reduce variability in practice, clinical recommendations need to be as specific as possible. That less specific recommendations can lead to large variability is shown by the indicators on neoadjuvant treatment (OC4 and GC4) and primary chemoradiotherapy (OC10). It was already discussed above that these indicators cannot be used to judge the quality of care at present. Variability is not surprising for the indicator "multidisciplinary discussion". As explained above, billing for multidisciplinary consultation is applied differently across centres. Therefore, the observed variability can be explained by administrative rather than qualitative reasons.

The variability of care was less obvious for the other process indicators. For staging CT for both cancer types, little variability was found. Conversely, the results for palliative combination chemotherapy for gastric cancer were very scattered, but within the 95% limits, which can be due to the low sample sizes. A similar picture was found for palliative care for both cancer types. However, the interpretation of these results is

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hampered by the fact that a centre not necessarily impacts on palliative care and that awareness about available structures and their reimbursement modalities in the palliative care setting is suboptimal. Palliative care is sometimes coordinated by the general practitioner or provided in another centre than where the patient was initially treated.

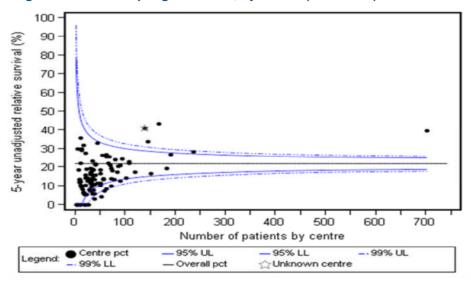
Figure 1 - Funnel plot of the 30-day mortality rate after oesophagectomy, by centre, adjusted for age and combined stage (2004-2008)



Note: Due to a low sample size for most centres and low percentages of deaths, one should be careful with the interpretation of adjusted rates; small changes might have a significant impact on the adjusted rate (observed rate / expected rate).

Therefore, this indicator should not be used to compare the quality of care between centres (although it remains valid to evaluate the quality of care on a national level).

Figure 2 - Funnel plot of the 5-year relative survival for patients diagnosed with oesophageal cancer, by centre (2004-2008)



All patients that could not be attributed to a centre were grouped and marked with an asterix on the funnel plot



4. UNKNOWN CANCER STAGE: A QUALITY INDICATOR IN ITSELF

A major finding of the present report was the high number of missing stages for oesophageal and gastric cancer reported to the Belgian Cancer Registry. Between 2004 and 2008, 28.9% of the combined stages for oesophageal cancer and 34.9% for gastric cancer were unknown. In about one third of cases, stages T, N and M were all unknown. There is variability in the reporting of cancer stage and a clear difference between high-volume (showing less missing data) and other centres, at least for oesophageal cancer (Table 5).

The high proportion of missing stages was already reported previously in 2 KCE reports concerning other cancer types ^{4, 5}. Searching a good explanation for the underreporting of information that is actually that basic

is superfluous. In some cases, the medical file probably contained insufficient information to decide on the final stage. In other cases, the necessary information was probably available but no final decision regarding the stage was recorded on file or paper. Finally, in some cases all necessary information and the final stage was probably available in the medical file, but never communicated to the Cancer Registry. Anyhow, the high number of missing stages is unacceptable and weakens the results of this report, since this information was needed for the elaboration or calculation of several indicators.

During the discussion with clinical experts, it became clear that reporting of cancer stage should be included as a quality indicator. Furthermore, actions should be undertaken to improve the registration of the cancer stage. Linking the reimbursement of the multidisciplinary discussion to the registration of the cancer stage could be a targeted intervention.

Table 5 – Missing or unknown combined cancer stage by hospital volume

	Low volume	Medium volume	Medium volume High volume	
	(<6 surgeries per year)	(6-19 surgeries per year)	(≥20 surgeries per year)	
Oesophageal cancer	35.2%	27.7%	5.8%	28.9%
Gastric cancer	39.3%	31.2%	33.2%	34.9%



5. ARE WE READY FOR THE CENTRALISATION OF CARE?

Centralisation of care for patients with upper gastrointestinal cancer was already recommended in the 2012 guidelines 8 . This recommendation was based on the evidence available from the scientific literature. This report confirms what was already known from this literature with Belgian data covering 5 years.

Firstly, it is clear that the care for patients with oesophagogastric cancer was not centralised at all. With the volume definitions that were used for the present report (high: ≥20 surgeries/year; medium: 6-19 surgeries/year; low: <6 surgeries/year), only two high-volume hospitals were identified for oesophageal cancer and only one for gastric cancer. Only about 35% and 5% of patients with oesophageal and gastric cancer, respectively, were treated in these high-volume centres.

Secondly, clear differences were found in the case-mix according to hospital volume. For oesophageal cancer, high-volume centres treated more men, younger patients, more adenocarcinomas and less stage IV tumours. For gastric cancer, high-volume centres treated more women, younger patients, and less stage IV tumours. These results suggest that high-volume centres treated patients with more favourable characteristics.

Thirdly, for patients with oesophagogastric cancer who underwent surgery, high hospital volume was significantly related to a lower postoperative mortality (for oesophageal cancer) and a better 5-year survival (for oesophageal [see Figure 2] and gastric cancer). For all patients with oesophageal or gastric cancer, whatever their treatment, hospital volume showed a significant association with 5-year survival.

Fourthly, the scores of process indicators that were measurable on the basis of administrative data did not provide an explanation for this volume-outcome relationship. Furthermore, where the case-mix suggested that high-volume centres were treating patients with more favourable characteristics, the volume-outcome relationship persisted after correction for age, sex, stage and histological type.

A big caveat with these results is the absence of information on comorbidity. It cannot be excluded that the differences in outcome according to volume can be explained by differences in co-morbidity, i.e. that high-volume centres are treating patients with less co-morbidity. To further explore this, co-morbidity of cancer patients (e.g. with the WHO performance status) should be registered in a consistent manner and it should be clearly defined what degree of co-morbidity is considered to be clinically relevant. Currently, the Belgian Cancer Registry records the WHO performance status at diagnosis of all patients. However, less than half of all files reported this information between 2004 and 2008. Another option would be to construct a co-morbidity score based on data from the Intermutualistic Agency.

Despite this caveat, these results cannot be ignored and confirm the previously published recommendation to centralise the care for patients with upper gastrointestinal cancer. This was supported in consensus by the experts involved in this project. However, this report does not allow to provide recommendations on how to organise this centralised care. No search for an ideal volume cut-off point or for essential characteristics of centres or care providers was done. 'Resection rate' was not selected as a quality indicator either, although it could provide an idea about the referral patterns in Belgium.



6. UNEXPLAINED AGE AND GENDER DIFFERENCES IN THE MANAGEMENT OF PATIENTS WITH UPPER GASTROINTESTINAL CANCER

6.1. Age differences

For almost all indicators, results were less favourable for patients aged 80+ (or even 70+ or 60+ for some indicators) (Table 6). An exception was palliative support for patients with metastatic oesophageal cancer, where patients aged 80 years and above showed more positive results. For treatment of patients with oesophageal cancer at a high-volume centre, the difference was not significant. In the absence of co-morbidity data, these results could not further be explored, although it can be assumed that co-morbidity might partly explain some of these results.

6.2. Gender differences

Some quality indicator results also suggest a different therapeutic approach for men and women with oesophagogastric cancer. However, when stratified by age, this gender difference was only found for multidisciplinary discussion and palliative support for patients with oesophageal cancer aged 80 years and above, and for staging CT (age categories 60-69y and 80+) and palliative combination chemotherapy (age category 70-79y) for patients with gastric cancer. In the absence of comorbidity data, no further stratification was possible for that factor. These differences remain, therefore, unexplained.



Table 6 - Process indicator results by age category

	< 50y (%)	50-59y (%)	60-69y (%)	70-79y (%)	80+ (%)
Oesophageal cancer					
Discussion at multidisciplinary team meeting within 1 month after incidence date	44.4	46.8	45.0	43.1	39.4 ^{\$}
Staging CT neck/thorax/abdomen	88.9	91.8	89.8	88.3	80.0\$
Neoadjuvant treatment of T ₂₋₄ N _{anv} M _{0-1a}	62.6	47.5	45.9	33.3 [§]	0.0§
Primary chemoradiotherapy	22.0	29.1	25.3	17.5 [§]	7.3 [§]
Palliative support within 3 months before death	50.0	43.8	41.7	40.5	53.9 ^{\$}
Treatment at high-volume centre	40.4	36.7	34.0	32.4	26.2
Gastric cancer					
Discussion at multidisciplinary team meeting within 1 month after incidence date	34.2	40.4	40.9	37.8	33.9 ^{\$}
Staging CT thorax/abdomen	78.1 [*]	86.4	88.7	87.9	79.6 ^{\$}
Neoadjuvant treatment of T ₂₋₄ N _{anv} M ₀	50.0	24.2	29.2	17.6 [§]	2.0 [§]
Palliative combination chemotherapy	66.7	71.6	61.2	35.4 [§]	7.8 [§]
Palliative support within 3 months before death	50.8	54.4	42.1 [£]	42.2 [£]	40.3 [£]
Treatment at high-volume centre	8.2	5.4	6.3	3.6 [§]	3.5 [§]

^{\$} Significant difference compared with 80y-. \$ Significant difference compared with 70y-. * Significant difference compared with 50y-. \$ Significant difference compared with 60y-.



The major strength of this report is the availability of a large population-based database of more than 10 000 patients with upper gastrointestinal cancer covering a period of 5 years. It is therefore one of the largest studies that, for example, studied the volume-outcome relationship in upper gastrointestinal cancer ²⁷. Patients were selected from the Belgian Cancer Registry, where the registration of cancer diagnoses is done through two data flows, i.e. a clinical network (oncological care programs) and a pathology network (pathological anatomy laboratories). These data flows result in a coverage of more than 98% of all cancer cases in Belgium.

Another strength of this report was the validation of the results by 6 Belgian hospitals. This validation showed that 92-100% of the patients were correctly assigned to the hospitals and that only small differences existed between the indicator results calculated using the hospital and medical file data versus the cancer registry data linked with the claims data of the health insurances (except for multidisciplinary consultation).

The lack of some pertinent variables in the readily available database (cancer registry data linked to administrative claims data from the Intermutualistic Agency) can be considered as the main weakness of this study, as 11 out of 29 indicators were not measurable using a

retrospective study design. Furthermore, essential information to risk-adjust the results, such as co-morbidity and socio-economic status, was unavailable. In addition to their lack of specificity and detail, administrative data are collected for reasons other than quality and are therefore associated with risks of up- under- or miscoding. All this illustrates the need to aim for adequate registration that obtains all the information needed to monitor and improve upper gastrointestinal cancer care. The registration of some variables (e.g. staging) should be mandatory, as explained above. Hence, in the future, prospective registration projects should be set up to add specific additional information to these results.

In addition, this study reported analyses based on the most recently available data with 2008 being the last available year. It can serve as a baseline to follow-up and to monitor the quality of care in the future.

Finally, between 2004 and 2008, about 35% of the staging information for oesophageal cancer remained unreported to the Belgian Cancer Registry hampering the correct measurement of the selected indicators. While this low level of reporting is probably multifactorial (see section 1 above), cancer stage reporting is one of the legal obligations of the responsible physician of the multidisciplinary meeting to hold the accreditation as oncological care program. To improve stage reporting, sanctions (e.g. withdrawal of the accreditation, suspension of the reimbursement of the multidisciplinary meeting and financing of data managers) could be considered if this obligation is not fulfilled.



8. KEY POINTS OF THE REPORT

- A set of quality indicators for upper gastrointestinal cancer covering the entire care pathway has been defined. Based on the current nomenclature and cancer registry data, the set contains 13 indicators that can be reliably measured. The following 5 quality indicators cannot be used at present: multidisciplinary consultation (oesophageal and gastric cancer), neoadjuvant treatment (oesophageal and gastric cancer), primary chemoradiotherapy (oesophageal cancer).
- Additional registration of the intention of treatment, co-morbidity, recurrence and some clinical data (resection margins, postoperative complications, lymph node status) would further increase the relevance and comprehensiveness of the indicator set.
- The underreporting of the cancer stage to the Belgian Cancer Registry is a major finding of this study. A mandatory reporting of these data is essential for quality projects such as the present one. Underreporting of cancer stage should be used as a quality indicator in itself.
- Based on 2004-2008 data, long-term survival appears to be excellent in Belgium. However, there are indications of underuse of recommended interventions, especially in elderly (female) patients. These results deserve further exploration. Some positive trends were also found, e.g. for staging CT in gastric cancer.
- During the period 2004-2008, (almost) all Belgian acute hospitals delivered care for patients with oesophagogastric cancer. Despite the absence of data on co-morbidity, a clear volume-outcome relationship was found for upper gastrointestinal cancer, both for post-operative mortality (oesophageal cancer) and 5-year survival (oesophageal and gastric cancer).



9. NICE TO KNOW: AND NOW?

This report contains different types of information to be picked up by different stakeholders.

Impulse for quality improvement initiatives

In the first place, Belgian centres and care providers will receive their results from the Belgian Cancer Registry for *individual feedback* in parallel with the publication of this report. From previous reports ^{4, 5} it is known that hospitals and care providers are sensitive to this information. The analysis per centre could allow to benchmark results from one centre against others. While variances do not necessarily indicate a problem, they do represent areas for further assessment and evaluation. Centres that desire engaging in a *quality improvement* approach can compare with other centres that scored higher on the incriminated indicators and understand their processes and practices before potentially adopting them. However, it will be more effective to focus on all aspects of organizational processes rather than on just one element, because the results of a best-in-class organization may be the result from numerous determinants ²⁶.

College of Oncology: interventions to improve quality in specific centres

Besides feedback, *targeted and corrective actions* are another essential element of the quality improvement cycle. As legally foreseen, the College of Oncology could perform visitations and audits of outlying centres to analyze the reasons for their over- or under-performance. Also 'good' centres can be visited to better understand which processes are adopted that lead to better results. Targets for improvement to be achieved within a specified timeframe should be defined in collaboration with the clinicians concerned ²⁶.

Importance of continuous data monitoring

Timeliness of information is an important issue in this approach, since many procedures can evolve overtime. For this study, data from 2004-2008 were used. Ideally, the delay between the incidence year and the availability of data for research and publication should be kept as short as possible and a delay of maximum 2 years should be pursued. The Belgian Cancer Registry, which masters the know-how in calculating indicators and

communicating results, could reproduce the presented analyses on 2010 data which are now available. For future comparison and monitoring, the 2004-2008 data could serve as baseline data. In addition to *recurrent evaluations* with the complete set of measurable indicators, *in-depth evaluations* could be conducted on specific indicators selected for their potential for improvement, the priority for stakeholders or national objectives pursued in the field of oncology.

Further refinement of quality indicators

Ideally, the methodological information available in this report should result in a *further refinement* of the measurable indicators and the *registration of additional data* to render the non-measurable indicators measurable in order to have a complete and relevant set of indicators (Table 7). Additional data include the intention of treatment, co-morbidity and recurrence but also clinical information, such as R0 resection, number of resected/evaluated lymph nodes and postoperative anastomotic leakage.

Need for an integrative quality system

Finally, as recommended previously ¹, all of the above-mentioned actions should be embedded in an *integrative quality system*. Future initiatives should start bottom-up, where clinical experts invite other stakeholders to implement these ideas in collaboration. The implementation of such a system should allow to keep the guidelines and quality indicators updated in collaboration with the KCE.

Need for centralisation

This report could be used as a starting point for the discussion about organisational issues, including the need for centralisation. The appropriate methodology for this discussion should be decided upfront. Important questions to be answered are: which minimal level of activity and experience is needed? Should the results on process and outcome indicators be used to deliver accreditation to centres? Are structural prerequisites (e.g. availability of radiotherapy facilities) recommended?

Whereas low- and medium-volume hospitals can of course deliver care of good quality, volume should not be the only focus of this discussion. The only available example of a similar discussion in the field of oncology in

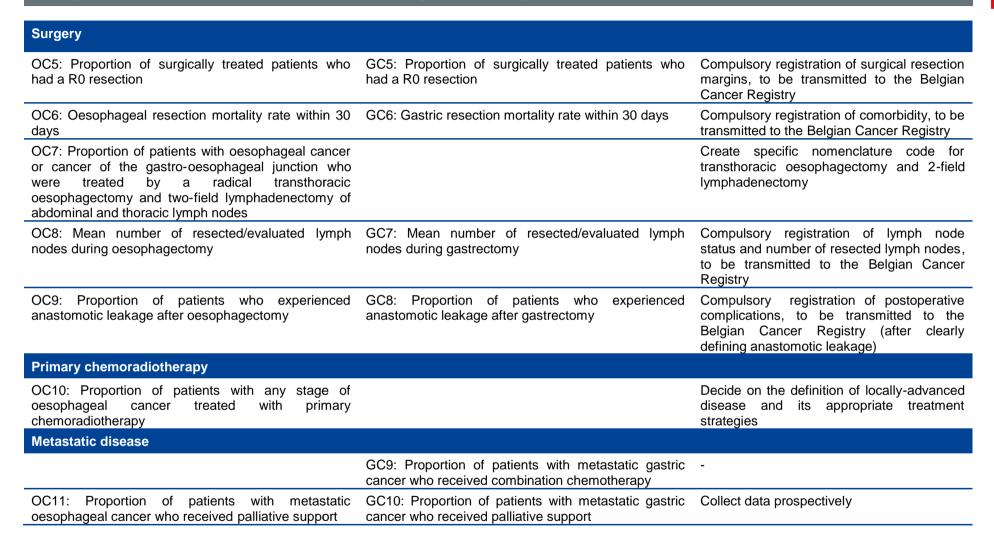


Belgium is breast cancer. Regulations were introduced by a Royal Decree on July 20th 2007. To be recognized as a breast clinic, a centre has to diagnose 150 new patients per year since 2012. In the case of oesophageal and gastric cancer, the numbers will inevitably have to be much lower. But then, the real issue boils down to the question: "What is the minimum number of cases, say over two or three years, that a clinician needs to treat, in order to be able to assure with reasonable statistical confidence to his/her patients that his/her practice is meeting the prevailing

quality standards?" This is an a priori statistical question, and from a theoretical angle, there is little point in accepting numbers lower than 30 to 40 as a long-term goal for offering sufficient safeguards. Meanwhile, in the short and medium term, we will have to accept more 'realistic' figures, but, not surprisingly, the literature does not offer much guidance. It will be up to the stakeholders to take their responsibility and draw a blueprint of the future, more centralised landscape.

Table 7 – Suggested actions to increase the measurability and interpretability of the selected quality indicators

Oesophageal cancer	Gastric cancer	Action
Staging		
OC1: Proportion of patients diagnosed with oesophageal cancer discussed at the multidisciplinary team meeting	GC1: Proportion of patients diagnosed with gastric cancer discussed at the multidisciplinary team meeting	Compulsory registration of multidisciplinary team meeting, to be transmitted to the Belgian Cancer Registry
OC2: Proportion of patients diagnosed with oesophageal cancer undergoing a CT neck/thorax/abdomen	GC2: Proportion of patients diagnosed with gastric cancer undergoing a CT thorax/abdomen	-
Treatment of mucosal cancer		
OC3: Proportion of patients diagnosed with cT1a oesophageal cancer and undergoing endoscopic mucosal resection who had an <i>en bloc</i> resection	GC3: Proportion of patients diagnosed with cT1a gastric cancer and undergoing endoscopic mucosal resection/endoscopic submucosal dissection who had an <i>en bloc</i> resection	Use TNM7 data Create nomenclature code for registration of en bloc resections
Neoadjuvant treatment		
OC4: Proportion of patients with oesophageal cancer beyond the mucosa (T_{2-4} N_{Any} M_{0-1a}) who received neoadjuvant treatment	GC4: Proportion of patients with a gastric cancer beyond the mucosa (T_{2-4} N_{Any} M_0) who received neoadjuvant treatment	Decide on the definition of locally-advanced disease and its appropriate treatment strategies







Recurrent disease			
OC12: Proportion of patients diagnosed with recurrent oesophageal cancer discussed at the multidisciplinary team meeting prior to any treatment	GC11: Proportion of patients diagnosed with recurrent gastric cancer discussed at the multidisciplinary team meeting prior to any treatment		
Generic indicators			
OC13: Five-year relative survival by stage	GC12: Five-year survival rates computed by stage	Compulsory registration of comorbidity, to be transmitted to the Belgian Cancer Registry	
OC14: Five-year overall survival	GC13: Five-year overall survival	Compulsory registration of co-morbidity, to be transmitted to the Belgian Cancer Registry	
OC15: Proportion of patients with oesophageal cancer surgically treated in high-volume hospitals in a given year	GC14: Proportion of patients with gastric cancer surgically treated in high-volume hospitals in a given year	Re-evaluate, taking into account co- morbidity and socio-economic status	



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■ RECOMMENDATIONS^a

To the Minister of Social Affairs and Public Health, after advice from the competent advisory bodies:

- The quality indicator set for upper gastrointestinal cancer should be embedded into a quality system with individual feedback and quality improvement actions.
- The results of the present report should be used as a starting point to urgently initiate the centralisation of care for patients with upper gastrointestinal cancer in Belgium.
- Reimbursement of the multidisciplinary oncological consultation (MOC-COM) of all cancer types should be made conditional on the compulsory and automatic registration of the cancer stage and essential predefined variables.

To the Belgian Cancer Registry:

- The following variables need to be added to the current list of variables with compulsory registration in the Cancer Registry:
 - Intention of treatment
 - Co-morbidity, using a consistent classification, and including an indication of the degree of clinical relevance
 - Recurrence
 - Lymph node status and number of resected/evaluated lymph nodes
 - Surgical resection margins
- The volume-outcome relationship for upper gastrointestinal care should be further explored and monitored taking into account co-morbidity.

^a The KCE is the only responsible for the recommendations.



To the scientific societies of surgeons, oncologists, radiotherapists and to the health care providers managing upper gastrointestinal cancer patients, including the College of Oncology:

- Health care providers are encouraged to evaluate their individual results on the quality indicators as transmitted by the Belgian Cancer Registry, to compare them with other organisations and to engage in a quality improvement process.
- Clinicians involved in the care for patients with upper gastrointestinal cancer should try to reach a consensus on the exact definition of locally-advanced disease and the indications for neoadjuvant treatment (for oesophageal and gastric cancer) and primary chemoradiotherapy (for oesophageal cancer).

Appropriate target values should be defined for each quality indicator.