Quality assurance and improvement in oncology using guideline-derived quality indicators –results of the Gynaecological Cancer Centers certified by the German Cancer Society (DKG)

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Abstract

Purpose: On the example of Gynaecological Cancer Centres (GCCs) certified by the German Cancer Society, this study evaluates results of medical guideline derived quality indicators (QIs) for cervical cancer (CC) and ovarian cancer (OC), examines how implementation of the indicators developed over the course-of-time, status of the guideline-compliant-care and identifies improvement measures.

Methods: QI results for patients with CC and OC treated in GCCs between 2015-2019 are analysed. The QIs median, overall proportion and standard deviation were calculated. Two-sided Cochran-Armitage tests were applied.

Results: QIs are divided in two categories: *process-organization (PO-QIs)* and *treatment-procedures (TP-QIs)*, to allow a differentiated analysis for identifying improvement measures.

PO-QIs that reflect the implementation of processes and structures show a high application. PO-QIs have tremendous influence on the quality of care, while being easy implementable through SOPs.

TP-QIs report on treatments that are performed in the GCC.

TP-QIs that report on systemic-therapies reach a plateau where the guideline is known, but patient-related-reasons meaningfully prevent further increase.

TP-QIs that report on surgical interventions fluctuate. Most relevant factors are practitioners' personal skills. Besides the discussion of results amongst peers during the audit, improvement measures could include surgical courses or coaching.

Conclusion: The analysis shows that a combination of different measures is necessary to anchor quality sustainably in health care and thus improve it.

Introduction

For quality assurance and to implement evidence-based guideline recommendations effectively in everyday oncological care a 'Quality Cycle Oncology' has been established in Germany. Its central elements are defined quality indicators (QIs) derived from strong recommendations of S3 oncological medical guidelines developed by the German Guideline Program in Oncology (GGPO) [1]. The German S3 guidelines are based on a systematic literature review, having a representative interdisciplinary and interprofessional expert panel including patient advocacy groups, and using a formal consensus finding process [1, 2]. An obligatory part of every S3 guideline development process is the definition of QI from the strong recommendations. These are considered suitable as a quality standard since it can be assumed that most of the patients will have a clear benefit from the addressed actions of these recommendations. In a multi-step process, interdisciplinary experts of the guideline group identify those strong recommendations of the S3 guideline whose comprehensive implementation improves the provision of care in a defined population and whose 'translation' in an indicator is possible [3].

The implementation rate of these QIs and thus the adherence to guideline recommendations is monitored and evaluated through the certification system implemented by the German Cancer Society (DKG), serving as one of the core elements of the quality assurance and improvement process of the certified cancer centres [3].

The results of the QIs are regularly fed back to the GGPO guideline groups to ensure the best possible exchange between the development of evidence- and consensus-based recommendations and clinical routine practice [4]. In the context of guideline updates, the existing quality indicators are also subject of the updating process. Here, the results of the quality indicators are reviewed, and a decision is made whether the quality indicator must be retained or changed or - in the case of complete implementation - can be discontinued [3].

As of January 2022, 31 tumour specific and cross-sectional S3 guidelines have been published and 192 quality indicators derived. Thereof 108 quality indicators are implemented in 18 tumour-specific certification procedures in a total of 1.715 certified centres including 142 outside of Germany.

In the present study, which was conducted in the scope of a qualifying thesis for the doctorate in medical science at the Charité university medicine, we present an example from the gynaecological cancer centre (GCC) certification system of the German Cancer Society (DKG).

The certification system for GCCs was developed in 2008 by the DKG and the Working Group for Gynaecological Oncology (Arbeitsgemeinschaft Gynäkologische Onkologie (AGO)) and the German Society for Gynaecology and Obstetrics (DGGG) [12]. As of 2019 a total of 164 GCCs are certified [5] and about 55% of all patients in Germany with a first diagnosed (= primary case) gynaecological

tumours[1] in 2019 were treated in these certified GCC[2] [5]. Many certified GCC have also joined together in the AGO's working group AG Ovar and are part of the AGO's quality assurance program (QS-OVAR).

Gynaecological tumours consist of several entities that differ in incidence, therapy, and prognosis. In 2017, approximately 38,000 women in Germany were diagnosed with a gynaecological neoplasm [6].

The GCCs like all other cancer centres of the DKG are multidisciplinary and interprofessional networks of qualified partners that represent the entire chain of health care. They commit themselves to adhering to the defined quality standards (i.e., minimum case numbers, tumour boards, high expertise of all network partners, etc.) and transparently disclose the results of their key performance indicators and guideline derived quality indicators to demonstrate their quality of care, guideline adherence and discuss, if necessary, improvement measures [7].

Especially for gynaecological tumours various studies have shown that the interdisciplinary cooperation, the highly specialised surgical expertise of the clinic and the surgeons as well as the surgical case volume have been of great benefit to patients and have a relevant influence on the clinical outcome [8-11].

Focus of this study will be on two selected gynaecological tumours, namely ovarian and cervical cancer. For both tumour entities S3 guidelines are available and regularly updated [12, 13] and QI's for these two entities have been obligatory to document in GCCs since 2014 for OC and 2015 for CC. For other gynaecological tumours, such as endometrial and vulvar, QI's have been implemented only recently, respectively 2018 and 2016 as well as for the vulvar carcinoma no S3 guideline is yet available.

With 3.1 % of all malignant neoplasms and 5.2 % of all cancer deaths in women, ovarian cancer is the gynaecological cancer with the highest mortality rates [22] and representing 19.2% of incident cases in gynaecological neoplasms [6]. Despite advances in screening and prevention measures, the invasive cervical carcinoma remains with 11.4% the third most common gynaecological neoplasm in women in Germany and worldwide [6, 14].

On the example of QIs for ovarian and cervical cancer this study sets out to investigate the temporal development of the implementation rate, report results for the time period between 2015-2019, evaluates the status of the guideline-compliant care and identify areas and corresponding measures to foster improvement. The goal of this paper is furthermore to raise awareness of the potential that guideline-based QI and their results have in order to contribute to quality assurance and improvement in clinical routine. The aim is to initiate a discussion and thus jointly define actions and measures to improve health service delivery to ovarian and cervical cancer patients.

[1]ICD-10 classifications C48, C51-C57
[2]Results according to ICD-10; Estimated number of new cancer cases in Germany 2017; Centre for Cancer Registry Data at the Robert Koch Institute, www.krebsdaten.de/abfrage, Data status: 30.07.2021. BOT not included because D-diagnosis

Patients And Method

Data Collection:

Each GCC that intends to be (re-)certified has to document the fulfilment of the requirements. Annually the results of the key performance indicators and quality indicators have to be reported to OnkoZert, the independent certification institute, that organizes the auditing procedure on behalf of the DKG.

After collecting from the centres, the datasets are analysed and tested for plausibility. Indicators mostly have target values or defined plausibility limits in which the certified centres have to give a mandatory statement of reasons as to why the limits were overstepped, i.e. in case of deviation from the guideline recommendation. When target values or plausibility thresholds are reached, centres do not have to give explanations for patients not treated accordingly. For a successful certification the cancer centres have to meet the target value or give a plausible explanation in case they are not meeting the value [15].

Centres are audited regularly by trained gynaecological oncologic medical experts who check before the audit the reported data from the previous calendar year and have insight into patient files during the audit to verify the data. Only verified data are published in the benchmarking reports. For example, 2019 data are audited during 2020, and published in 2021. The data presented here are based on the 2015 - 2019 patient cohort. Only data from centres that were certified throughout the complete year and had no change in the tumour documentation system are included.

The QI included in this study are derived according to a defined methodology [16] from the two evidence-based guidelines on diagnostic, therapy and follow-up of malignant ovarian tumours and patients with cervical cancer published by the GGPO [12, 13]. The treatment

guidelines, the corresponding QI and the QI-set collected via the certification programme are regularly updated. In this analysis only QIs that were included in the DKG dataset at least since 2014 as well as continued to be included in 2021 were taken into consideration. QI's that over the course of time were discontinued were not included in this analysis. An overview of discontinued QI can be seen in table 1.

Table 1 Discontinued QI for Ovarian and Cervical Cancer

Indicator	Implementation period	Reason for discontinuation
Ovarian Cancer QI		
Non adjuvant chemotherapy of early ovary carcinoma	2014 -2018	Indicator was discontinued due to complete implementation
Platinum-containing chemo-therapy early ovary carcinoma	2013 – 2018	Indicator was discontinued due to complete implementation
Chemotherapy of platinum-resistant and/or refractory first recurrence	2013 – 2015	Indicator was suspended in the course of the 2015/2016 S3 guideline update due to new recommendations
Combined treatment of platinum-sensitive recurrence	2013 – 2015	Indicator was suspended in the course of the 2015/2016 update due to new recommendations
No adjuvant therapy BOT (Borderline Tumour Ovar)	2013 -2018	Indicator was discontinued due to complete implementation
Genetic testing offer	2019	Was only included in data sheet since 2019
Cervical Cancer QI		
Cisplatinum-containing radio-chemotherapy	2014 – 2015	Indicator was discontinued due to decision to only include 5 QI per tumor-entity in the data sheet for certification.[1]
Adjuvant radio(-chemo) therapy	2014- 2015	Indicator was discontinued due to decision to only include 5 QI per tumor-entity in the data sheet for certification.
Histological confirmation	2014- 2015	Indicator was discontinued due to decision to only include 5 QI per tumor-entity in the data sheet for certification.
Spread diagnosis for local recurrence	2014 – 2015	Indicator was discontinued due to decision to only include 5 QI per tumor-entity in the data sheet for certification.
Pelvic Exenteration	2014 – 2018	Indicator was discontinued due to complete implementation in the data sheet for certification.
Complete diagnostic report cervical conization	2021	Will be included in next update of data sheet

Data analyses

Descriptive analysis about case distribution, patient numbers and indicator definitions were performed. QI results for patients with cervical cancer (CC) and ovarian cancer (OC) treated in GCCs between 2015 and 2019 wFere analysed. Only patients from such GCCs were taken into consideration, that had certified status over the entire time period. The median proportion of the centres and overall proportion was calculated for every QI. Two-sided Cochran-Armitage tests were applied to detect trends over time. Standard deviation on centre-level over the course of time were calculated to analyse fluctuations.

Statistical analyses are done using R version 3.5.1 and the Data-WhiteBox, a data analysing tool developed by OnkoZert; Cochran–Armitage tests were calculated using XLSTAT Version 2019.2.1 with excluding centres which had missing values at any reporting point. A p-value ≤ 0.05 was considered statistically significant.

The data analysis and study concept were reviewed and approved by the ethic committee of Charité university medicine in November 2021.

[3] https://www.krebsgesellschaft.de/zertkomm-protokolle.html?file=files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Protokolle_Zertkomm/Protokoll%20ZertKomm%20Gyn%207.%20Juni%202016.pdf&cid=32660

Results

The number of certified GCCs increased steadily from 2015 to 2019 from 112 to 149 as well as the number of patients with a primary diagnosis of a gynaecological malignancy treated in GCCs (from 11,587 to 14,986). Therefore, even though the incidence of OC and CC in Germany has been decreasing over the course of time from 7,318 to 7,292 and 4,606 to 4,341 respectively [6], the number of patients treated for these two tumour entities has increased in the GCCs (OC: 3,301–3,798 and CC: 2,059–2,479) [5].

The indicators are defined and categorized in Table 2a and 2b including numerator, denominator and plausibility corridor for reported QI results. QIs were divided in two categories (1) *process organization (PO-QIs)* and (2) *treatment procedures (TP-QIs)*, to allow a differentiated analysis in order to identify areas and corresponding measures to foster improvement in the implementation rate.

Process organization QIs are defined as indicators that document the implementation of processes and structures, which are an explicit implementation recommendation of the medical guideline, within the certified network.

Treatment procedure QIs are defined as indicators that report on treatments that are performed by the members of the certified network e.g., surgical interventions or recommendations for systemic therapies.

5 QIs were included in the category treatment procedures (4 for OC, 1 for CC), 4 QI in process organization (1 for OC, 3 for CC).

Table 3 presents the results of 9 QIs (5 OC, 4 CC) from 75 GCCs treating 17,495 OC primary cases (= incident cases) and 10,969 CC primary cases between 2015–2019.

The implementation rate for PO-QIs that reflect the application of processes and structures, remained stable on a very high implementation level or increased steadily over course of time to a very high implementation level (e.g., CC: details in pathology report for lymphonodectomy – median 2015: 88.0% to 2019: 97.8%; OC: operation of advanced ovary carcinoma by a gynaecological oncologist – median 2014: 100.0% to 2019 100.0%).

The implementation rate for TP-QIs that report on treatment methods show overall a good respectively high implementation rate yet the median fluctuates slightly over the course of time (e.g., OC: macroscopic complete resection advanced OC – median 2014: 58.8%; 2015: 62.5%; 2016: 70.0%; 2017: 69.6%; 2018: 68.3.0%; 2019: 75.0%).

Breaking down the TP-QI category further down, TP-QIs that address recommendations for systemic therapy show a good to very good implementation rate, however, the analysis indicates that the median is not only fluctuating but decreasing over course of time (OC: Post-operative chemotherapy advanced ovary carcinoma – median 2014: 94.6% to 2019: 88.9%; OC: First-line chemotherapy of advanced ovary carcinoma – median 2014: 69.2% to 2019: 60.1%).

In contrary, the overall median for TP-QIs results referring to surgical interventions show a good to very good implementation right and increase over the past 4 years. The median is fluctuating over the course of time (QI 1 surgical staging early OC – median 2014: 75.0% to 2019: 81.8%; QI 2 Macroscopic complete resection advanced OC – mean 2014: 58.8% to 2019: 75.0%)

Calculating the SD by using the annual QI quota of each centre the overall mean SD all QI was calculated and is displayed in a boxplot diagram in Fig. 1. Analysis of implementation rate on the individual centre-level shows that the results within one centre can vary over the course of time. Mean SD for PO-QIs is lowest between 4.4–18.2 (e.g., QI 14 Presentation at the tumour conference CC, mean SD 4.4), mean SD for TP-QIs that address systemic therapies lays between 11.8–16.2 (e.g., QI 12 Post-operative chemotherapy advanced OC mean SD11.8and mean SD for TP-QIs reporting surgical intervention is the highest between 15.0-19-1 (e.g., QI 1 Surgical staging early OC cumulative mean SD 19.1).

The Cochran-Armitage test shows positive trends for 5 out of 9 QI. Positive trends in both categories show 4 QI in treatment procedures and 1 QI in process organization. Trend analyses were conducted over the course of 4 years for the QI 2 “macroscopic complete resection advanced OC”, QI 4 “postoperative chemotherapy advanced OC” and QI 5 “first-line chemotherapy of advanced OC”. For QI 9 “Cytological/histological lymph node staging” the analysis was conducted over the course of 3 years.

Table 2
a Definition of indicators ovarian carcinoma (numerator, denominator, evaluation of results, and category)

	Name	Numerator	Denominator	Evaluation of results	Category
Quality indicators for treatment of ovarian carcinoma					
1	Surgical staging early ovary carcinoma	Primary cases of the denominator with surgical staging with: - Laparotomy - Peritoneal cytology - Peritoneal biopsies - Bilateral adnex exstirpation - Hysterectomy, where appropriate extraperitoneales procedure - Omentectomy at least infracolic - Bilateral pelvic and para-aortal lymphonodectomy	Surgical primary cases ovary carcinoma FIGO I – IIIA	Plausibility corridor > 20%	Treatment procedures
2	Macroscopic complete resection advanced ovary carcinoma	Surgical primary cases ovary carcinoma FIGO IIB-IV with macroscopic complete resection	Surgical primary cases with an ovary carcinoma FIGO IIB-IV	Plausibility corridor > 30% and < 90%	Treatment procedures
3	Surgery of advanced ovary carcinoma by a gynaecological oncologist	Surgical primary cases ovary carcinoma FIGO IIB-IV, whose definitive surgical therapy was performed by a gynaeco-oncologist	Surgical primary cases ovary carcinoma FIGO IIB-IV after conclusion of surgical therapy	Plausibility corridor > 50%	Process organization
4	Post-operative chemotherapy in advanced ovary carcinoma	Surgical primary cases ovary carcinoma FIGO IIB-IV with post-operative chemotherapy	Surgical primary cases ovary carcinoma FIGO IIB-IV and chemotherapy	Plausibility corridor > 30%	Treatment procedures
5	First-line chemotherapy of advanced ovary carcinoma	Primary cases ovary carcinoma FIGO IIB-IV with 6 cycles first-line chemotherapy carboplatin AUC 5 and paclitaxel 175 mg/m2	Primary cases ovary carcinoma FIGO IIB-IV	Plausibility corridor > 20%	Treatment procedures

Table 2
b Definition of indicators ovarian carcinoma (numerator, denominator, evaluation of results, and category)

	Name	Numerator	Denominator	Evaluation of results	Category
Quality indicators for treatment of cervixal carcinoma					
6	Presentation at the tumour conference	Patients (primary cases and "non-primary cases") presented at the tumour conference	Patients with an initial diagnosis, recurrence or new remote metastasis of a cervical carcinoma	Plausibility corridor > 20%	Process organization
7	Details in the pathology report on initial diagnosis and tumour resection	“Surgical primary cases" cervical carcinoma with complete pathology reports with details of: - Histological type according to WHO - Grading - Detection/non-detection lymph and vein infiltration (L and V status) - Detection/non-detection perineural infiltrates (Pn status) - Staging (pTNM und FIGO) in the case of conizated patients bearing in mind the conisation results - Depth of invasion and spread in mm in the case of pT1a1 and pT1a2 - Three-dimensional tumour size in cm (from pT1b1) - • Minimum distance to the resection margins	"Surgical primary cases" with cervical carcinoma and tumour resection	Plausibility corridor > 0.01%	Process organization
8	Details in the pathology report for lymphonodectomy	"Surgical cases" with a pathology report containing details of: - Number of affected lymph nodes in relation to removed lymph nodes - Assignment to sampling localisation (pelvic/para-aortal) - Details of the biggest spread of the largest lymph node metastasis in mm/cm - Details of the detection/non-detection of capsel penetration by lymph node metastasis.	"Surgical cases" with cervical carcinoma and lymphonodectomy	Plausibility corridor > 0.01%	Process organization
9	Cytological/histological lymph node staging	"Total cases" with cytological/histological lymph node staging	"Total cases" with cervical carcinoma FIGO stages ≥ IA2-IVA	Plausibility corridor > 0.01%	Treatment procedures

Table 3
Quality indicators ovarian and cervical cancer; treatment years 2014–2019

	Indicator	2019 Median, Absolute Patient Nr Overall proportion	2018 Median, Absolute Patient Nr Overall proportion	2017 Median, Absolute Patient Nr Overall proportion	2016 Median, Absolute Patient Nr Overall proportion	2015 Median, Absolute Patient Nr Overall proportion	2014 Median, Absolute Patient Nr Overall proportion	C-A test
Ovarian Carcinoma								
1	Surgical staging early ovarian carcinoma	81.8% 504/630 80.0%	85.7% 506/647 78.2%	80.0% 485/617 78.6%	85.7% 501/636 78.8%	83.3% 473/603 78.4%	75.0% 384/589 65.2%	0,067
2	Macroscopic complete resection advanced ovary carcinoma	75.0 920/1269 72.5%	68.3% 880/1275 69.0%	69.6% 873/1231 70.9%	70.0% 921/1318 69.9%	62.5% 849/1345 63.1%	58.8% 858/1406 59.9%	0,002
3	Surgery of advanced ovary carcinoma by a gynaecological oncologist	100.0% 1191/1269 93.9%	100.0% 1192/1275 93.5%	100.0% 1089/1231 88.5%	100.0% 1211/1318 91.2%	92.3% 1166/1345 86.7%	100.0% 1215/1406 86.4%	0.077
4	Post-operative chemotherapy of advanced ovary carcinoma	88.9% 923/1130 81.7%	90.9% 914/1117 81.8%	90.0% 954/1081 88.3%	91.7% 1031/1169 88.2%	90.9% 1064/1191 89.3%	94.6% 1157/1265 91.5%	0.021
5	First-line chemotherapy of advanced ovary carcinoma	60.3% 957/1661 57.6%	61.1% 968/1633 59.3%	63.6% 1004/1559 64.4%	60.0% 1014/1649 61.5%	62.5% 1088/1669 65.2%	69.2% 1113/1649 67.5%	0,022
Cervical Carcinoma								
6	Presentation at the tumour board	100.0% 1857/1913 97.1%	100.0% 1716/1777 96.6%	100.0% 1779/1865 95.4%	100.0% 1695/1777 95.4%	100.0% 1710/1793 95.4%	n/a	0,670
7	Details in the pathology report on initial diagnosis and tumour resection	92.3% 798/874 91.3%	78.4% 652/832 78.4%	68.8 612/879 69.6%	75.3% 631/890 70.9%	71.3% 648/889 72.9%	n/a	0.001
8	Details in the pathology report for lymphono-dectomy	97.8% 652/669 97.5%	95.0% 667/705 94.6%	90.9% 683/743 91.9%	89.6% 661/735 89.9%	88.0% 706/794 88.9%	n/a	0.170
9	Cytological/histological lymph node staging	72.9% 777/1028 75.6%	78.2% 792/979 80.9%	71.8% 774/1042 74.3%	69.4% 819/1169 70.1%	63.2% 718/1140 63.0%	n/a	0.009

Discussion

This article presents for the first time a differentiated overview of the implementation level and development of guideline derived QI results for OC and CC in certified GCCs.

The results of the evaluated QIs show that the recommendations of the guidelines are implemented to a high or very high extent in the certified GCCs. The quality of care is made visible and results between centres can be compared. Grouping the analysed QI into two categories – process organization and treatment procedures – offers the opportunity to assess the improvement potential of QI in a differentiated way and allows to identify suitable measures for improvement which can be implemented in the certified centres.

QIs that reflect the implementation of processes and structures within the certified networks show a very good application. The results illustrate that QIs related to procedural aspects have a very high implementation rate (2019: QI 3: 100%; QI 6: 100%, QI 7: 92.3%; QI 8: 97.8%). The excellent implementation rate of this category of QIs has been realized often right from its introduction (e.g., QI 1 and QI 6 each 2015: 100% and 2019: 100%) and is maintained over the course of time. For instance, mandating that surgical therapy of advanced ovarian cancer can only be performed by specialized gynaecologists not only improves outcomes and is linked to longer survival [10, 11, 17, 18], but is also easily achievable via a top-down process arrangement. Same process can be applied within the network and to cooperation partners regarding implementation of QI 6 (= tumour board presentation rate) and defining mandatory information included in pathology reports such as initial diagnosis, tumour resection and if applicable indicating that lymphadenectomy is complete (= QI 7 and QI 8).

These procedural QIs have tremendous influence on the quality of care for patients, while being relatively easy implementable in GCCs, e.g., through standard operating procedures and handling instructions. This is also shown by a consistently high implementation rate resp. low mean SD of the PO-QI on the individual centre level. Hence, in principle, these indicators and corresponding target values are easily reachable for every certified centre, while taking into account justifiable individual cases such as emergency surgery, preventing the presentation at the pre-therapeutic tumour board. In case of repeated not-justifiable non-fulfilment of this indicator group, a “deviation” in the audit will be given. An ultimately failure to fulfil the indicators can lead to the withdrawal of the certificate.

Results from QIs that report on treatment procedures such as surgical interventions and recommendations for systemic therapy present a slightly different picture. For evaluation of adherence to recommendations for treatment procedures it has to be taken into account that situations in routine care are very complex and conclusions from raw QI data on quality of care are not easily possible [18]. For example, QIs results not reaching a pre-defined threshold (target value) do not necessarily indicate insufficient performance of the providers. Under such circumstances, additional information is needed to decide whether quality of care is adequate or not [18]. Therefore, the given explanations by the certified centres are discussed with the auditor during the on-site audit and checked through random samples of patient files. If explanations of the centres seem to be not adequate, the auditors pronounce “deviations” that need to be remedied by the centres [19]. If explanations are plausible and justifiable no further action is required.

QIs that call for the implementation of systemic therapies in line with the guideline recommendations show a good yet decreasing implementation rate over course of time in this analysis (QI 4: 2014 94.6% to 2019 88.9% and QI 5 2014 69.2% to 2019 60.3%). Explanations from the centres that fell below the target value included for both QI mainly patient-related reasons (i.e., patient death after surgery, patient wish, existing comorbidities and/or poor general health, therapy termination due to side effects). For QI 5 (= First-line chemotherapy of advanced OC) comorbidities and poor general health often also caused changes in therapy regimes. Patients being treated ex domo / outside the network as well as time of data reporting time (i.e., patients can only be counted in the numerator when the therapy is completed) were named as reasons why patients even though the recommendations for chemotherapy was provided during the tumour boards were missing. It must be kept in mind that written explanations have only to be provided in case the number of patients is below the threshold (QI 4 < 30%; QI 5 < 20%) i.e., if the overall number of eligible patients in the numerator or the median decreases, but remains above the threshold, the certified GCCs do not have to provide a reason.

Thus, based on this preliminary evaluation, it can be argued, that in contrast to the results of the PO-QIs the implementation rate for QI documenting application of systemic therapies reaches a plateau where the guideline recommendation is known to the practitioners, but patient-related reasons meaningfully prevent a further increase of the rate. Hence fluctuations of the implementation rate and higher mean SD of these TP-QIs on the individual centre level are to be expected. The decreasing implementation rate could be in relation to higher age and/or existence of multiple comorbidities and/or other therapy regimes. Unfortunately, this cannot be further explored with the present data set as socio-demographic information and detailed information about comorbidities is not yet available or too superficial.

In contrast, TP-QIs that report on surgical interventions offer more room for improvement measures. This set of Qis not only reflects patient-related factors (i.e., comorbidities, poor overall health status, patient rejection of surgery) but also the professional expertise of the surgical team. The surgical therapy is one of the fundamental pillars of the treatment strategy for OC and CC. It is not only the most important diagnostic instrument, but also has direct and strong influence on the prognosis and is part of the is part of a mostly multimodal and interdisciplinary therapy concept [20]. Like QI reporting on systemic therapy, the data shows an increase over the course of time and also reaches a plateau in the implementation rate (i.e., QI 1 2014: 75% to 2019 81.8%; QI 2 2014: 58.8% to 2019: 75.0%% and QI 9 2015 63.2% to 2019 72.9%). While keeping in mind that the denominator of the surgical QIs was often small, explanations for not meeting Q9 (=

cytological/histological lymph node staging) target value included mostly the application of a radio chemotherapy prior to the cytological/histological lymph node staging. For QI 2 (= macroscopic complete resection advanced OC) existence of multiple (distant) metastasis was given as the most frequent reason for a not complete macroscopic resection. As reported above, some patients also decided to undergo the procedures outside of the certified network. However, besides patient-related topics, the most frequent reasons for not reaching the QI target value include inoperable situs due to advanced spreading of carcinoma or inter-operative assessment which deemed the surgery as not possible. In the case of QI 2 it was stated several times that the tumour size could only be reduced but not removed. The data unfortunately does not allow to assess if other surgical teams would have come to different conclusion and assessments. During the audit, auditors, and physicians of the GCC discuss if the results are justifiable, but explanations regarding the deviations are typically brief and often superficial [21].

Following further limitations need to be pointed out in the light of the data interpretation. Firstly, only aggregated data is submitted by the individual centres, hence assessment of individual patients' information in regard to severity of the case or socio-demographics is not possible. Secondly, centres included in this analysis could be prone to a selection bias as often only already good performing centres are joining quality assurance programmes. Also, the data investigated here cannot be linked to survival data from registries.

As for these QIs the most relevant factors are the personal skills of the practitioners combined with technical prerequisites the opportunity for identifying measures for improvement are given. Thus, measures for improvement of the implementation rate of this QI-set, besides the discussion of results amongst peers during the audit, could include offers of surgical courses or coaching, additionally.

Interestingly, the data also shows that on the individual centre level the results for macroscopic complete resection, sugical staging early OC and cytological/hostological LN staging can widely vary from one year to another with an overall standard deviation of up to 19. Reasons for these fluctuations cannot be provided with the current data available. When interpreting the results, we have to bear in mind the primary purpose of the data collection, i.e., creating a basis for the decision of whether or not the certificate should be issued. [21]. Further investigation is thus necessary. None withstanding, one hypothesis could be that, for instance, staff changes in the surgical team could explain why several centres with high indicator results in one year can have lower results in the forthcoming year. It could be argued that meanwhile, the certified GCCs who maintain a constantly high implementation rate provide a good environment for surgeons in training and could be the ones selected to offer coaching courses for other GCCs.

Conclusion

To achieve best possible treatment outcome for women with gynaecological malignancies, synergistic collaboration of all disciplines and professional groups involved in oncological care as well as pursuing specialization of the physicians are important elements [22].

QIs support the establishment of guideline-based treatment in everyday clinical practice and motivate practitioners to critically reflect on their treatment results. In the audit procedures, these results are discussed, and measures are identified that enable better application of the guideline contents. The effectiveness of these measures is reviewed in the next audit one year later. The results of the QIs will be reported to the medical guideline development groups and provide information on how and to what extent a recommendation is implemented in everyday clinical practice and thus offer additional suggestions for the further development of the guidelines. Furthermore, the results of this analysis with the focus on ovarian and cervical cancer suggest that dividing the analyzed QI into two categories - process organization and treatment procedures - provides an opportunity to evaluate the QI improvement potential in different ways and allows the determination of appropriate improvement measures and therefore shows that a combination of different measures is necessary in order to anchor quality sustainably in health care and thus improve it.

Declarations

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Competing Interests

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Author Contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Ellen Griesshammer. The first draft of the manuscript was written by Ellen Griesshammer and all authors commented on previous versions of the

manuscript. All authors read and approved the final manuscript.

Data Availability

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Charité University (Date 9 November 2021/No. EA4/222/21).

Consent to participate

Not applicable

Consent to publish

Not applicable

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Figures

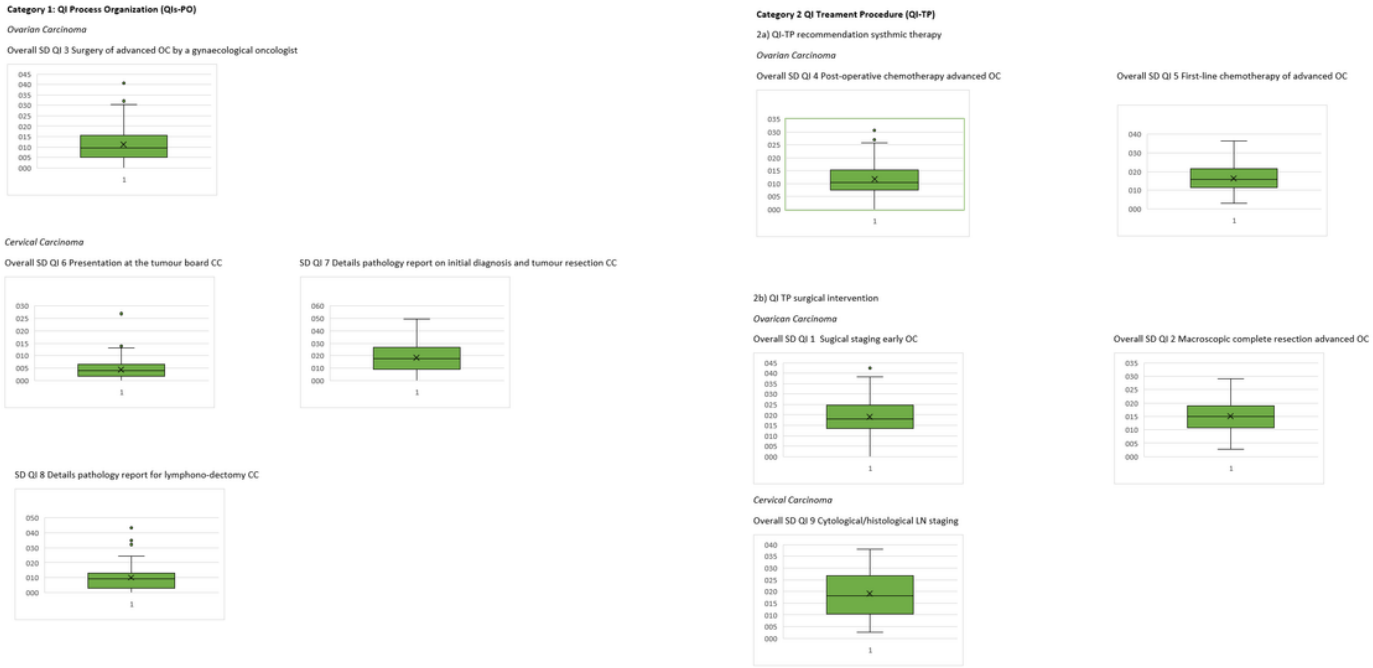

Figure 1

Means of overall standard deviation of centres annual quotas evaluated QI between 2014-2019