Aus der Klinik für Gynäkologie mit Zentrum für onkologische Chirurgie -
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DISSERTATION

Certified gynaecological cancer centres: Analysis of guideline-based quality indicators for endometrial, ovarian and cervical cancer

Zertifizierte gynäkologische Krebszentren: Analyse leitlinienbasierter Qualitätsindikatoren für Endometrium-, Eierstock- und Gebärmutterhalskrebs

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ADT	*Association of German Tumour Centres*
AGO	*Working Group for Gynaecological Oncology*
AWMF	*Association of Scientific and Medical Societies*
CA-test	*Cochran-Armitage tests*
CC	*cervical carcinoma*
DGGG	*German Society for Gynaecology and Obstetrics*
DKG	*German Cancer Society*
DKH	*German Cancer Aid*
DS	*Data Sheets*
EC	*endometrial carcinoma*
GCCs	*Gynaecological Cancer Centres*
GDG	*Guideline Development Group*
GGPO	*German Guideline Program in Oncology*
GIN	*Guideline International Network*
MeSH	*Medical Subject Headings*
NKP	*National Cancer Plan*
OC	*ovarian carcinoma*
PO-QIs	*Process organization quality indicators*
QIs	*Quality Indicators*
QIWG	*Quality Indicator Working Group*
QS-OVAR	*AGO's quality assurance program*
TP-QIs	*treatment procedures quality indicators*

Zusammenfassung

Zur Qualitätssicherung und zur effektiven Umsetzung evidenzbasierter Leitlinienempfehlungen im onkologischen Versorgungsalltag wurde in Deutschland der Qualitätszirkel Onkologie etabliert. Dessen zentrale Elemente sind die Qualitätsindikatoren (QI). Die QI Umsetzungsrate und die Einhaltung der Leitlinienempfehlungen wird durch das Zertifizierungssystem der Deutschen Krebsgesellschaft (DKG) überwacht und ausgewertet.
In dieser Dissertation wird erstmals der systematische Prozess der QI Ableitung und Aktualisierung auf Basis der Leitlinien für die Diagnostik, Therapie und Nachsorge für Patientinnen mit Endometrium- (EC), Zervix- (CC) und Ovarialkarzinom (OC) beschrieben sowie ein differenzierter Überblick über die Implementierungsrate und -entwicklung der QI-Ergebnisse für OC und CC in den zertifizierten Gynäkologischen Krebszentren (GCC) gegeben.
Die vorgestellten Ergebnisse der Dokumentenrecherche zur QI-Entwicklung verdeutlichen einen Unterschied im Reifegrad der QI-Sets sowie die Verflechtung zwischen Leitlinienaktualisierung und dem Feedback aus der klinischen Routine anhand von QI-Implementierungsdaten, die Hinweise auf Verbesserungs- und Neuentwicklungspotential für QIs liefern.
Der zweite Teil wertet QI-Ergebnisse für Patientinnen mit CC und OC, die zwischen 2015 und 2019 in GCCs behandelt wurden, aus. Der Median, der Gesamtanteil, die Standardabweichung sowie zweiseitige Cochran-Armitage-Tests wurden berechnet. Zur Analyse wurden die QIs in zwei Kategorien unterteilt: Prozessorganisation (PO-QIs) und Behandlungsabläufe (TP-QIs), um eine differenzierte Analyse zur Identifizierung von Verbesserungsmaßnahmen zu ermöglichen. PO-QIs, die die Umsetzung von Prozessen und Strukturen widerspiegeln, weisen ein hohes Implementierungsniveau auf. PO-QIs haben einen großen Einfluss auf die Qualität der Versorgung und sind durch SOPs leicht zu implementieren. TP-QIs berichten über Behandlungen, die in den zertifizierten GCC durchgeführt werden. TP-QIs, die systemische Therapien thematisieren, erreichen ein Implementierungsplateau, bei dem die Leitlinie bekannt ist, aber patientenbezogene Faktoren einen weiteren Anstieg sinnvollerweise verhindern. TP-QIs, die chirurgischen Eingriffe thematisieren, schwanken in der Implementierungsrate. Hier sind u.a. die wichtigsten Faktoren die persönlichen Fertigkeiten der Ärzte. Neben der Diskussion der Ergebnisse unter Fachkollegen während des Audits könnten Verbesserungsmaßnahmen für TP-QIs chirurgische Kurse oder Coaching umfassen.

Zusammenfassend: Die Leitlinienempfehlungen sind in GCC in einem hohen bzw. sehr hohen Maße umsetzen. Durch die Analyse von QI Ergebnissen wird die Qualität der onkologischen Versorgung transparent und ein Vergleich zwischen verschiedenen GCC ist möglich. Eine Kombination verschiedener Maßnahmen ist notwendig, um QIs zu aktualisieren und die Qualität in der Versorgung nachhaltig zu verankern und nachhaltig zu verbessern.

Abstract

For quality assurance and in order to implement evidence-based guideline recommendations effectively in everyday oncological care a Quality Cycle Oncology has been established in Germany. Its central elements are the quality indicators (QIs). The implementation rate of these QIs and adherence to guideline recommendations is monitored and evaluated through the certification system implemented by the German Cancer Society (DKG).

This dissertation describes for the first time the systematic process behind compiling and updating QIs based on the guidelines for diagnosis, therapy and follow-up for patients with endometrial (EC), cervical (CC) and ovarian cancer (OC) as well as presenting a differentiated overview of the implementation rate and development of QI results of DKG certified Gynaecological Cancer Centres (GCC).

The presented results of the document search on QI development illustrate a difference in the maturity of QI sets as well as the interconnectedness between guideline updates and feedback from clinical routine based on QI implementation data, which provide indications for improvement and new development potential for QIs.

In a second step, QI results for patients with CC and OC treated in GCCs between 2015 and 2019 were analysed. The median, overall proportion, standard deviation and two-sided Cochran-Armitage tests were calculated. QIs were divided into 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 degree of application. PO-QIs have a tremendous influence on the quality of care and are easy to implement 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-factors meaningfully prevent further increase. TP-QIs that report on surgical interventions fluctuate. The 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.

Concluding it can be state that the guideline recommendations are implemented to a high or very high degree in GCC. By analysing QI results, the quality of oncology care becomes transparent and a comparison between different GCC is possible. A combination of different measures is necessary to update QIs and to sustainably anchor and ultimately improve quality in care.

1 Introduction

With over 450,000 new cases per year, oncological diseases are the second most common cause of death in Germany after cardiovascular diseases and represent a high proportion of the incidence of disease among the German population [1, 2], often of a long duration and with a lasting physical and mental impact on the lives of patients and their relatives [2]. This poses significant challenges, especially as treatment usually requires the coordinated and interdisciplinary cooperation of various professional groups who take different approaches to therapy. In addition, discussions about how to provide high-quality but economical oncological care will be intensified by the rapid progress in the development of medical innovations.

Gynaecological tumours consist of several entities that differ in incidence, therapy, and prognosis. Around 38,000 women were diagnosed with a gynaecological neoplasm in 2017 in Germany [1]. Interdisciplinary cooperation, along with the highly specialised surgical expertise of the clinic, benefit patients significantly and influence clinical outcomes for gynaecological tumours, in particular, as demonstrated by a number of studies [3-6]. The highest mortality rate is attributable to ovarian cancer, constituting 3.1% of all malignant neoplasms, 5.2% of all cancer deaths among women and 19.2% of the incidence of gynaecological neoplasms [1]. The invasive cervical carcinoma continues to be the third most common gynaecological neoplasm in women in Germany and worldwide at 11.4% [1, 7], despite the progress in screening and preventive treatment. The fourth most common gynaecological cancer at 4.8% is the endometrial carcinoma, accounting for 1.9% of all cancer-related deaths among the female gender [8].

To ensure high-quality care for oncological patients, it is necessary to apply a variety of tools, depending on the resources available.

In 2008, the Federal Ministry of Health launched the National Cancer Plan (NKP) in cooperation with the Association of German Tumour Centres (ADT ADT), the German Cancer Society (DKG) and German Cancer Aid (DKH) [9], in order to develop a comprehensive national strategy focussing on early cancer detection and treatment to combat the disease. Recommendations were put forward in four areas and in 13 working groups, with input by all the involved partners from professional societies, patient organisations and bodies of the autonomous governing bodies within the health care system (Organe der Selbstverwaltung im Gesundheitswesen). One of the greatest achievements to date of the ongoing NKP project has been to define an oncology quality cycle [10]. Evidence-

based medical guidelines are the starting point from which the requirements for certification of care networks are derived, as well as quality indicators for measuring the quality of care. Within the certification system, the certified centres report key performance figures annually and the results are published in benchmark reports [2]. The certification committees and guideline groups discuss the results of the annual reports and examine whether the quality measures collected provide grounds for changing guideline recommendations or certification requirements (see figure 1) [2].
For better contextualization of the research the three core elements, their interactivity and intertwinement are described in more detail in the next paragraphs.

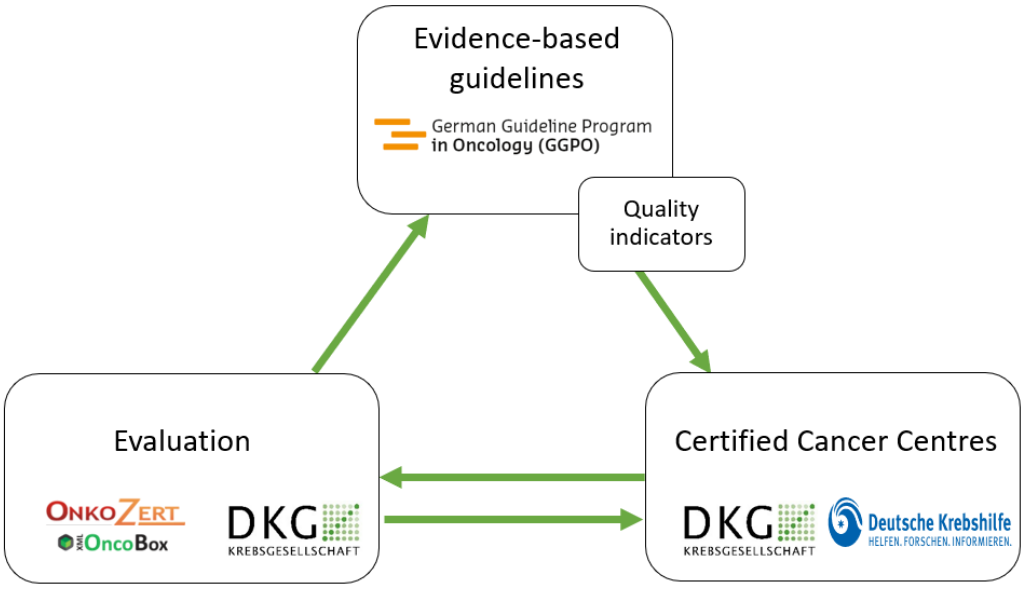

Figure 1 Quality cycle in oncology [modified Griesshammer et al 2019 [2]

1.1 Evidence-based medical guidelines

Medical guidelines form the starting point of the quality cycle in oncology and systematically produce reports for practitioners and patients to make informed decisions in specific clinical situations. In 2008, a consortium of DKH, DKG and AWMF founded the Guideline Programme in Oncology (GGPO) [11]. The guidelines are exclusively of the highest methodological level, referred to as S3, which defines that it is put together by all medical and non-medical professional groups and patient representatives for whom the guideline is intended. In addition, a systematic search of the scientific evidence and the assignment of recommendation grades by the guideline authors must take place within the framework of a formal consensus procedure [12]. Furthermore, an obligatory step in the preparation

or updating of the guidelines is the derivation of quality indicators (QI) from strong recommendations ("must" recommendations, recommendation grade A according to the AWMF recommendation grading scheme) of the guideline [2, 11].

1.2 Quality Indicators

In order to improve the quality of care and to achieve the goals of health care, the measurement and evaluation of quality is the central step, which forms the basis for all further measures [13, 14].
In Germany, indicator-based methods for quality measurement and assessment in health care have primarily emerged from initiatives of scientific societies and have been used for decades, primarily with the goals of research and quality improvement [15, 16].
With the start of the German Guideline Programme in Oncology (GGPO) in 2008, a concept for the standardized derivation of quality indicators in oncology was developed [11]. The quality indicators derived within the framework of the GGPO are adopted in the requirement catalogues of the cancer centres certified according to the certification system of the German Cancer Society (see below) and are thus in active application [17]. Every QI is a fraction that is usually composed as: "Number of patients for whom a specific procedure was followed" / "Number of patients for whom a specific procedure was used" [2].
In order to assure an optimal exchange between routine clinical practice and the development of evidence-based and consensus-based recommendations, the GGPO guideline groups are regularly provided with updates about the QI results and the extent to which the guideline has been implemented in practice, allowing them to assess the guideline and how practicable the recommendations and indicators are for everyday use [18].
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 successful implementation or update of the guideline - can be discontinued [19].
Recently the living guideline concept has been introduced to most of the guidelines in the GGPO to ensure a more dynamic updating of the recommendations as the development and updating of guidelines can be slow, often with month or years between a guideline and the next update. The new approach conducts an annual literature research followed

by methodically processing is conducted. Quality Indicators are updated only every three years within the living guideline concept.
The feedback to the guideline groups thus closes the quality cycle in oncology and is at the same time the starting point for the renewed start of the process.
As of January 2022, 31 tumour-specific and cross-sectional S3 guidelines have been published, setting out 192 quality indicators, of which 108 have been implemented in 18 tumour-specific certification procedures in 1,715 certified centres, including 142 outside of Germany [20].
Therefore in the context of this study quality indicators are understood as measurable elements of care that can be used to determine the quality of care, as they are based on the evidence- or consensus-based recommendations of the S3 guidelines and thus on the desired quality [21]. Accordingly, they can also be used for quality improvement, as they reflect the treatment goals or requirements in the treatment of tumour patients [17, 21]. In general, it is areas of the healthcare system where potential for improvement has been identified by guideline developers and others that are targeted by QIs, acting as benchmarks compared to other institutions and as internal quality management for healthcare providers [11].

1.3 Cancer Centre Certification Programme and Gynaecological Cancer Centres

The certification of the first breast cancer centres in 2003 marked the start of the cancer centre certification system and certification procedures for almost all types of tumour were set up by 2022. The voluntary certification system is designed to set up tumour-specific treatment networks, whereby inpatient and outpatient service providers ensure a high standard of care for oncological patients, based on evidence-based guidelines [22]. Starting with early detection and diagnosis, followed by treatment, aftercare and palliation, they provide care throughout the healthcare chain [23]. The structure of the centres is multidisciplinary, actively integrating not only medical professions but also other groups such as psycho-oncology and social work, allowing all aspects of an oncological disease to be handled competently. All network partners must prove their qualitative and quantitative competence in order to gain certification [2].
The catalogues with the requirements for structure, process and quality standards are created by experts in the certification commissions. The commissions, like the cancer networks, are interdisciplinary, multi-professional and tumour specific [2]. The certification

commissions can be understood as the legislative body in the certification system. Each commission consists of 30-40 experts from their respective medical societies, scientific societies, working groups, and self-help organizations [2]. They meet every two years to discuss the results from the certified centres and to ensure the updates of the CoR in a timely manner [22].

In 2008, DKG, the Working Group for Gynaecological Oncology (AGO) and the German Society for Gynaecology and Obstetrics (DGGG) developed the certification system for Gynaecological Cancer Centres (GCC) [17].

As of 2019 a total of 164 GCCs are certified [24] 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] [24]. 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).

The GCCs, like other DKG certified cancer centres, are dedicated to observing the specified quality standards, such as minimum case numbers, tumour boards, the competence of all network partners, transparently revealing the outcome of their key performance and quality indicators in order to prove their care standards and compliance with guidelines and to discuss whether any improvement measures are needed [25].

Three types of gynaecological tumour – endometrial, ovarian and cervical – are the focus of this study, for which S3 guidelines have been drawn up and are regularly updated [7, 8, 26]. Documentation by means of QIs has been obligatory in GCCs since 2014 for ovarian carcinoma (OC), 2015 for cervical carcinoma (CC) and 2019 for endometrial carcinoma (EC). As yet, no other gynoncological guideline has so far reached the S3-status.

1.4 Objective

The overall goal of this dissertation is to present and analyse the quality of care in gynaecological cancer centres as well as to present the implementation level of the guideline-derived quality indicators. Furthermore, this study aims at raising awareness of the great potential of guideline based QIs and their results, so as to benefit quality assurance and improvement in oncology and in the clinical routine.

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[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

Based on the current state of research and based on the practical example of DKG certified Gynaecological Cancer Centres, the following objectives were defined, and corresponding questions were formulated:

1.5.1 Developing and updating quality indicators

For the contextual backdrop this paper presents the methodology of QI development in the context of the development of GGPO evidence-based, clinical guidelines and reports the updating process of QIs from the certified cancer centres for the care of endometrial carcinoma (EC), cervical carcinoma (CC) and ovarian carcinoma (OC).

Research question 1: How are quality indicators developed and updated to become part of the quality cycle in oncology and thus instruments of the quality assurance and improvement process of certified centres?

1.5.2 Implementation and results of quality indicators

For the research study conducted in the scope of the dissertation QI results for CC and OC for the time period 2015-2019 are reported and analysed and thus presenting an approach how to evaluate the status of care in certified GCC. Suitable measures for improvement in compliance with the guidelines are identified.

Research question 2: How has the implementation of quality indicators for OC and CC implemented in certified GCC evolved over time, and what changes are evident in specific groups of indicators over time?

2 Methods

For a better understanding and contextualization of the results of the present research, the methods section is divided into two parts. The first section describes the process of QI development and updating according to the method paper from the GGPO [11].
The second part illustrates the applied methodological approach for analysing QI results of the GCC certified by the DKG.

2.1 Developing and updating quality indicators

QI measurement based on guidelines and specific recommendations has been discussed for several years and up until now no process has been established as a gold standard methodology. Instead, the processes are heterogeneous, as proven in a systematic review by Langendam et al [27]. The methodological approach for QI development used by the GGPO is based on a reporting standard defined by the Performance Measures Working Group (PMWG) of the Guideline International Network (GIN) [28]. A detalied description of the QI development methodology with a flowchart illustration (Figure 2) will be given in the following paragraphs.

2.1.1 Data Collection

According to GGPO regulations, it is obligatory to set up an interdisciplinary “Quality Indicator Working Group” (QIWG) for every development and updating of an evidence-based (S3) guideline, comprising GDG representatives as well as representatives from the cancer registries, the cancer centre certification programme and patient advocacy groups to cover the respective guideline topics. The last consensus conference at the latest sees the election of the members of the QIWG, who convene for the first time after the agreement on all the guideline recommendations [11].
A triad of delegated methodologists from the GGPO, AWMF and the cancer centre certification programme of the DKG (table 1) supervise this procedure [11].

Table 1 Composition of the QIWG working group [own illustration]

Number of representatives	Institution	Voting right
3 - 7	Experts from the GDG	+
1 - 2	Patients and patient representatives from the GDG	+
1	Cancer Registries	-
1	Certification system DKG	-
2	GGPO office and AWMF (one representatives from each)	-

Only strong grade A recommendations, which can also be evidence-based or consensus-based, are selected from the guideline when preparing the first QIWG meeting, as they address measures with an evident benefit for the majority of patients and are therefore deemed suitable for QI development. The definition of nominator and denominator are also prepared ahead of the first meeting wherever possible [29].

Furthermore, a systematic literature search for international QIs through bibliographic databases including PubMed and Cochrane library and websites of known national and international institutions that develop or publish oncology QIs is conducted [11]. A Google search for grey literature (i.e. materials and research produced by organizations outside of the traditional commercial or academic publishing and distribution channels) is carried out as well. The purpose of the international QI search is to flag up additional aspects to be considered by the GDG when putting together further recommendations, explanations or amendments [30]. The national and international QIs that are selected are attributed to topics for which there are not yet strong guideline recommendations.

At the first QIWG meeting, all the group members are provided with information about the intended procedure and with a short training in the planned methodology. Any potential conflicts of interest among them were already assessed and documented during the guideline update process, in accordance with AWMF specifications for developing guidelines.

A predetermined exclusion criteria template (table 2), derived from criteria specified by the German Assessment Tool QUALIFY [31], forms the basis of the preselection of

potential (new) QIs as part of the meeting. A QI is not accepted unless at least 75% of the eligible voters agree [11].

Table 2 Exclusion criteria for preselection of potential QI [own illustration]

Criteria
1. The recommendation cannot be operationalized (in terms of measurability)
2. No potential for improving patient care
3. Lack of comprehensibility and / or great effort to collect data in proportion to benefit
4. Other reasons (i.e., duplicates Qis from two different recommendations)

The active group members are given further information for the subsequent assessment of the preselected potential QIs. An assessment of the availability of data in cancer registries is provided by a representative, in line with the ADT/GEKID uniform basic oncology data set [11, 32], in order to specify whether there is a need for cancer centres to document additional data for a QI or whether existing data at cancer registries and certified cancer centres could be used for calculating the QI.

In addition, representatives of the certification programme present existing QIs and the results reported by the GCC, followed by discussions among the participants as to what course of action should be taken, whether the existing QI should remain the same, be modified, suspended or eliminated. The latter evidently does not apply to the initial development of QIs based on guidelines put together for the first time [33].

QIs are evaluated in the written assessment according to the questions below and in consideration of relevance, the effort required to collect data and how practicable potential QIs are. A QI is accepted on the condition that a minimum of 75% of the voters give an affirmative answer to questions 1-3 and 5 and negative to question 4 (table 3) [11].

Table 3 Questions to assess suitability of a QI [own illustration]

Questions
1. Does the QI state relevant improvement potential for patient care?
2. Is the QI set out clearly and unambiguously?
3. Does the QI refer to an aspect of care that care providers can influence?
4. Are there any risks for misconduct due to the QI that cannot be remedied?
5. Is the required data routinely documented by care providers or can additional data be collected without undue effort?

Comments on risk adjustment (are there any patient characteristics, e.g. age, comorbidities, or cancer stage, that may have an influence on QI results?) or relevant implementation barriers could be added [11]. The outcome of the written assessment is reviewed and discussed at a second meeting of the QI working group in order to agree on a final set of QIs, which is passed on to the cancer registries and the certification commission of the DKG [11].

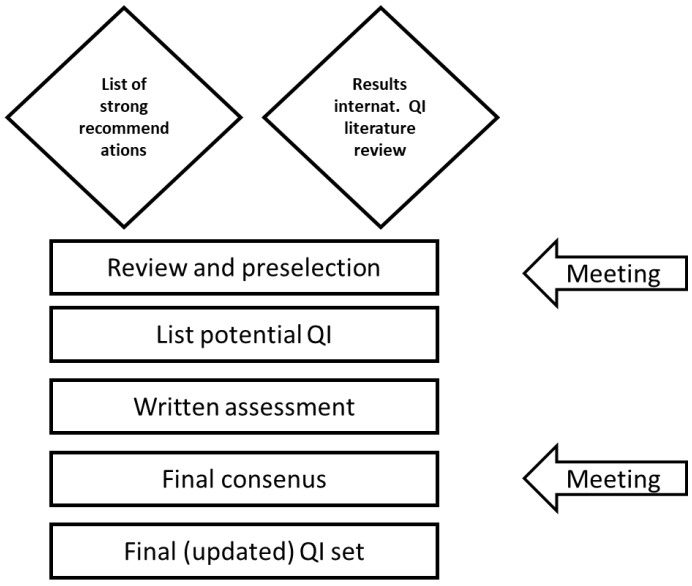

Figure 2 Flowchart of methodological approach for QI development within the GGPO [modified Rückher et al 2021[30]]

The primary list of potential quality indicators including the reasons for exclusion, the above-mentioned compilation of international quality indicators and the results of the

written assessment are available on request from the guideline secretariat or the office of the Oncology Guideline Programme.

2.1.2 Data Analysis

Based on the S3 guidelines for OC, CC and EC the development and updating process of the QI sets is reported by analysing documentation from the corresponding QIWG. The following documents[3], developed during the work of the tumour specific QIWG, were assessed and evaluated: (1) list of potential QIs before and after initial review and preselection, (2) results of the international QI search, (3) results of written assessment, including additional comments and (4) final consensus of the QIWG members.

2.2 Analysis of quality indicators results

2.2.1 Data Collection

The tumour-specific certification commission discusses whether the preliminary new and/or updated QI will be implemented in the certified cancer centre. By being implemented, documented, and annually analysed in the certified cancer centres the QIs and their results are piloted and thus evaluated for practicability, plausibility, and validity.
The meeting of requirements laid out in the Catalogue of Requirements (CoR) must be documented by each GCC to be (re)certified. The outcome of the aggregated key performance and quality indicators must be reported to OnkoZert, an independent certification institute that arranges the auditing procedure for DKG, every year.
The submitted datasets are subject to analysis and are tested for plausibility after collection from the certified centres, which in case of deviations from guideline recommendations are obliged to state reasons why the defined limits and target values set out by the indicators were exceeded or fell short. As long as the results are within the target values and plausibility limits, centres do not need to justify patient treatment. Certification is dependent on the cancer centres either meeting the target values or providing a plausible explanation if this is not the case [34].
Trained gynaecological and oncological medical experts audit the centres regularly, after checking the reported data from the previous calendar year and verifying it through insight

[3] Source from the GGPO intranet (not publicly accessible)

into patient files. The benchmarking reports only publish verified data. For example, data from 2019 was audited in 2020 and published in 2021.
The 2015-2019 group of patients forms the basis for the QI data presented in this study, only including data from centres certified throughout the year and with a consistent tumour documentation system.

2.2.2 Data analyses

The descriptive analysis of case distribution, patient numbers and indicator definitions only took account of QIs that had been part of the DKG data set since at least 2014 and continuously up until 2021, rejecting QIs that had been discontinued during that period (see table 5 and 7). Therefore, the analysis only included QI results for patients undergoing CC and OC treatment in GCCs between 2015 and 2019, with a certified status throughout this time period, applying two-way Cochran-Armitage tests (CA tests) to identify trends over time. For each QI, there was a calculation of the average ratio of the centres and the overall ratio. EC QI were not included in the evaluation as mandatory data reporting only started in 2019.
The R version 3.5.1 and the WhiteBox, a data analysis tool developed by OnkoZert, are applied in statistical analyses. XLSTAT Version 2019.2.1 was used for calculating Cochran-Armitage tests (CA-test), which excluded centres where values were missing at any given reporting stage. A p-value ≤ 0.05 was accorded statistical significant. In November 2021, the ethics committee of Charité University medicine reviewed and approved the data analysis and study concept.
For analysis QI were divided into two categories: process organization QIs and treatment procedure QI. *Process organisation QIs* are indicators that document the implementation of processes and structures that are explicit recommendations by the medical guideline within the certified network [35].
Treatment procedure QIs are indicators that report treatments carried out by members of the certified network, such as surgical interventions or systemic treatment recommendations [35].
The derived QIs, including their operationalization, are presented. Subsequently, the results of the implemented QIs for OC and CC are displayed, analysed over time and based on this, the implications for quality assurance and improvement in certified GCC are discussed.

3. Results

3.1 Developing and updating quality indicators

3.1.1 QIs for endometrial cancer

2018 saw the publication of the first version 1.0 of the S3 guideline for diagnosis, treatment and aftercare of endometrial cancer patients, which is still valid [8]. An updated version including an updated QI set is planned for publication in October 2022.
The so-called consultation version of the new guideline is already available online [36]. However, the consultation version of a guideline is not the final version and not yet authorised by the persons and organisations involved. During this phase the guideline is open for feedback and comments by the professional public. The QI updating process is also already completed but not yet published.
A summary of 32 new and modified strong recommendations was presented at the kick-off QIWG meeting in 2022. During the first meeting of the working group for endometrial cancer, 10 of the 32 strong guideline recommendations were preselected to be suitable as potential QIs for the assessment process according to the criteria defined in table 3. After the assessment process 8 QIs, 4 new and 4 existing, were agreed to be accepted in the final QIWP meeting for endometrial cancer.
As QI for social counselling and QI for presentation at the interdisciplinary tumour board are mandatory for all patients with an initial diagnosis of a gynaecological malignancy in GCC, both QIs are already implemented since 2011. The other two existing QI for patient with an endometrial carcinoma were included for the first time in the data sheet GCC in 2018 on a voluntary basis. In 2019 it became mandatory for all certified GCC to document. For both QIs the denominator definitions were modified, however rather editorial adjustments than content changes (i.e. ICD codes were deleted and p53-wt and pNsn0 was included). If the 4 newly defined QIs will be documented in the certified GCC or through the cancer registries will only be decided in 2023 after the convening of the GCC certification commission.
Out of 21 hits from the international QI search in March 2022, 5 papers were retained including 71 EC QIs (6 QI in Benoit et al 2020 [37]; 10 QI in Bonte et al. 2018 [38]; 29 QI in Concin et al, 2021 [39], 5 QI in Larouzèe et al 2019 [40], 13 QI in Luyckx et al 2020[41]; 8 QI in ISD – Scottish Cancer Task Force [42]). There was a correlation

between 8 of the 71 QIs with strong guideline recommendations. Actual reported results for proposed QIs are only available in 3 out of 5 of the identified papers.

Many of the indicators identified through the international search correspond to “should” or “could” recommendations in the GPPO guideline or are a subset of already implemented requirements in the GCC. For instance, out of the 6 QI presented in Benoit et al [37] one indicator correspond to a DKG QI, five to “should” recommendations. Table 4 shows the EC QI updating process and the corresponding definition of numerator and denominator.

Table 4 Updating process of QI-Set for endometrial cancer [own illustration]

	Initial QI set (2013)	**Operationalization**	**1st update QI set (2022)**	**QIs recorded in DS (2019)**	**Explanation**
1	No systematic lymphadenectomy for type-I- EC	Numerator: no systematic lymphadenectomy for type-I-endometrial carcinoma pT1a/b G1/2 cN0	Modified	Yes	Editorial amendments
		Denominator: patients with initial diagnosis of endometrial carcinoma, c/p T1a, G1/G2, cN0, LVSI neg			
2	No adjuvant chemotherapy for type-I-EC	Numerator: no adjuvant chemotherapy for type-I-endometrial carcinoma pT1a/b G1 cN0/pN0 o. pT1a/b G2 cN0/pN0	Modified	Yes	Editorial amendments
		Denominator: all patients with initial diagnosis of endometrioid or other type I endometrial carcinoma (ICD-0: 8380/3, 8570/3, 8263/3, 8382/3, 8480/3), pT1a/b G1 cN0/pNsn0 p53-wt o. pT1a/b G2 cN0/pNsn0, p53-wt			
3	Social counselling	Numerator: number of patients who receive social counselling	Unchanged	Yes	
		Denominator: all patients with a first diagnosis of endometrial carcinoma and first treatment at the centre			
4	Presentation at the tumour board	Numerator: number of patients presented at the tumour board	Unchanged	Yes	
		Denominator: all patients with an endometrial carcinoma			
5	Immunohistochemical determination of p53 and MMR proteins	Numerator: patients of the denominator with immunohistochemical determination of p53 and the MMR proteins	New	No	To be decided 2023
		Denominator: all patients with a histologically confirmed initial diagnosis of EC (incl. M1)			
6	POLE examinations	Numerator: patients of the denominator with POLE examination	New	N0	To be decided 2023
		Denominator: all patients with initial diagnosis of endometrial carcinoma >pT1a u./o. G3 u./o. p53-abn u./o. LVSI pos. u./o. MSI/MMR pos. or Initial diagnosis of type 2 endometrial carcinoma (serous, clear cell, carcinosarcoma)			
7	Sole postoperative vaginal brachytherapy	Numerator: denominator patients with sole postoperative vaginal brachytherapy	New	No	To be decided 2023
		Denominator: all patients with initial diagnosis of endometrial carcinoma stage pT1b, G1 or G2 pNX/0, p53-wt, L1CAM negative, without extensive LVSI with surgery.			
8	Chemotherapy with carboplatin and paclitaxel	Numerator: patients of the denominator with chemotherapy with carboplatin and paclitaxel	New	No	To be decided 2023

		Denominator: patients with Initial diagnosis of endometrial cancer and adjuvant chemotherapy			

3.1.2 QIs for cervical carcinoma

The publication of the first S3 guideline (1.0) for the diagnosis, treatment and aftercare of cervical carcinoma patients back in September 2014 was followed by a first update (2.1) in May 2021 and the most recent version (2.2) in March 2022 [7]. Since 2021 this guideline applies the living-guideline concept.

The initial set of 9 QIs was set out in 2014, followed by an update in September 2020 that saw the addition of a total of 13 new strong recommendations, published in May 2021.

At the first guideline-update meeting of the QIWG, a summary of the existing and new potential QIs was followed by a discussion. 9 QIs from the first version of the guideline (2014) were checked for strong recommendation updates and 11 of the 13 new recommendations were eliminated on the basis of the criteria set out in table 3.

Of the total of 169 hits that was achieved by the international QI search, 42 were retained following the screening process, albeit only 8 full texts were available and included. A total of 51 CC QIs were identified (14 QI in Bonte et al 2019 [38]; 12 QI in Cibula et al 2020 [43]; 1 in DeGroff et al 2014 [44]; 1 QI in Iwamoto et al 2016 [45]; 3 QI in Luyckx et al 2020 [41]; 10 QI in Watanabe et al.2018 [46], 8 QI ISD Scotland Helath Indicators [47]; 2 QI Belgian Health Care Knowledge Cenre [48]) and 13 QIs corresponded to the proposed guideline indicators.

Two updates were made to the existing QI 2 “Details in pathology report in case of initial diagnosis and tumour resection”, adding the metric or percentage depth of invasion in relation to cervical wall thickness in radical hysterectomy, as well as “for pT1b tumours endocervical stroma” as a supplement to the minimum distance to the resection margins.

The proposal was put forward to add the second new recommendation “Complete report of conisation findings” as a possible new QI, as well as to discontinue the QI 9 asking for “R0 resection for exenteration” and to add the new strong recommendation “lymphonodectomy preparations” to the existing QI 3 “Details in pathology report in case of lymphonodectomy”, extending it with the bullet point: “Detection of isolated tumour cells or micro metastases”.

When the working group reconvened, they agreed on all the proposed updates, additions and new QIs. Table 5 shows the operationalization and update procedure for the CC QI set.

The QI 1-4 have been documented and implemented in the certified GCC since 2015, therefore results are available and presented in table 7. The documentation of QI 5-8 at the GCC was discontinued in 2018 and is now included with the ADT/GEKID uniform basic oncology data set, reducing documentation outlay for the GCCs. QI 9 was discontinued due to low numbers in numerator and high implementation rate in the certified centres. Lastly, instead of GCCs, the certified dysplasia units will collect QI 10.

Table 5 Updating process of QI-Set for cervical cancer [own illustration]

	Initial QI set (2013)	**Operationalization**	**1st update QI set (2021)**	**QIs recorded in DS (2019)**	**Explanation**
1	Presentation tumour board	Numerator: number of patients with presentation in the tumour board Denominator: all patients with initial diagnosis, recurrence, or new distant metastasis of cervical carcinoma.	Unchanged	Yes	
2	Details in the pathology report on initial diagnosis and tumour resection	Numerator: number of patients with reports of findings with information on: • Histological type according to WHO • Grading • Detection/absence of lymphatic or venous infiltrates (L- and V- status) • Detection/absence of perineural sheath infiltrates (Pn status) • Staging (pTNM and FIGO) in conised patients, taking into account conisation findings • Depth of invasion and extension in mm in pT1a1 and pT1a2 • Depth of invasion in relation to cervical wall thickness (metric or percentage) for radical hysterectomy • Three-dimensional tumour size in cm (from pT1b1) • Minimal distance to resection margins (for pT1b tumours endocervical stroma) • R-classification (UICC) Denominator: all patients with initial diagnosis of cervical carcinoma and tumour resection.	Revised	Yes	Update strong recommendations
3	Details in the pathology report for lymphonodectomy	Numerator: number of patients with report of findings with information on:	Revised	Yes	

		• Number of affected lymph node in relation to removed lymph node • Assignment to localisation of removal (pelvic/paraaortic) • Indication of the largest extent of the largest lymph node metastasis in mm/cm • Indication of absence/evidence of capsular rupture of lymph node metastasis. Detection of isolated tumour cells or micro metastases. Denominator: all patients with cervical carcinoma and lymphonodectomy.			Addition of new strong recommendation to indicator
4	Cytological/histological lymph node staging	Numerator: number of patients with cytological/histological lymph node staging Denominator: all patients with cervical carcinoma FIGO stage >= IA2 - IVA.	Unchanged	Yes	QI was discontinued due to decision to only include 5 per tumour entity in certification data sheet
5	Cisplatinum-containing radio-chemotherapy	Numerator: number of patients with cisplatin-containing radio/chemotherapy Denominator: all patients with initial diagnosis of cervical cancer and primary radio/chemotherapy.	Unchanged	No (implemented from 2014-2015)	QI was discontinued due to decision to only include 5 per tumour entity in certification data sheet
6	Adjuvant radio(chemo) therapy	Numerator: number of patients with adjuvant radio/chemotherapy Denominator: all patients with initial diagnosis of cervical cancer and radical hysterectomy.	Unchanged	No (implemented from 2014-2015)	QI was discontinued due to decision to only include 5 per tumour entity in certification data sheet
7	Histological confirmation	Numerator: number of patients with pretherapeutic histological confirmation Denominator: all patients with cervical carcinoma and therapy with local recurrence.	Unchanged	No (implemented from 2014-2015)	QI was discontinued due to decision to only include 5 per tumour entity in certification data sheet

8	Spread diagnosis for local recurrence	Numerator: all patients with imaging diagnosis (CT thorax and abdomen to exclude distant metastases). Denominator: all patients with local recurrence of cervical carcinoma.	Unchanged	No (implemented from 2014-2015)	QI was discontinued due to decision to only include 5 per tumour entity in certification data sheet
9	Pelvic exenteration	Numerator: Number of patients with local R0 resection Denominator: All patients with cervical carcinoma and tumour reccurence and pelvic exenteration	Deleted	No (implemented from 2014-2018)	Low numbers in numerator and high implementation rate
10	Complete diagnostic report conisation	Numerator: all patients of the denominator with reports of findings with information on: • Type of lesion (CIN, ACIS, SMILE) • Localisation (endo/ectocervical) • Extension • In case of invasion with indication of size extension, lymphatic, blood vessel as well as perineural sheath invasion • Grading Status of resection margins (R status) Denominator: all patients with HSIL (CIN II/III), ACIS, SMILE u/o cervical carcinoma who received conisation.	New	No	Will be documented certified dysplasia units

3.1.3 QIs for ovarian carcinoma

The currently available 5.1 edition of the S3 guideline for the diagnosis, treatment and aftercare of malignant ovarian tumours, which also uses the living guideline concept, was published in May 2022 [26], following the initial version back in June 2013 and updates in October 2016, November 2017, January 2019 and March 2020. The quality indicator sets initially established in 2013 were update in 2019 and then again in 2021. In the most recent update, the strong recommendations for the existing QI were reviewed as well as two new strong recommendations newly assessed.

A total of 35 hits were achieved in the international QI search, of which 9 were retained after the screening procedure and 8 were included as full texts. A total of 51 QIs were found (8 QI in Alejandra et al 2021 [49]; 8 in Baldewpersad et al 2021 [50]; 17 in Bonte et al 2019 [38]; 5 QI in Llueca et al 2020 [51]; 5 QI in Luyckx et al 2020 [41]; 8 QI in European Society of Gynaecological Oncology [52]), of which 21 corresponded to proposed guideline indicators.

At the kick-off QIWG meeting there was a summary and discussion of the existing and newly proposed QIs. It was proposed to discard the QI 10 “No adjuvant therapy BOT” and QI 11 “No adjuvant chemotherapy for early ovarian carcinoma”, as the results of the certified GCC showed satisfactory fulfilment of the targets, while a modification was suggested for QI 5 “First-line chemotherapy for advanced ovarian carcinoma”, as the underlying recommendation had been amended from ≥ FIGO IIB to ≥ FIGO II. A modification of the numerator, separate doses and time was also considered necessary. A suspension of QI 8 “Combination therapy for platin-sensitive recurrence” was proposed until the guideline was next updated, because platinum-sensitive recurrence had not been specified and therefore the QI was deemed as non-verifiable.

After assessment, the two new strong recommendations in the guideline update were rejected as QIs due to unsuitability (compare table 2). In the absence of new QIs to assess, the second QIWG meeting was suspended. This left a total of 7 QIs in the QI set for ovarian carcinoma, of which the certified GCC is now documenting and implementing six.

Table 7 shows the operationalization and update procedure for the QI set.

Table 6 Updating process of the QI-Set for ovarian carcinoma [own illustration]

	Initial QI set (2013)	**Operationalization**	**1st update QI set (2016)**	**2nd update QI set (2019)**	**3rd update QI set (2021)**	**QI recorded in DS (2019)**	**Explanation**
1	Surgical staging early OC	Numerator: patients of the denominator with surgical staging with: • Laparotomy • Peritoneal cytology • Peritoneal biopsies • Adnexexstirpation on both sides • Hysterectomy, extraperitoneal procedure if necessary • Omentectomy at least infracolic Bilateral pelvic and paraaortic lymphonodectomy	Unchanged	Unchanged	Unchanged	Yes	n/a
		Denominator: all patients with initial diagnosis of ovarian cancer FIGO I-IIIA.					
2	Macroscopic complete resection of advanced ovarian carcinoma	Numerator: patients of the denominator with macroscopically complete resection.	Unchanged	Revised	Unchanged	Yes	Update strong recommendation
		Denominator: all patients with initial diagnosis of ovarian cancer ≥ FIGO IIB and surgical tumour removal without prior chemotherapy.					
3	Surgery for advanced ovarian carcinoma by a gynaecological oncologist	Numerator: patients in the denominator whose definitive surgical therapy was performed by a gynaecologic oncologist.	Unchanged	Unchanged	Unchanged	Yes	n/a
		Denominator: all patients with initial diagnosis of ovarian cancer FIGO ≥IIB after completion of surgical therapy.					
4		Numerator:	Unchanged	Unchanged	Revised	Yes	

	Post-operative chemotherapy for advanced ovarian carcinoma	patients of the denominator with postoperative chemotherapy. Denominator: All patients with initial diagnosis of ovarian cancer ≥ FIGO II and chemotherapy					Update strong recommendation (numerator FIGO II instead of FIGO IIB)
5	First-line chemotherapy for advanced ovarian carcinoma	Numerator: patients of the denominator with first-line chemotherapy carboplatin and paclitaxel. Denominator: all patients with initial diagnosis of ovarian cancer ≥ FIGO II.	Unchanged	Unchanged	Revised	Yes	Update strong recommendation (numerator FIGO II instead of FIOGIIB; deletion number cycles and dosage)
6	Genetic testing offer	Numerator: patients of the denominator with offer genetic testing. Denominator: all patients with initial diagnosis of ovarian cancer.		New	Unchanged	Yes (since 2020)	n/a
7	Platinum-containing chemotherapy early ovarian cancer	Numerator: patients in the denominator receiving platinum-containing chemotherapy. Denominator: all patients with initial diagnosis of ovarian cancer FIGO IC or IA/B with grade 3.	Unchanged	Unchanged	Unchanged	No (implemented from 2013-2015)	Discontinued due to complete implementation
8	Combination therapy for platinum-sensitive recurrence	Numerator: patients of the denominator with platinum-containing combination therapy. Denominator: all patients with platinum-sensitive recurrence of ovarian cancer and recurrence chemotherapy, outside of clinical trials.	Suspended	Suspended	Deleted	No (implemented from 2013-2018)	Suspended due to new recom-men-dations
9	Intra-operative tumour rupture	Numerator: number of patients with Intraoperative tumor rupture Denominator: all patients with Initial diagnosis of an OC FIGO IA o IB	Unchanged	Deleted	n/a	No (implemented from 2013-2016)	Indicator is suspended from 2016 due to the change in FIGO

							classification. No longer a strong recommendation
10	No adjuvant therapy for BOT	Numerator: Number of patients with adjuvant therapy Denominator: all patients with initial diagnosis of BOT	Unchanged	Unchanged	deleted	No (implemented from 2013-2018)	Discontinued due to full implementation
11	No adjuvant chemotherapy early OC	Numerator: number of patients with adjuvant Chemotherapy Denominator: all patients with initial diagnosis of OC FIGO IA, G 1 and complete surgical staging	Unchanged	Unchanged	Deleted	No (implemented from 2013 – 2018)	Discontinued due to complete implementation
12	Chemotherapy for platin-resistant first recurrence	Numerator: number of patients with non-platinum monotherapy with pegylated liposomal Doxorubicin, topotecan, Gemcitabine o. Paclitaxel Weekly Denominator: all patients with platinum- resistant and/or - refractory first relapse of an OC and initial recurrence chemotherapy outside of clinical trials	Suspended	Suspended	Suspended	No	Due to the lack of a definition of platinum-sensitive recurrence, the QI is considered non-verifiable.
13	Counselling social service	Numerator: number of pat. with Counselling by the Social service Denominator: all patients with initial diagnosis of OC and treatment in the centre	Unchanged	Unchanged	deleted	No	Overall indicator for all patients in GCC

Analysis of quality indicators results

2015 to 2019 saw a consistent rise in the number of certified GCCs from 112 to 149, as well as in the number of patients treated in GCCs for a primary diagnosis of a gynaecological malignancy, from 11,587 to 14,986 [24]. This accounts for the fact that the number of patients treated for OC and CC has increased in the GCCs from 3,301 to 3,798 for OC and from 2,059 to 2,479 for CC [24], despite the fact that the incidence of these two types of tumour has decreased over time from 7,318 to 7,292 and 4,606 to 4,341 respectively [1] between 2015 to 2019. Over time, the incidence of endometrial cancer has increased in Germany from 10,355 to 10,451 and the number of treated patients rose between 2015 and 2019 from 3,791 to 5,995 [1].

Since the QIs for EC had only been implemented for one full year in 2019, this section of the analysis only includes the QIs for OC and CC.

The results of 5 OC and 4 CC QIs from 75 GCCs are shown on tables 7 and 8. Between 2015 and 2019, the GCCs treated 17,495 primary cases of OC and 10,969 primary cases of CC [24].

Table 7 QI results for ovarian cancer implemented in GCC between 2015 – 2019 [modified Griesshammer et al 2022[35]]

No.	Quality Indicator	Target values	2019[4] Absolute patient no. Overall ratio	2018 Absolute patient no. Overall ratio	2017 Absolute patient no. Overall ratio	2016 Absolute patient no. Overall ratio	2015 Absolute patient no. Overall ratio	2014 Absolute patient no. Overall ratio	C-Atest[5] p-value
1	Surgical staging of early ovarian cancer	<20%	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 ovarian cancer	≥ 30%	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 advanced ovarian cancer by gynaecologic oncologist	<50%	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	Postoperative chemotherapy advanced ovarian cancer	<30%	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 advanced ovarian cancer	<20%	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

[4] The absolute number as well as the overall ratios are based on the cumulative data of all certified centres

[5] Cochran-Armitage test for trend, p-value is reported

Table 8 QI results for cervical cancer implemented in GCC between 2014 – 2019 [modified Griesshammer et al 2022[35]]

No.	Quality indicator	Target values	2019[6] Median[7] Absolute patient no. Overall ratio	2018 Median Absolute Patient Nr Overall ratio	2017 Median Absolute patient no. Overall ratio	2016 Median Absolute patient no. Overall ratio	2015 Median Absolute patient no. Overall ratio	C-A test[8] p-value
1	Presentation at tumour board	≥ 80%	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%	0,670
2	Details in the pathology report on initial diagnosis and tumour resection	≥ 80%	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%	0.001
3	Details in the pathology report for lymphonodectomy	≥ 80%	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%	0.170
4	Cytological/histological lymph node staging	≥ 60%	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%	0.009

[6] The absolute number as well as the overall ratio are based on the cumulative data of all certified centres

[7] The median is based on the rate of the individual certified centre.

[8] Cochran-Armitage test for trend, p-value is reported

The indicators are defined and categorized in table 9. 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.

Table 9: Categorisation of QI documented on GCC data sheet (2015-2019) [own illustration]

Nr.	Category	QI documented on GCC data sheet
Ovarian carcinoma		
QI 1	Treatment procedures	Surgical staging in early ovary carcinoma
QI 2	Treatment procedures	Macroscopic complete resection in advanced OC
QI 3	Process organisation	Surgery of advanced OC by a gynaecological oncologist
QI 4	Treatment procedures	Post-operative chemotherapy in advanced OC
QI 5	Treatment procedures	First-line chemotherapy in advanced OC
Cervical carcinoma		
QI 6	Process organisation	Presentation at the tumour board
QI 7	Process organisation	Details in the pathology report on initial diagnosis and tumour resection
QI 8	Process organisation	Details in the pathology report for lymphonodectomy
QI 9	Treatment procedures	Cytological/histological lymph node staging

The category of treatment procedures included 5 QIs (4 for OC, 1 for CC), while process organisation comprised 4 QIs (1 for OC, 3 for CC) (table 9).

A consistent very high implementation rate or a steady increase over time was displayed by PO QIs, which show to what extent processes and structures have been applied (e.g. CC: details in pathology report for lymphonodectomy – median 2015: 88.0% increasing to 2019: 97.8%; OC: operation of advanced ovary carcinoma by a gynaecological oncologist – median 2014: 100.0% staying stable to 2019: 100.0%).

A relatively high implementation rate overall was displayed by the TP QIs reporting on treatment methods, although the average is subject to a degree of fluctuation over time (e.g., OC: macroscopic complete resection in advanced OC – median 2014: 58.8%; 2015: 62.5%; 2016: 70.0%; 2017: 69.6%; 2018: 68.3.0%; 2019: 75.0%).

To further break down the TP QI category, a good to very good implementation rate is displayed by TP QIs relating to systemic therapy recommendations, but according to the

analysis the average not only fluctuates but decreases over time (OC: post-operative chemotherapy for advanced ovary carcinoma – median 2014: 94.6% to 2019: 88.9%; OC: first-line chemotherapy for advanced ovary carcinoma – median 2014: 69.2% to 2019: 60.1%).
Contrary to this, the TP QI results relating to surgical intervention results display an overall average good to very good implementation rate that fluctuates over time but has increased over the last 4 years (QI 1 surgical staging of early OC – median 2014: 75.0% to 2019: 81.8%; QI 2 macroscopic complete resection for advanced OC – median 2014: 58.8% to 2019: 75.0%)
5 out of 9 QIs have shown a positive trend according to the Cochran-Armitage test, 4 of which are in the category of treatment procedures and 1 in process organisation.

Trends were analysed over a period of 4 years for QI 2 “macroscopic complete resection for advanced OC”, QI 4 “post-operative chemotherapy for advanced OC” and QI 5 “first-line chemotherapy for advanced OC”, whereas this analysis was carried out over a period of 3 years for QI 9 “Cytological/histological lymph node staging”.

4. Discussion

4.1 Short summary of results

This dissertation describes for the first time the systematic process behind compiling and updating QIs in accordance with the German evidence-based guidelines for endometrial, cervical and ovarian carcinoma, as well as presenting a differentiated overview of the implementation rate and development of QI results in accordance with the guideline for OC and CC in certified GCCs.

The purpose of QIs is to assess the results of patient care and to improve its quality accordingly [12], for which it is essential that the QIs are based on the latest medical knowledge and that the criteria of relevance, scientific foundation, practicality, influenceability of indicator outcomes, data availability, risk adjustment and implementation obstacles are taken into consideration [2, 30]. The approach presented comprises multiple steps, starting with using strong guideline recommendations as a basis for QIs, followed by a selection and evaluation in accordance with the mentioned criteria, coupled with carrying out an international QI search to widen the perspective [11].

The catalogue of requirements of the GCC certified according to the German Cancer Society system actively apply the presented quality indicators [17].

The certified GCCs implement the guideline recommendations to a high or very high degree, as proven by the results of the evaluated QIs, showing the quality of care and enabling a comparison of the results of different centres.

The improvement potential of QIs can be assessed in detail by dividing the analysed QI into the two categories of process organisation and treatment procedures, as well as enabling the identification of appropriate improvement measures that the certified centres can put into practice.

4.2 Development and updating quality indicators

The levels of maturity vary between the three presented QI sets, clearly showing how updating the guideline and feedback from clinical routine by means of QI implementation data are interwoven and what improvements could be made for further QI updates and new developments. It must be taken into consideration with regard to quality indicators that it normally takes more than 2 years until the first results for the guideline indicators

are available to report, due to the fact that it is necessary to consider a long enough time period, usually at least one calendar year, as well as an adequate number of patients or events. Furthermore, it may be necessary to set up new processes, structures and data fields in order to implement a new quality indicator and to apply a recommendation in everyday care. It is therefore advisable for the indicator only to be mandatory in certification as from the second year of observation [33] thus EC QI data does not allow any conclusions to be drawn about patient care yet.

The most frequently updated and longstanding guideline and QI set within the certified GCC are for ovarian carcinoma, with availability of implementation data since 2014 and regular feedback between the QIWG and certified GCC. The revision of the QI entitled “first-line chemotherapy for advanced OC” represents a good example of how the development of recommendations and clinical routine feedback through GCC data are positively interwoven. It had been proven by the implementation data reported by the GCC that it made sense to separate doses and duration from the substance in the numerator. Previously it showed the number of patients with 6 cycles of first-line chemotherapy with carboplatinum AUC 5 and paclitaxel 175mg/m2, whereas the new version stated the number of patients with first-line chemotherapy with Carboplatin and Paclitaxel [24, 26]. The numerator can therefore still include the addition of further substances, e.g. in the context of studies, while the QI documentation can include a larger number of patients and provide meaningful results. Therefore, rapidly changing areas such as specific therapeutics should not be included in the operationalization of a QI [33]. Further, by keeping the definitions of the QI numerator and denominator as simple as possible misinterpretation during the documentation process can be prevented. Having an “either or” in the numerator often excludes a strong recommendation from becoming a QI because it cannot be operationalized as the measurability is not given.

The living guideline concept has been developed and applied since 2021 to ensure a more rapid update when new evidence becomes available (i.e. results from the currently ongoing ECLAT study [53]) with the goal to improve the timeliness of the guidelines and to be able to react fast and if necessary adapt implemented QIs.

The foundation of every grade A “must” recommendation and therefore every QI has to be an advanced evidence research based on numerous high-quality studies (i.e., for grad 1++ rating: high-quality meta-analyses, systematic reviews of RCTs or RCTs with very low risk of systematic errors (bias)) or strong expert consensus (>95% of those with voting

rights is necessary) [11]. Building up a solid advanced evidence foundation in order to proclaim a grade A recommendation takes time.

For instance, in the OC guideline from 2013 [54] 2 phase II studies [55, 56] were able to show a significantly prolong progression-free survival by administering bevacizumab in parallel with chemotherapy and as maintenance therapy for a total of 12 and 15 months, respectively. However, data on overall survival were not (yet) available. Hence the guideline recommendation read “in advanced ovarian cancer (IIIB-IV), additional treatment with bevacizumab *could* be considered”. In 2019 data on overall survival from the above studies became available. Further studies on the topic, however, showed that overall survival was significantly improved only in subgroups (high tumour burden, stage IV or high-grade serous subtype), and deterioration in quality of life was small but significant [57-59]. The recommendation remained therefore unchanged. Only in the update of 2021 the body of knowledge and thus the number of studies in regard to maintenance therapy had substantially increased. Amongst others the SOLO-1 study [60] and the PAOLA-1/AGO-OVAR 20 [61] study investigated different combination of the efficacy of maintenance therapy with the PARP inhibitor Olaparib in patients with high-grade serious or endometroid ovarian carcinoma, tubal carcinoma or primary peritoneal carcinoma taking into account the BRCA mutation status. Overall, the studies were able to show a significantly improvement in the progression free survival. No negative changes in the quality of life due to maintenance therapy were detected. The recommendation in the guideline was consequently modified. However, as data on overall survival of the studies is not yet available, the guideline group agreed on a “should” recommendation: “In advanced ovarian cancer (III-IV), additional maintenance therapy should be given”. Similarly can be seen in the EC guideline update from 2018 to 2022 where a total of 3 recommendations were upgraded from “should” to “must” based on the growing body of evidence, i.e. “Post-operative sole vaginal brachytherapy”, “Adjuvant chemotherapy with Carboplatin and Paclitaxel” and “Precurtain radiotherapy with simultaneous chemotherapy (PORTEC 3 schemata).”

QI development incorporates an international search for QIs that are used in other settings, which aims to compare the identified international strong recommendations and those that are already part of the S3 guideline. The QIWP assesses whether a QI found during the additional search is relevant for the S3 guideline update and whether it might prompt an innovation or modification, as well as analysing whether it is an existing or

potential new QI and whether the recommendation has already been included as a standard in the CoR [11]. Focus is always on those international QIs that have been implemented and where results are available.

For instance, discussion was prompted at the QIWG for CC by the results of the international QI search, with a focus on the proposal to document the ratio of patients with surgically treated cervical cancer with clear resection margins [38, 41], along with the ratio of patients undergoing radical radiotherapy with treatment lasting no longer than 6 days [38, 41], and to include these in the next guideline update.

It was proposed that the findings should be a subject of discussion at the forthcoming meeting of the GCC Certification Commission, as they include topics that are relevant for implementation such as the recurrence rate of 2 years in patients at stage pT1b1 with negative lymph nodes (LNs) after primary surgical treatment for cervical cancer [43]. Interestingly, this recommendation was not deemed suitable to be implemented as a classical QI in the data sheet, but rather proposed to be included as a standard in the certification documents (= on-site review of the implementation process). Thus, QI, as a tool for quality improvement, is not suitable for all areas with potential for improvement. Therefore, the cancer centre certification system offers different options, quantitative and qualitative, how to include strong recommendations from the evidence-based guidelines in the clinical routine.

Unfortunately, more often than not the international search does not produce results that make a relevant contribution to the updating of the QI and/or certification requirements while being a time and cost consuming exercise. Therefore, it recently has been questioned whether the search for international QIs, which often yield no information about the applied deriving methodology and rarely displays any results of the proposed QIs, should be restructured or even completely dismissed.

4.3 Analysis of quality indicators results

Newly developed and updated QI are implemented in the certified cancer centre in cooperation with the cancer centre certification commissions. By being implemented in the certified cancer centres the QIs and their results can be analysed and used for quality assurance and improvement in oncological care and give a first impression of the status of patient care for specific tumour entities. Implementing, documenting, reflecting and analysing QI results is crucial not only for quality assurance and assessment of level of

guideline compliant care but also to define measures for continuous quality improvement of quality of care.

In summary, the guideline contents are implemented to a high or very high degree at the certified GCCs for the evaluated QIs, showing the quality of care and allowing a comparison of results between centres.

In the article accompanying the dissertation, Griesshammer et al [35] carried out a thorough analysis of the implementation rate and results of QIs for CC and OC between 2015-2019, introducing a categorisation of QIs into two groups. This allows a differentiated overview of the degree of implementation and makes it easier to identify suitable improvement measures that can be taken at the certified centres.

There has been a wide application of QIs that reflect the implementation of processes and structures within the certified networks, with results showing a very high implementation rate for the category of QIs pertaining to procedural aspects (2019: QI 3: 100%; QI 6: 100%, QI 7: 92.3%; QI 8: 97.8%), often achieved immediately after their introduction (e.g., QI 3 and QI 6 each 2015: 100% and 2019: 100%) and maintained over the course of time (*compare table 9 for QI numbering*).

For example, making it mandatory for surgical treatment of advanced ovarian cancer to be carried out exclusively by specialised gynaecologists has a positive impact on results and life expectancy [5, 6, 55, 56], as well as being easy to achieve by means of a top-down process structure. It is possible to apply the same process within the network and among cooperation partners when it comes to implementing QI 6 (= tumour board presentation rate) and specifying the mandatory information to be included in pathology reports, e.g. initial diagnosis, tumour resection and an indication that lymphadenectomy is complete, if applicable (= QI 7 and QI 8).

The quality of patient care is significantly influenced by these procedural QIs that are relatively easy to implement at GCCs, for example through standardised operating procedures and handling instructions.

It is therefore easily possible in principle for each certified centre to achieve the target values of these indicators, in consideration of legitimate individual cases such as emergency surgery, which precludes presentation at the pre-treatment tumour board. The audit states a “deviation” if this indicator group is repeatedly and unjustifiably not fulfilled. The certificate may be withdrawn in case of an ultimate failure to meet the requirements of the indicators.

A somewhat different picture is presented by results from QIs reporting on treatment procedures such as surgical interventions and systemic therapy recommendations.
The analysis shows that a good but decreasing implementation rate over time applies to QIs calling for the implementation of systemic therapy in accordance with guideline recommendations (QI 4: 2014 94.6% to 2019 88.9% and QI 5 2014 69.2% to 2019 60.3%).
For both QIs, the centres which did not meet the target values provided explanations that primarily included patient-related reasons (e.g. patient death after surgery, patient wishes, existing comorbidities and/or poor general state of health, termination of treatment due to side effects). Regarding QI 5(= first-line chemotherapy for advanced OC), treatment regimens were also often changed due to comorbidities and poor general health.
Reasons for patients being missing, despite chemotherapy recommendations being issued during the tumour boards, included patients being treated outside the network, as well as the data reporting time, i.e. patients only being included in the numerator upon completing treatment. Bearing in mind in this respect that only if the number of patients is below the threshold (QI 4 <30%; QI 5 <20%) is it necessary to provide a written explanation. In other words, if the overall number of eligible patients in the numerator remains above the threshold but decreases on average, reasons do not need to be given by the GCCs.
This preliminary evaluation provides a basis for arguing that contrary to the results of the PO QIs, the implementation rate for QIs that document the application of systemic therapy reaches a steady plateau, whereby the practitioners are aware of the guideline recommendations but a further increase in rate cannot be reached on patient-related grounds.
A higher age and/or multiple comorbidities and/or other treatment regimens could be linked to the decreasing implementation rate. However, the present data set does not allow this to be investigated further, as socio-demographic information and details of comorbidities are not yet available or not in adequate depth.
A wider scope for improvement measures, on the other hand, is presented by TP IQs that report on surgical interventions, reflecting not only patient-related factors such as comorbidities, a poor overall state of health and patient rejection of surgery but also the competence of the surgical team. Surgical treatment is a fundamental pillar in the treatment strategy for OC and CC, representing an important diagnostic tool as well as directly and

strongly influencing the prognosis, as part of a largely multimodal and interdisciplinary concept of treatment [57].

Over time, the data shows an increase in the implementation rate before levelling out, as for the QI reporting on systemic therapy (e.g. 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%).

Reasons for not achieving the target value of QI 9 (= cytological/histological lymph node staging) included undergoing radio/chemotherapy before the cytological/histological lymph node staging, in consideration of the fact that there was often a small denominator on the surgical QIs. The most common reason for no complete macroscopic resection with regard to QI 2 (= macroscopic complete resection in advanced OC) was stated as the presence of multiple (distant) metastases. Furthermore, some patients decided to undergo treatment outside of the certified network, as stated above. Alongside these patient-related reasons, the most commonly stated grounds for not achieving the QI target value include an inoperable situs due to the advanced spread of carcinoma or the surgery being considered unfeasible during the interoperative assessment. It was repeatedly stated for QI 2 that it was only possible to reduce the size of the tumour but not to remove it. Whether other surgical teams would have made the same assessment and reached the same conclusions cannot be determined on the basis of this data, unfortunately. GCC auditors and physicians discuss at the audit whether the results are justifiable, albeit any explanations for discrepancies tend to be brief and lacking in detail [58].

The personal competence of the practitioners in combination with technical prerequisites are most relevant for identifying potential improvement measures with regard to these QIs. The option of additional surgical courses or coaching could be among the measures for improving the implementation rate of this QI set, alongside peer discussions of the results at the audit.

On an individual centre level, there can be a wide variation from year to year in the results for macroscopic complete resection, surgical staging for early OC and cytological/histological LN staging, as shown interestingly by the data. The current data available cannot provide explanations for these fluctuations. The primary purpose of the data collection must be taken into consideration when interpreting the results, forming a basis for deciding whether the certificate should be issued [58]. It is therefore necessary to investigate further. One hypothesis for explaining why various centres with high indicator results one year can have lower results the next could be staff changes within the surgical team. It is

plausible that certified GCCs with a consistently high implementation rate offer a good environment for surgeons in training and may be chosen to offer coaching courses for other GCCs.

4.4 Limitations of the study and implications for further research

Little data has been published to date on the methodology behind the development of QIs based on guidelines and a wide variety of approaches are taken [44, 59, 60] . Similarly, few publications deal with updating existing QIs derived from guidelines [33, 61]. We have sought here to contribute to increasing the transparency of this process and maybe to raising the quality of cancer care, based on established QI processes in Germany based on guidelines. In order to offer a complete picture, it is necessary to implement additional measures to those described here.

It must be taken into consideration that only process-related and structural indicators are addressed when using guideline-based QIs and implementing them does not necessarily being about the required improvement in patient-related outcomes such as quality of life, morbidity or overall life expectancy [29]. Nevertheless, it may be assumed that the recommendations of the guideline group were based on indication of a positive effect on the endpoints because of the advised intervention [29].

A particular challenge is posed by the follow-up of individual patients in the long term, due to the involved centres usually having no direct access to this data. In order to track the individual progress of diseases over time, linking the data collected by various centres with clinical cancer registry data will be a useful resource [33].

Moreover, the process does not provide for patient- reported outcomes to be included, for which other methods such as patient surveys and separate documentation are needed [30, 33].

In order to evaluate the compliance of treatment procedures with recommendations, the highly complex nature of routine care situations must be taken into consideration, and it is not easy to draw conclusions about the quality of care from raw QI data [58]. For example, the fact that the results of a QI have not achieved a predefined target value does not necessary signify an underperformance by the providers. An assessment of the quality of care requires additional information in this case [58]. As part of the on-site audit, the explanations provided by the certified centres are therefore discussed with the auditor, who checks random patient files. The auditors pronounce a “deviation” if the centre

provides inadequate explanations which the centres must remedy, whereas no further action is needed if the explanations are deemed plausible and adequate [22].

When it comes to interpreting data, the following further limitations must be highlighted. Firstly, it is not possible to assess information about individual patients regarding socio-demographics or the severity of the case as the individual centres only submit aggregated data. Secondly, it is possible that a selection bias applies to the centres included in this analysis, as it is often only centres that are already performing well that participate in quality assurance schemes. Thirdly, it is not possible to link the data studied here with survival data from registries.

5. Conclusions

It is important for all the involved disciplines and professional groups, as well as specialised medics, to collaborate closely in order to ensure optimal treatment and results for women with gynaecological malignancies. Practitioners are encouraged to reflect critically on the outcome of their treatment with the help of QIs, which also help to cement everyday clinical practice and treatment based on the content of guidelines. In the audit procedures, these results are discussed, and measures are identified that enable better application of the guideline contents.

Existing comorbidities, rejection of therapy or other factors pertaining to patients often prevent the target values from being reached. Quality assurance is achieved by taking a procedure in line with guidelines and certification into account and modifying it on the basis of consultation with patients and/or partners at the centre. Should the recommendations in the guideline not be applied systematically, however, then the auditor and the centre will decide on measures for enforcing the guideline, followed by an audit for evaluating the success of these measures. Thus, with the certification, a classic Plan-Do-Check-Act cycle is implemented in oncological care, which is based on the recommendations of the guideline.

The QI improvement potential can be assessed variously and suitable measures for improvement can be identified by classifying the analysed QIs as either process organisation or treatment procedures, as shown by analysing the QI results for ovarian and cervical cancer. It shows that a combination of different measures is necessary in order to anchor quality sustainably in health care and thus improve it.

Regular reports to the medical guideline development groups on the QI results provide information on the degree to which everyday clinical practice is implementing the recommendations, as a basis for further proposals as to how the guidelines could be developed and improved. Hence through the Quality Circle in Oncology a Plan-Do-Check-Act cycle has also been implemented successfully on the system-level.

With the described structures and processes of quality assurance and improvement in oncology, it has been possible to establish a system in everyday clinical practice that is actively used by practitioners and at the same time generates important findings for further developments in oncology. A unique selling point has been realised for oncology in Germany, which defines the quality of oncological treatment, records differences between

the actual and target state of treatment and is oriented towards the continuous improvement of quality.

Up until today the participation in the cancer centre certification program is voluntary even though various studies show the significant improvement for patient-related outcomes (i.e. overall survival, hospital lethality, follow-up resection rate) when treated in a certified centre [62-67]. Only slowly the legislative in Germany is catching up and the KHSG (Krankenhausstrukturgesetz = Act on the Reform of Hospital Care Structures) that came into effect January 2016 has for the first time placed a focus on the quality of treatment. Discussions on health policy have therefore had an increasing emphasis on the quality of the certified centres in line with guidelines. This positive development includes awarding additional funds, such as to certified so called Oncology Centres of the German Cancer Society, consisting of more than one tumour entity, in certain federal states, in accordance with § 9 par. 1a no. 2 KHEntgG (Krankenhausentgeltgesetz = Hospital Fees Act), drawn up in cooperation with the GKV Spitzenverband Spitzenverband Bund der Krankenkassen = National Association of Health Insurance Funds).

Minimum volume regulation discussions, as well as the proposal for the organised cervical carcinoma screening programme of the G-BA (Gemeinsamer Bundesausschuss = Federal Joint Committee), also consider these certified centres. Quality-assured care in certified centres is thus increasingly used as a health policy instrument for the definition and design of care structures.

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Statutory Declaration

“I, *Ellen Griesshammer*, by personally signing this document in lieu of an oath, hereby affirm that I prepared the submitted dissertation on the topic “Certified gynaecological cancer centres: Analysis of guideline-based quality indicators for endometrial, ovarian and cervical cancer [*Zertifizierte gynäkologische Krebszentren: Analyse leitlinienbasierter Qualitätsindikatoren für Endometrium-, Eierstock- und Gebärmutterhalskrebs*], inde-pendently and without the support of third parties, and that I used no other sources and aids than those stated.
All parts which are based on the publications or presentations of other authors, either in letter or in spirit, are specified as such in accordance with the citing guidelines. The sections on method-ology (in particular regarding practical work, laboratory regulations, statistical processing) and results (in particular regarding figures, charts and tables) are exclusively my responsibility.

My contributions to any publications to this dissertation correspond to those stated in the below joint declaration made together with the supervisor. All publications created within the scope of the dissertation comply with the guidelines of the ICMJE (International Committee of Medical Journal Editors; http://www.icmje.org) on authorship. In addition, I declare that I shall comply with the regulations of Charité – Universitätsmedizin Berlin on ensuring good scientific practice.

I declare that I have not yet submitted this dissertation in identical or similar form to another faculty.

The significance of this statutory declaration and the consequences of a false statutory declara-tion under criminal law (Sections 156, 161 of the German Criminal Code) are known to me.”

Date Signature

Declaration of your own contribution to the publications

Ellen Griesshammer contributed the following to the below listed publications:

Publication 1: Griesshammer, E., Wesselmann, S., Beckmann, M.W., Dannecker, C., Wagner, U., Sibert, N.T., Armbrust, R., Sehouli, J.,: Quality assurance and improvement in oncology using guideline-derived quality indicators –results of Gynaecological Cancer Centres certified by the German Cancer Society (DKG), Journal of Cancer Research and Clinical Oncology, 2022

Contribution:

- Study conception and design was developed by me and discussed with co-authors
- First draft of the manuscript till final version was written by me
- Statistical analyses were developed and executed by me based on discussion with supervisors
- Discussion was developed and written by me; co-authors provided comments
- All tables except table 7 and 8 were developed and prepared by me.

_____

Signature, date and stamp of first supervising university professor / lecturer

_____

Signature of doctoral candidate

Excerpt from Journal Summary List

Journal Data Filtered By: **Selected JCR Year: 2021** Selected Editions: SCIE,SSCI
Selected Categories: **"ONCOLOGY"** Selected Category Scheme: WoS
Gesamtanzahl: 246 Journale

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfaktor
1	CA-A CANCER JOURNAL FOR CLINICIANS	61,124	286.130	0.09703
2	NATURE REVIEWS CANCER	66,699	69.800	0.05330
3	Nature Reviews Clinical Oncology	22,751	65.011	0.04148
4	LANCET ONCOLOGY	79,244	54.433	0.13790
5	ANNALS OF ONCOLOGY	68,844	51.769	0.11379
6	JOURNAL OF CLINICAL ONCOLOGY	195,709	50.717	0.24244
7	Molecular Cancer	32,250	41.444	0.03386
8	CANCER CELL	57,294	38.585	0.07359
9	Cancer Discovery	31,182	38.272	0.06475
10	JAMA Oncology	27,216	33.006	0.08103
11	Nature Cancer	2,315	23.177	0.00816
12	Journal of Hematology & Oncology	15,318	23.168	0.02209
13	Journal of Thoracic Oncology	27,842	20.121	0.03995
14	Trends in Cancer	6,389	19.161	0.01397
15	SEMINARS IN CANCER BIOLOGY	14,777	17.012	0.01217
16	Cancer Communications	2,334	15.283	0.00391
17	CLINICAL CANCER RESEARCH	115,272	13.801	0.11972
18	CANCER TREATMENT REVIEWS	12,869	13.608	0.01455
19	Annual Review of Cancer Biology-Series	1,098	13.340	0.00327
20	CANCER RESEARCH	161,957	13.312	0.09051
21	NEURO-ONCOLOGY	20,825	13.029	0.02439

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfaktor
22	LEUKEMIA	37,644	12.883	0.05281
23	Journal of the National Comprehensive Cancer Network	11,409	12.693	0.02340
24	JOURNAL OF EXPERIMENTAL & CLINICAL CANCER RESEARCH	21,000	12.658	0.02369
25	Journal for ImmunoTherapy of Cancer	17,971	12.469	0.03889
26	Liver Cancer	2,266	12.430	0.00279
27	Cancer Immunology Research	13,374	12.020	0.02275
28	JNCI-Journal of the National Cancer Institute	42,351	11.816	0.03266
29	BIOCHIMICA ET BIOPHYSICA ACTA-REVIEWS ON CANCER	8,255	11.414	0.00673
30	npj Precision Oncology	1,529	10.092	0.00306
31	EUROPEAN JOURNAL OF CANCER	42,283	10.002	0.04364
32	Frontiers of Medicine	3,310	9.927	0.00495
33	JOURNAL OF PATHOLOGY	23,413	9.883	0.01467
34	Blood Cancer Journal	5,662	9.812	0.01211
35	CANCER LETTERS	45,756	9.756	0.03380
36	CANCER AND METASTASIS REVIEWS	8,658	9.237	0.00541
37	BRITISH JOURNAL OF CANCER	57,544	9.075	0.03668
38	ONCOGENE	81,646	8.756	0.05014
39	Biomarker Research	1,811	8.633	0.00231
40	Experimental Hematology & Oncology	1,325	8.593	0.00159
41	Clinical and Translational Medicine	3,641	8.554	0.00433
42	JACC: CardioOncology	614	8.422	0.00197
43	BREAST CANCER RESEARCH	14,509	8.408	0.01230

Selected JCR Year: 2021; Selected Categories: "ONCOLOGY"

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfaktor
44	European Urology Oncology	2,263	8.208	0.00571
45	INTERNATIONAL JOURNAL OF RADIATION ONCOLOGY BIOLOGY PHYSICS	53,680	8.013	0.03572
46	Cancer Nanotechnology	755	7.917	0.00059
47	BIODRUGS	3,113	7.744	0.00409
48	OncoImmunology	16,984	7.723	0.02608
49	Gastric Cancer	8,180	7.701	0.01146
50	npj Breast Cancer	1,825	7.519	0.00534
51	Molecular Oncology	10,088	7.449	0.01098
52	INTERNATIONAL JOURNAL OF CANCER	63,848	7.316	0.04705
53	Clinical Epigenetics	7,035	7.259	0.01153
54	CELLULAR ONCOLOGY	3,031	7.051	0.00296
55	CANCER	80,797	6.921	0.05721
56	RADIOTHERAPY AND ONCOLOGY	25,363	6.901	0.02575
57	ESMO Open	3,418	6.883	0.00811
58	CANCER IMMUNOLOGY IMMUNOTHERAPY	13,535	6.630	0.01220
59	CRITICAL REVIEWS IN ONCOLOGY HEMATOLOGY	12,063	6.625	0.01274
60	Cancers	56,338	6.575	0.07275
61	Oncogenesis	4,572	6.524	0.00664
62	CANCER SCIENCE	21,270	6.518	0.02009
63	Cancer Cell International	11,032	6.429	0.01119
64	MOLECULAR CANCER RESEARCH	12,521	6.333	0.01158
65	Molecular Therapy-Oncolytics	2,599	6.311	0.00406

Selected JCR Year: 2021; Selected Categories: "ONCOLOGY"

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfaktor
66	NEOPLASIA	10,164	6.218	0.00671
67	LUNG CANCER	16,814	6.081	0.01736
68	MOLECULAR CANCER THERAPEUTICS	24,911	6.009	0.02006
69	ORAL ONCOLOGY	15,089	5.972	0.01498
70	Current Oncology Reports	4,214	5.945	0.00673
71	American Journal of Cancer Research	9,438	5.942	0.01066
72	ENDOCRINE-RELATED CANCER	8,931	5.900	0.00732
73	INTERNATIONAL JOURNAL OF ONCOLOGY	22,192	5.884	0.01410
74	CANCER GENE THERAPY	4,649	5.854	0.00320
75	STEM CELLS	23,222	5.845	0.01184
76	ONCOLOGIST	18,814	5.837	0.02482
77	Advances in Cancer Research	3,514	5.767	0.00224
78	Frontiers in Oncology	43,416	5.738	0.05962
79	CANCER IMAGING	2,779	5.605	0.00303
80	Therapeutic Advances in Medical Oncology	4,034	5.485	0.00622
81	JCO Precision Oncology	3,366	5.479	0.01188
82	PROSTATE CANCER AND PROSTATIC DISEASES	3,875	5.455	0.00583
83	SEMINARS IN RADIATION ONCOLOGY	3,100	5.421	0.00302
84	SEMINARS IN ONCOLOGY	5,860	5.385	0.00334
85	Cancer Biology & Medicine	2,700	5.347	0.00315
86	GYNECOLOGIC ONCOLOGY	31,104	5.304	0.02524
87	BONE MARROW TRANSPLANTATION	16,828	5.174	0.01411
88	Cancer & Metabolism	1,394	5.146	0.00141

Selected JCR Year: 2021; Selected Categories: "ONCOLOGY"

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfaktor
89	MOLECULAR CARCINOGENESIS	7,727	5.139	0.00622
90	Breast Cancer-Targets and Therapy	1,110	5.088	0.00139
91	CURRENT TREATMENT OPTIONS IN ONCOLOGY	2,884	5.080	0.00480
92	Cancer Research and Treatment	4,216	5.036	0.00627
93	Journal of Hepatocellular Carcinoma	748	4.962	0.00099
94	ONCOLOGY RESEARCH	3,519	4.938	0.00380
95	CLINICAL ONCOLOGY	5,096	4.925	0.00556
96	JOURNAL OF IMMUNOTHERAPY	4,107	4.912	0.00247
97	CANCER BIOLOGY & THERAPY	9,867	4.875	0.00508
98	Targeted Oncology	2,294	4.864	0.00344
99	HEMATOLOGICAL ONCOLOGY	2,393	4.850	0.00465
100	Clinical Lung Cancer	4,830	4.840	0.00720
101	Translational Oncology	5,133	4.803	0.00594
102	Journal of Gynecologic Oncology	2,658	4.756	0.00364
103	CARCINOGENESIS	21,884	4.741	0.00715
104	Clinical and Translational Radiation Oncology	1,452	4.739	0.00332
105	Translational Lung Cancer Research	4,443	4.726	0.00679
106	Cancer Medicine	16,201	4.711	0.02816
107	Hormones & Cancer	1,045	4.667	0.00103
108	INTERNATIONAL JOURNAL OF GYNECOLOGICAL CANCER	10,569	4.661	0.01049
109	BMC CANCER	46,148	4.638	0.05196
110	BREAST CANCER RESEARCH AND TREATMENT	26,837	4.624	0.02640

Selected JCR Year: 2021; Selected Categories: "ONCOLOGY"

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfaktor
111	CLINICAL & EXPERIMENTAL METASTASIS	4,236	4.510	0.00223
112	JOURNAL OF NEURO-ONCOLOGY	16,733	4.506	0.01490
113	Journal of Oncology	3,937	4.501	0.00415
114	Journal of Bone Oncology	1,247	4.491	0.00165
115	Journal of Cancer	14,324	4.478	0.01948
116	OncoTargets and Therapy	20,189	4.345	0.02645
117	ANNALS OF SURGICAL ONCOLOGY	38,645	4.339	0.03584
118	JOURNAL OF CANCER RESEARCH AND CLINICAL ONCOLOGY	11,257	4.322	0.01062
119	ACTA ONCOLOGICA	10,397	4.311	0.01084
120	Radiation Oncology	9,044	4.309	0.00986
121	CANCER CYTOPATHOLOGY	3,514	4.264	0.00438
122	GENES CHROMOSOMES & CANCER	6,079	4.263	0.00470
123	BREAST	7,219	4.254	0.00861
124	Radiology and Oncology	1,530	4.214	0.00188
125	Current Hematologic Malignancy Reports	1,591	4.213	0.00280
126	Pigment Cell & Melanoma Research	5,837	4.159	0.00368
127	EXPERIMENTAL CELL RESEARCH	25,250	4.145	0.01352
128	ONCOLOGY REPORTS	27,364	4.136	0.02055
129	Analytical Cellular Pathology	998	4.133	0.00092
130	CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION	23,000	4.090	0.01963
131	Journal of Cancer Survivorship	4,363	4.062	0.00646
132	EJSO	13,825	4.037	0.01516

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ORIGINAL ARTICLE – CLINICAL ONCOLOGY

Quality assurance and improvement in oncology using guideline-derived quality indicators – results of gynaecological cancer centres certified by the German cancer society (DKG)

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Abstract

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

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

Results QIs are divided into 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 degree of application. PO-QIs have a tremendous influence on the quality of care and are easy to implement 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-factors meaningfully prevent further increase. TP-QIs that report on surgical interventions fluctuate. The 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.

Keywords Quality indicators · Quality assurance · Health service research · Certification

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) (Langer and Follmann 2015). The German S3 guidelines are based on a systematic literature review, the presence of a representative interdisciplinary and interprofessional expert panel, including patient advocacy groups, and the use of a formal consensus-building process (Langer and Follmann 2015; Nothacker et al. 2014). An obligatory part of every S3 guideline development process is the definition of QIs from strong recommendations. These

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are considered suitable as a quality standard since it can be assumed that most patients will gain a clear benefit from the addressed actions of these recommendations. In a multistep 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' to an indicator is possible (Langer et al. 2017).

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), which serves as one of the core elements of the quality assurance and improvement process for certified cancer centres (Langer et al. 2017).

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 (Beckmann et al. 2016). In the context of guideline updates, the existing quality indicators are also subject to the updating process. Here, the results of the quality indicators are reviewed, and a decision is made as to whether the quality indicator must be retained or changed or, in the case of complete implementation, can be discontinued (Langer et al. 2017).

As of January 2022, 31 tumour-specific and cross-sectional S3 guidelines had 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 within the scope of a qualifying thesis for a 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) (Leitlinienprogramm Onkologie. Deutsche Krebsgesellschaft, Deutsche Krebshilfe, AWMF): S3-Leitlinie Diagnostik, Therapie und Nachsorge maligner Ovarialtumoren 2021). As of 2019, a total of 164 GCCs had been certified (Krebsgesellschaft e.V. Jahresbericht der zertifizierten Gynäkolgoischen Krebszentren 2020), and about 55% of all patients in Germany with a first diagnosis (primary case) of a gynaecological tumour[1] in 2019 were treated in these certified GCC[2] (Krebsgesellschaft e.V. Jahresbericht der zertifizierten Gynäkolgoischen Krebszentren 2020). 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 (Robert Koch Institut 2016).

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 and guideline adherence and discuss, if necessary, improvement measures (Mensah et al. 2017).

Especially for gynaecological tumours, various studies have shown that the interdisciplinary cooperation and highly specialised surgical expertise of the clinic and surgeons as well as the surgical case volume have been of great benefit to patients and have had a relevant influence on the clinical outcome (Wright et al. 2011; Bristow et al. 2009; Bois et al. 2009; Munstedt et al. 2003).

The focus of this study will be on two selected gynaecological tumours, namely ovarian and cervical cancers. For both tumour entities, S3 guidelines are available and regularly updated (Leitlinien Programm Onkologie (Deutsche Krebsgesellschaft, Deutsche Krebshilfe, AWMF). S3-Leitlinie Diagnostik, Therapie und Nachsorge maligner Ovarialtumoren; Leitlinien Programm Onkologie (Deutsche Krebsgesellschaft Deutsche Krebhilfe, AWMF). S3-Leitlinie Diagnostik, Therapie und Nachsorge der Patientin mit Zervixkarziom 2021), and in GCCs it has been obligatory to document QIs for these two entities since 2014 for OC and 2015 for CC. For endometrial and vulvar tumours, QIs have been implemented only recently, in 2018 and 2016, respectively, and no S3 guideline is yet available for vulvar carcinoma.

Comprising 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 (Wesselmann et al. 2014; Robert Koch Institut 2016), representing 19.2% of incident cases of gynaecological neoplasms (Robert Koch Institut 2016). Despite advances in screening and prevention measures, invasive cervical carcinoma, at 11.4% of cases, remains the third most common gynaecological neoplasm

[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.

in women in Germany and worldwide (Robert Koch Institut 2016; Leitlinien Programm Onkologie (Deutsche Krebsgesellschaft Deutsche Krebshilfe, AWMF). Prävention des Zervixkarzinoms 2020).

Using the example of QIs for ovarian and cervical cancer, this study set out to investigate the development of the implementation rate over time, report results for the time period between 2015 and 2019, evaluate the status of guideline-compliant care and identify areas and corresponding measures to foster improvement. A further goal of this paper is to raise awareness of the potential of guideline-based QIs and their results to contribute to quality assurance and improvement in the 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.

Patients and methods

Data collection

Each GCC that intends to be (re-)certified must document fulfilment of the requirements. Annually, the results of key performance and quality indicators must be reported to OnkoZert, the independent certification institute that organizes the auditing procedure on behalf of the DKG. After collection 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 the 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 successful certification, cancer centres have to meet the target value or give a plausible explanation if they are not meeting the value (Adam et al. 2018).

Centres are audited regularly by trained gynaecological oncologic medical experts who check the reported data from the previous calendar year before the audit 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 QIs included in this study are derived according to a defined methodology (German Guideline Program in Oncology (German Cancer Society, German Cancer Aid, Association of the Scientific Medical Societies). Development of guideline-based quality indicators: methodology for the German Guideline Program in Oncology 2021) from the two evidence-based guidelines on the diagnosis, therapy and follow-up of malignant ovarian tumours and patients with cervical cancer published by the GGPO (Leitlinien Programm Onkologie (Deutsche Krebsgesellschaft, Deutsche Krebshilfe, AWMF). S3-Leitlinie Diagnostik, Therapie und Nachsorge maligner Ovarialtumoren 2021; Leitlininien Programm Onkologie (Deutsche Krebsgesellschaft Deutsche Krebhilfe, AWMF). S3-Leitlinie Diagnostik, Therapie und Nachsorge der Patientin mit Zervixkarziom 2021). 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 from 2014 onward and still included as of 2021 were taken into consideration. QIs that had been discontinued over time were not included in this analysis. An overview of discontinued QIs can be seen in (Table 1).

Data analyses

Descriptive analysis of the 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 were analysed. Only patients from GCCs that had certified status over the entire time period were considered. 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. The standard deviations on the centre level over time were calculated to analyse fluctuations.

Statistical analyses were performed using R version 3.5.1 and the Data-WhiteBox, a data analysis tool developed by OnkoZert. Cochran–Armitage tests were calculated using XLSTAT Version 2019.2.1, excluding centres that 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 ethics committee of Charité University Medicine in November 2021.

Results

The number of certified GCCs increased steadily from 2015 to 2019 from 112 to 149, and the number of patients with a primary diagnosis of a gynaecological malignancy treated in GCCs increased from 11,587 to 14,986. Therefore, even though the incidence of OC and CC in Germany has been decreasing over time from 7318 to 7292 and 4606 to 4341, respectively (Robert Koch Institut 2016), the number of patients treated for these two tumour entities has increased in GCCs (OC: 3301–3798 and CC: 2059–2479)

Table 1 Discontinued QIs for Ovarian and Cervical Cancer

Indicator	Implementation period	Reason for discontinuation
Ovarian Cancer QIs		
Non-adjuvant chemotherapy of early ovarian carcinoma	2014–2018	Indicator was discontinued due to complete implementation
Platinum-containing chemo-therapy for early ovarian 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 Ovarian Tumour)	2013–2018	Indicator was discontinued due to complete implementation
Genetic testing offer	2019	Was only included on the data sheet since 2019
Cervical Cancer QIs		
Cisplatinum-containing radio-chemotherapy	2014–2015	Indicator was discontinued due to decision to only include five QIs per tumour entity on the data sheet for certification
Adjuvant radio(-chemo) therapy	2014–2015	Indicator was discontinued due to decision to only include five QIs per tumour entity on the data sheet for certification
Histological confirmation	2014–2015	Indicator was discontinued due to decision to only include five QIs per tumour entity on the data sheet for certification
Spread diagnosis for local recurrence	2014–2015	Indicator was discontinued due to decision to only include five QIs per tumour entity on the data sheet for certification
Pelvic exenteration	2014–2018	Indicator was discontinued due to complete implementation on the data sheet for certification
Complete diagnostic report cervical conization	2021	Will be included in next update of data sheet (Kurzprotokoll zur Sitzung der Zertifizierungskommission Gynäkologische Krebszentren 2017)

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

(Krebsgesellschaft and e.V. Jahresbericht der zertifizierten Gynäkolgoischen Krebszentren 2020).

The indicators are defined and categorized in (Table 2) including the numerator, denominator and plausibility corridor for the reported QI results. QIs were divided into 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 explicitly recommended by the medical guideline within the certified network.

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

Five QIs were included in the category treatment procedures (four for OC, one for CC) and four QIs in process organization (one for OC, three 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 and 2019.

The implementation rate for PO-QIs that reflect the application of processes and structures either remained stable on a very high implementation level or increased steadily over 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 ovarian 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 an overall high implementation rate, yet the median fluctuates slightly over 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, 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

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

Name		Numerator	Denominator	Evaluation of results	Category
Quality indicators for the treatment of ovarian carcinoma					
1	Surgical staging of early ovarian carcinoma	Primary cases of the denominator with surgical staging with –Laparotomy –Peritoneal cytology –Peritoneal biopsies –Bilateral adnexal extirpation –Hysterectomy; where appropriate, extraperitoneal procedure –Omentectomy at least infracolic –Bilateral pelvic and para-aortal lymphonodectomy	Surgical primary cases ovarian carcinoma FIGO I – IIIA	Plausibility corridor > 20%	Treatment procedures
2	Macroscopic complete resection of advanced ovarian carcinoma	Surgical primary cases of ovarian carcinoma FIGO IIB-IV with macroscopic complete resection	Surgical primary cases with ovarian carcinoma FIGO IIB-IV	Plausibility corridor > 30% and < 90%	Treatment procedures
3	Surgery of advanced ovarian carcinoma by a gynaecological oncologist	Surgical primary cases of ovarian carcinoma FIGO IIB-IV, whose definitive surgical therapy was performed by a gynaecooncologist	Surgical primary cases of ovarian carcinoma FIGO IIB-IV after conclusion of surgical therapy	Plausibility corridor > 50%	Process organization
4	Post-operative chemotherapy in advanced ovarian carcinoma	Surgical primary cases of ovarian carcinoma FIGO IIB-IV with post-operative chemotherapy	Surgical primary cases of ovarian carcinoma FIGO IIB-IV and chemotherapy	Plausibility corridor > 30%	Treatment procedures
5	First-line chemotherapy for advanced ovarian carcinoma	Primary cases of ovarian carcinoma FIGO IIB-IV with six cycles of first-line chemotherapy carboplatin AUC 5 and paclitaxel 175 mg/m.^{2}	Primary cases of ovarian carcinoma FIGO IIB-IV	Plausibility corridor > 20%	Treatment procedures
Name		Numerator	Denominator	Evaluation of results	Category
Quality indicators for the treatment of cervical carcinoma					
6	Presentation at the tumour board	Patients (primary cases and 'non-primary cases') presented at the tumour board	Patients with an initial diagnosis, recurrence or new remote metastasis of a cervical carcinoma	Plausibility corridor > 20%	Process organization

Table 2 (continued)

Name		Numerator	Denominator	Evaluation of results	Category
7	Details in the pathology report on initial diagnosis and tumour resection	'Surgical primary cases' of 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 and FIGO) in the case of conisated 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 centimetres (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 The number of affected lymph nodes in relation to removed lymph nodes Assignment to sampling localisation (pelvic/para-aortal) Details of the widest spread of the largest lymph node metastasis in millimetres/centimetres Details of the detection/non-detection of capsule 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 for ovarian and cervical cancers; 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 of 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 of advanced ovarian 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 for advanced ovarian 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
4s	Post-operative chemotherapy for advanced ovarian 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 for advanced ovarian 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

Table 3 (continued)

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
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

The median is based on the rate of the individual certified centre. The absolute number as well as the overall proportions are based on the cumulative data of all certified centres

C-A Test, Cochran-Armitage test for trend, *p*-value is reported

decreasing over time (OC: post-operative chemotherapy advanced ovarian carcinoma—median 2014: 94.6% to 2019: 88.9%; OC: first-line chemotherapy of advanced ovarian carcinoma—median 2014: 69.2% to 2019: 60.1%).

By contrast, the overall median for TP-QI results referring to surgical interventions show a good to very good implementation rate, which increased over the past 4 years. The median fluctuates over time (QI 1 surgical staging in 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 using the annual QI quota of each centre, the overall mean SD of all QI was calculated and is displayed in a boxplot diagram in (Fig. 1a, b). Analysis of the implementation rate on the individual centre level shows that the results within one centre can vary over time. The mean SD for PO-QIs is the lowest, between 4.4 and 18.2 (e.g., QI 14 presentation at the tumour board CC, mean SD 4.4), the mean SD for TP-QIs that address systemic therapies lies between 11.8 and 16.2 (e.g., QI 12 post-operative chemotherapy for advanced OC, mean SD 11.8), and the mean SD for TP-QIs reporting surgical intervention is the highest, between 15.0 and 19.1 (e.g., QI 1 surgical staging early OC cumulative mean SD 19.1).

The Cochran-Armitage test shows positive trends for five out of nine QI. Positive trends in both categories show four QIs in treatment procedures and one 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.

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 can be compared between centres. Grouping the analysed QIs into two categories—process organization and treatment procedures—offers the opportunity to assess the improvement potential of QIs in a differentiated way and allows identification of 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 are very well applied. The results illustrate that QIs related to procedural

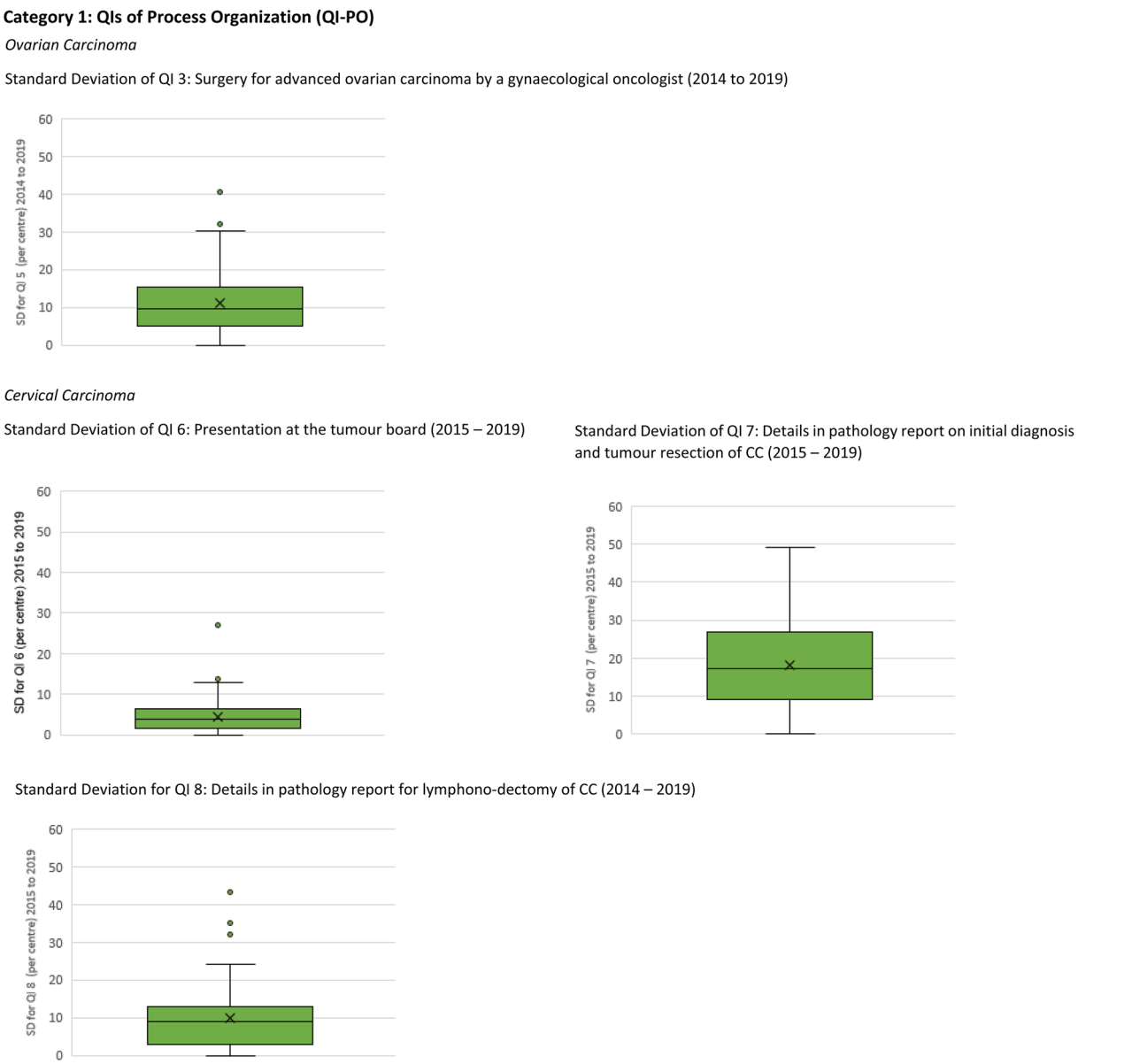

Fig. 1 Means of overall standard deviations of centres annual quotas for QIs evaluated between 2014 and 2019

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 often been realized right from its introduction (e.g., QI 1 and QI 6 each 2015: 100% and 2019: 100%) and is maintained over time. For instance, mandating that surgical therapy for advanced ovarian cancer can only be performed by specialized gynaecologists not only improves outcomes and lengthens survival (Bois et al. 2009; Munstedt et al. 2003; Begg et al. 1998; Junor et al. 1999) but is also easily achievable via a top-down process arrangement. The same process can be applied within the network and to cooperation partners regarding implementation of QI 6 (tumour board presentation rate) and the definition of mandatory information to be included in pathology reports, such as initial diagnosis, tumour resection and, if applicable, indication that lymphadenectomy is complete (QI 7 and QI 8).

These procedural QIs have a tremendous influence on the quality of patient care, 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 and 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,

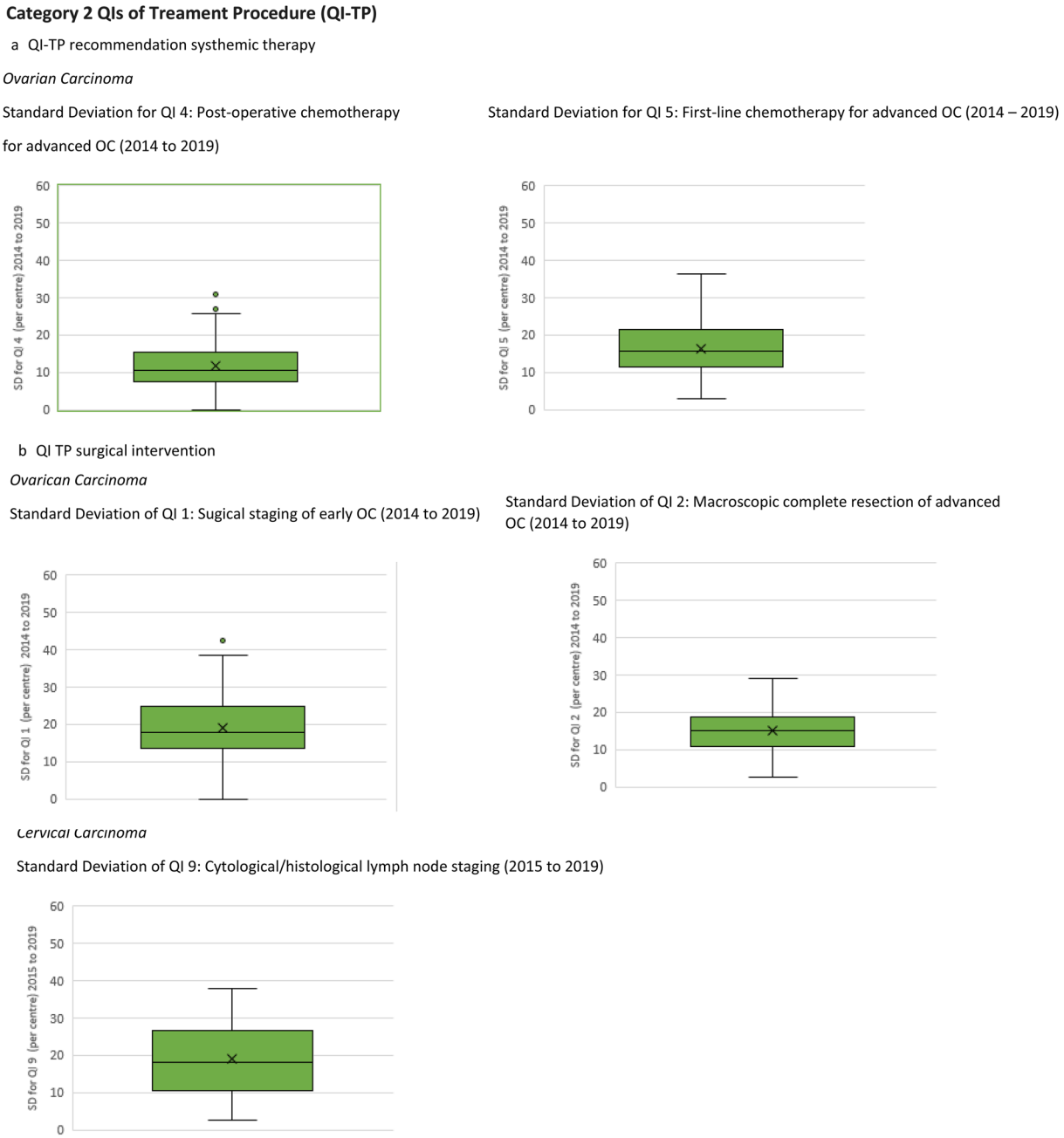

Fig. 1 (continued)

preventing presentation at the pre-therapeutic tumour board. In the case of repeated not-justifiable non-fulfilment of this indicator group, a 'deviation' in the audit will be given. An ultimate failure to fulfil the indicators can lead to 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 must be considered that situations in routine care are very complex, and conclusions from raw QI data on quality of care are not readily possible (Junor et al. 1999). For example, QI results that do not reach a pre-defined threshold (target value) do not necessarily indicate insufficient performance on the part of the providers. Under such circumstances, additional information is needed to decide whether quality of care is adequate or not (Junor et al. 1999). 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 not to be adequate, the auditors pronounce 'deviations' that need to be remedied by the centres (Kowalski et al. 2017). If the 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 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 QIs, 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 the time of data reporting (i.e., patients can only be counted in the numerator when the therapy is completed) were named as reasons why patients were missing even though the recommendations for chemotherapy was provided during the tumour boards. It must be kept in mind that written explanations only have 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 QIs documenting the application of systemic therapies reaches a plateau where the guideline recommendation is known to the practitioners, but patient-related factors prevent a further meaningful increase in 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 an older age and/or the 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 are not yet available or too superficial.

By contrast, TP-QIs that report on surgical interventions offer more room for improvement measures. This set of QIs reflects not only patient-related factors (i.e., comorbidities, poor overall health status, patient rejection of surgery) but also the professional expertise of the surgical team. Surgical therapy is one of the fundamental pillars of the treatment strategy for OC and CC. Not only is it the most important diagnostic instrument; it also has a direct and strong influence on prognosis and is part of a mostly multimodal and interdisciplinary therapy concept (Sehouli et al. 2019). Like QIs reporting on systemic therapy, the data show an increase over time and also reach 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 the Q9 (cytological/histological lymph node staging) target value mostly included the application of radio chemotherapy prior to cytological/histological lymph node staging. For QI 2 (macroscopic complete resection of advanced OC), the existence of multiple (distant) metastasis was given as the most frequent reason for an incomplete 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 included 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 could only be reduced in size but not removed. The data unfortunately do not allow us to assess if other surgical teams would have come to different conclusions 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 (Inwald et al. 2019).

The following further limitations need to be pointed out in the light of the data interpretation. Firstly, only aggregate data are submitted by the individual centres, hence assessment of individual patients' information regarding case severity or socio-demographics is not possible. Secondly, the centres included in this analysis could be prone to a selection bias as often only centres that are already performing well join 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, and when these are combined with technical prerequisites, opportunities to identify 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 additionally include offers of surgical courses or coaching.

Interestingly, the data also show that on the individual centre level, the results for macroscopic complete resection, sugical staging of early OC and cytological/hostological LN staging can vary widely from one year to another, with an overall standard deviation of up to 19. Reasons for these fluctuations cannot be provided with the currently available data. When interpreting the results, we must bear in mind the primary purpose of data collection, i.e., creating a basis for the decision of whether or not the certificate should be issued (Inwald et al. 2019). Further investigation is thus necessary. Notwithstanding, one hypothesis could be that, for

instance, staff changes in the surgical team could explain why several centres with high indicator results in 1 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 the best possible treatment outcomes for women with gynaecological malignancies, synergistic collaboration across all disciplines and professional groups involved in oncological care as well as the pursuit of specialization by physicians are important elements (Wesselmann et al. 2014).

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 1 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 further development of the guidelines. Furthermore, the results of this analysis, with a focus on ovarian and cervical cancer, suggest that dividing the analysed 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 to anchor quality sustainably in health care and thus improve it.

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Declarations

Conflict of interest The authors have no relevant financial or non-financial interests to disclose.

Ethical 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).

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Curriculum Vitae

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