# Development, Implementation and Evaluation of a Quality Management System for Cross-Sectoral Psycho-Oncological Care in Germany

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# Summary

**Introduction.** High-quality psycho-oncology care enhances patients' satisfaction, adherence to treatment, and overall well-being. Because in Germany rendering consistent care faces difficulties such as fragmented health care systems, integrating a quality management system may address these challenges by ensuring consistent, evidence-based care, enhancing interprofessional collaboration, continuously improving quality, and optimising resource allocation.

**Objectives.** The dissertation aims to develop, implement, and assess a quality management system for a multidisciplinary psycho-oncology approach care. Special attention is given to the development of quality indicators, the use of a participatory quality development approach, and the evaluation of the proposed concept. The purpose of this dissertation is to advance the furtherance of psycho-oncological care in Germany by identifying and assessing prospective measures and a quality management framework.

**Methods.** An embedded mixed methods design was implemented with a focus on quantitative data. Quality indicator development was based on the RAND/UCLA Appropriateness Method in combination with a Delphi technique. Participatory tools were used in the continuous improvement process, and the level of participation was assessed through a longitudinal survey. To evaluate the implementation of the quality management system, a utility analysis was carried out.

**Results.** A profound quality management system has been put in place comprising structural and procedural tools that cater to both internal and external necessities. A set of 16 quality indicators was operationalised and reviewed for relevance, comprehensibility, and suitability. The findings showcase that integrating a sustainable participatory quality development process into the quality management system is feasible but certain difficulties were also identified. The evaluation of the implementation of the quality management systems resulted in a utility score of 4.2 out of 5.0 (84.0%), indicating successful implementation. The implementation of top-down elements, such as contracts and manuals, was comprehensive, whereas bottom-up aspects, such as quality circles, presented more challenges.

**Conclusion.** This dissertation successfully implemented a robust quality management system to enhance psycho-oncological care, achieving key objectives such as developing and digitally integrating comprehensive quality indicators. Despite successful stakeholder engagement, challenges in balancing bottom-up dynamics with top-down structures were identified, highlighting the crucial role of active leadership. The study underscores the importance of quality management, especially in the context of digital transformation and psycho-oncological care, emphasizing the need for further research on cost-effectiveness and implications of digital transformation.

# Zusammenfassung

**Einleitung.** Eine hochwertige psychoonkologische Versorgung wird mit gesteigerter Patientenzufriedenheit, höherer Therapietreue und einem verbesserten Wohlbefinden in Zusammenhang gebracht. Allerdings existieren in Deutschland Herausforderungen bezüglich der Bereitstellung konsistenter Leistungen, aufgrund fragmentierter Gesundheitssysteme und limitierter Ressourcen. Um diesen Herausforderungen zu begegnen, ist ein Qualitätsmanagementsystem erforderlich, das eine einheitliche und evidenzbasierte Versorgung gewährleistet, die interprofessionelle Zusammenarbeit fördert, die Qualität kontinuierlich verbessert und die Ressourcenallokation optimiert.

**Zielsetzung.** Qualitätsmanagement kann die Gesamtqualität der Versorgung deutlich verbessern und unerwünschte Effekte reduzieren. In dieser Dissertation wird ein Qualitätsmanagementsystem für eine sektorenübergreifende psychoonkologische Versorgungsform entwickelt, implementiert und evaluiert. Ein besonderer Schwerpunkt liegt dabei auf der Entwicklung von Qualitätsindikatoren, der Implementierung eines partizipativen Qualitätsentwicklungsansatzes sowie der Evaluation des entwickelten Konzepts. Durch die Untersuchung und das Aufzeigen von Lösungsansätzen soll ein Beitrag zur Weiterentwicklung der psychoonkologischen Versorgung in Deutschland geleistet werden, indem prospektive Maßnahmen und ein Qualitätsmanagementsystem für diese komplexe Versorgungssituation identifiziert und evaluiert werden.

**Methoden.** Es wurde ein eingebettetes Mixed Methods Design mit Fokus auf quantitativen Methoden angewandt. Die Entwicklung der Qualitätsindikatoren beruht auf der RAND/UCLA Appropriateness Method in Verbindung mit einer Delphi-Technik. Zur Qualitätsentwicklung wurden partizipative Instrumente in einen kontinuierlichen Verbesserungsprozess integriert und der Partizipationsgrad wurde mittels einer Längsschnittbefragung erfasst. Zur Bewertung der Umsetzung des Qualitätsmanagementsystems wurde eine Nutzwertanalyse durchgeführt.

**Ergebnisse.** Es wurde ein umfassendes Qualitätsmanagement eingeführt, welches strukturelle und prozessuale Instrumente umfasst und auf interne und externe Anforderungen ausgerichtet ist. Im Rahmen dessen wurde ein Set von 16 Indikatoren erfolgreich in der Praxis angewendet und als relevant, nachvollziehbar und angemessen bewertet. Die Ergebnisse belegen die Machbarkeit der Integration eines nachhaltigen, partizipativen Qualitätsentwicklungsprozesses in das Qualitätsmanagementsystem. Allerdings wurden auch einige Herausforderungen identifiziert. Die Bewertung der Umsetzung des Qualitätsmanagementsystems ergab eine effektive Implementierung mit einer Bewertung von 4,2 von 5,0 (84,0%). Die Umsetzung von Top-Down-Elementen wie Verträgen und Handbüchern wurde umfassend durchgeführt, während Bottom-Up-Aspekte wie Qualitätszirkel größere Herausforderungen darstellten.

**Fazit.** Im Rahmen dieser Dissertation wurde ein robustes Qualitätsmanagementsystem zur Verbesserung der psychoonkologischen Versorgung eingeführt. Dabei wurden wichtige Ziele erreicht, wie die Entwicklung und digitale Integration umfassender Qualitätsindikatoren. Es wurden jedoch Herausforderungen identifiziert, die sich aus dem Ausgleich zwischen Bottom-up-Dynamik und Top-down-Strukturen ergaben. Dies unterstreicht die entscheidende Rolle der aktiven Führung. Die Studie betont die Bedeutung des Qualitätsmanagements im Kontext der digitalen Transformation und der psychoonkologischen Versorgung. Es ist anzumerken, dass weitere Forschung zur Kosteneffizienz und den Auswirkungen der digitalen Transformation erforderlich ist.

## List of Abbreviations

| | |
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| AI | Artificial Intelligence |
| BGB | German Civil Code |
| CAPSYS | Computer-Aided Assistance System Psycho-Oncology |
| CI | Critical Incident |
| DIN | German Institute for Standardisation |
| EN | European standard |
| EPC | Event-Driven Process Chain |
| ePROM | Electronic Patient Reported Outcome Measure |
| HADS | Hospital Anxiety and Depression Scale |
| IoT | The Internet of Things |
| ISO | International Organisation for Standardisation |
| IT | Information Technology |
| JCAHO | Joint Commission on Accreditation of Healthcare Organizations |
| NCP | National Cancer Plan |
| NFC | New Forms of Care |
| nFC-isPO | New Form of Care Integrated, Cross-Sectoral Psycho-Oncology |
| QI | Quality Indicator |
| QM | Quality Management |
| QMS | Quality Management System |
| PDCA | Plan-Do-Check-Act |
| PIC | Patient Informed Consent |
| PHR | Participatory Health Research |
| PREM | Patient-Reported Experience Measures |
| PRISMA | Preferred Reporting Items of Systematic Reviews and Meta-Analyses |
| PROM | Patient-Reported Outcome Measures |
| PS | Psychosocial Specialist |

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|---|---|
| PT | Psychotherapist |
| PQD | Participatory Quality Development |
| RAND/UCLA | RAND Corporation/University of California, Los Angeles |
| SARS-CoV-2 | Severe Acute Respiratory Syndrome Coronavirus 2 |
| SCB | German Social Code Book |
| SHI | Statutory Health Insurance |
| SOP | Standard Operating Procedure |
| SQUIRE | Standards for Quality Improvement Reporting Excellence |

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# Gender Disclaimer

The author is committed to promoting equality and fairness for all individuals. Throughout this dissertation, inclusive language is used wherever possible to ensure gender neutrality and inclusivity. Whilst every effort has been made to balance readability and inclusivity, it is recognised that in certain instances gendered terms or pronouns may still be used. Please be assured that this is not intended to exclude or diminish any gender, but rather is an editorial choice to improve clarity and readability.

It is important to recognise the diversity of gender identities and expressions. Therefore, wherever possible, gender-neutral language has been used to be inclusive of all individuals without prejudice. Any use of gender-specific terms should be interpreted as inclusive of all genders, with the intention of promoting equality and avoiding any form of discrimination or exclusion.

# Chapter 1

## Introduction

The impact of cancer extends beyond the physical realm, making it essential to address the psychological, emotional, and social aspects of the disease to enhance patient well-being and improve treatment outcomes [1–3]. Psycho-oncology, an interdisciplinary field at the intersection of psychology and oncology, is crucial in providing comprehensive care to cancer patients. The provision of high-quality psycho-oncological support is linked to enhanced patient satisfaction, alleviated psychological distress, augmented treatment adherence, and amplified overall quality of life [4–6]. Research has emphasized the positive impact of psycho-oncological interventions on a variety of outcomes, including emotional adjustment, symptom management, and overall satisfaction with healthcare provision [4, 7–9].

Nevertheless, delivering consistent, patient-centred psycho-oncological care across different healthcare settings remains challenging, despite its recognized importance. Service provision variations, limited resources, and fragmented healthcare systems can result in gaps and disparities in the provided care. The coordination and integration of care for psycho-oncological patients is rendered more complex by the involvement of multiple healthcare providers across various sectors, including primary care, oncology clinics, and community-based organizations [10, 11]. Thus, according to several studies, significant advancements are required, both internationally and specifically in Germany [10, 12–16].

In Germany, the provision of comprehensive and high-quality psycho-oncological care also represents a pressing and ongoing challenge. Neumann et al. (2009) highlighted the difficulties in accessing psycho-oncological services, particularly the fragmented nature of such care in Germany [17, 18]. The prevailing healthcare system lacks an integrated, funded, and cross-sectoral strategy that efficiently coordinates care among diverse healthcare providers participating in a patient's journey with cancer [15, 16]. In Germany, there are currently approximately 170 outpatient psychosocial cancer counselling centres that provide information, support, and advice on dealing with the disease, as well as social law issues, in addition to inpatient care [19, 20]. Almost 72,000 consultations were conducted in 2022 [21]. However, the capacity of cancer counselling services in the outpatient sector is constrained by demographic trends and the resulting increase in new cancer cases in the medium term [11, 15, 22]. As a result, the available resources are anticipated to decrease, thereby obstructing the capacity to address the growing requirement for psycho-oncological services [16]. The challenges in psycho-oncological care include structural and organizational issues but also the limited availability and accessibility of services [23]. While psycho-oncological support is widely recognized as important for all patients, there are still discrepancies concerning its geographical distribution and resource allocation. Consequently, patient access to care across different regions in Germany is inequitable [16]. Despite an increasing recognition of the psychosocial needs of cancer patients, meaningful disparities and significant gaps remain in the delivery of psycho-oncological support.

To overcome these challenges, a comprehensive quality management approach is claimed for. This approach should focus on enhancing the integration, coordination, and accessibility of psycho-oncological care [24–27]. Quality management is essential to effectively manage the intricacies of providing top-notch psycho-oncological care. It involves methodical development, implementation, and evaluation of processes, ensuring that healthcare services meet pre-set standards and constantly enhance. A sturdy quality management system can act as a fundamental basis for attaining uniform, evidence-based care, fostering continuous improvement of care services, and optimising resource allocation [28, 29]. By systematically identifying and proactively addressing gaps in the provision of psycho-oncological support, the implementation of quality assurance measures within the quality management framework is intended to substantially enhance the overall care experience, to mitigate negative psychological effects, and to lead to improved patient outcomes [16, 30].

Furthermore, quality management in psycho-oncological care can encourage the implementation of evidence-based treatments, facilitates collaboration among professionals, and promotes a patient-centred approach. It provides a comprehensive framework for detecting and addressing gaps in the provision and delivery of psycho-oncological support, optimising the allocation of resources, and promoting continuous improvement in quality [18, 30, 31]. The importance of implementing a thorough quality management system in psycho-oncology is underscored by the potential repercussions of inadequate care. Insufficient psychological support throughout the cancer trajectory has been linked to heightened psychological distress, impaired coping mechanisms, reduced adherence to treatment, poorer quality of life, and suboptimal treatment outcomes [32–36]. Furthermore, an increased healthcare utilisation is linked with anxiety and depression in oncology patients [37, 38]. It has also been recognized that psycho-oncological care carries economic advantages, which accentuates the requirement for quality control procedures to maintain elevated care standards [39–41].

In summary, psycho-oncological care and its quality management in Germany present noteworthy challenges. Due to the complex nature of psycho-oncology care, tailored and systematic quality management is imperative to enhance effectiveness and manage the quality of cross-sectoral psycho-oncology care. Filling this gap can potentially enable healthcare providers to offer more consistent, evidence-based, and patient-centred support. This, in turn, can enhance the quality of psycho-oncology care and ultimately improve patient outcomes.

# Chapter 2

## Psycho-Oncology in Germany

The worldwide incidence of cancer is on the rise [42, 43], with Germany alone experiencing almost 500,000 new cases annually [22, 44]. Experts predict that by 2030, there will be a minimum of 23% increase in cancer cases caused by the aging population and targeted cancer treatments [22, 44–46]. Cancer patients frequently suffer from mental health conditions like anxiety, depression, or both, alongside emotional distress [32, 33, 44, 47–50]. Unaddressed informational and psychosocial healthcare requirements have the potential to cause distress, with the highest incidence occurring during the acute phase of treatment [32, 33, 44, 50–52]. Psycho-oncology examines the interplay between cancer diagnosis, emotional well-being, and healthcare quality, combining oncology and psychology [15, 23, 26, 32, 53]. Evidence-based psycho-oncological interventions have shown to improve psychosocial challenges emotional distress, impaired quality of life, and other mental impediments [4, 8, 9, 44]. The expanding body of for psycho-oncology has stimulated the demand for health policy makers to convert scientific discoveries into clinical practice at both national and international levels [12, 14, 26, 44, 54–58]. According to recent research, between 28% and 55% of incident cancer cases in Germany seek mental health or social support services [44, 59–61]. Previous research suggests that merely 9% out of 6,000 cancer patients reported receiving psycho-oncological care during hospitalisation, with only 3% utilising the services of psychosocial cancer counselling [44, 62]. Conversely, roughly 50% of all cancer patients have an empirically confirmed requirement for psycho-oncological care, while around 30-50% of psychologically distressed cancer patients would utilise these services [15, 32, 44, 61, 63, 64]. Only a small number of patients have received psychotherapy or psychological counselling, or both, according to sources [62, 65]. There have been various challenges in planning and providing these services, including inadequate communication of a patient's subjective need for psychological support or inadequate recognition and assessment by the oncological treatment team of the patient’s objective need [15]. Where a need is recognised, a dearth of prompt and appropriate cross-sector support services typically arises, owing to inadequate and non-standardised financing in both inpatient and outpatient facilities [15, 44].

The National Cancer Plan (NCP) in Germany advocates for the incorporation of the psycho-oncology domain into biomedical cancer treatment and cancer aftercare. In addition, the NCP strongly recommends the advancement of ‘oncological care structures and quality assurance’ [24, 44, 66]. The Association of the Scientific Medical Societies in Germany (AWMF) published evidence-based guidelines for psycho-oncological diagnosis, counselling, and treatment of adult cancer patients in 2014, which were updated in 2023 [53, 67]. As a hallmark of quality, each institution is mandated to formulate and implement a written plan for psycho-oncological patient care [25, 44]. These requirements are not only intricate and regarded as a fundamental aspect of oncological care but also need to fulfil demands for accessible and needs-based care while being subject to legally binding quality assurance conditions [25–27, 44, 68]. Despite substantial efforts in developing, implementing and disseminating psycho-oncological services, both nationally and internationally [12, 14–16, 44], there is still significant progress to be made. This includes uniform and sustainable financing and cross-sectoral care [19, 44].

# Chapter 3

## Theoretical Background

Chapter 2 explored the German psycho-oncological care environment and its challenges. In Chapter 3, current frameworks and approaches are examined to establish context for later discussions on managing and ensuring quality (Chapter 3.1). The theoretical background concludes by describing a new form of care called 'Integrated, Cross-Sectoral Psycho-Oncology (nFC-isPO)' (Chapter 3.2).

### 3.1. Quality and Quality Management

The significance of managing and providing quality healthcare continues to rise [69–72]. Quality is a core concept across all healthcare settings, including inpatient, outpatient, and rehabilitation areas [73, 74]. Nevertheless, defining quality and its related aspects lacks a single universally-accepted approach.

> ‘Unfortunately, we have used these words in so many different ways that we no longer clearly understand each other when we say them.’
>
> *A. Donabedian (1981) [75]*

Most definitions of quality interpret it as meeting requirements [76–79]. Quality can be broadly described as how well a product or a service achieves its characteristics and features, in other words, the extent to which requirements are fulfilled. These requirements could be internally or externally established, mandatory or presumed, and are recognised as a quality objective, as portrayed in Figure 1 [79].

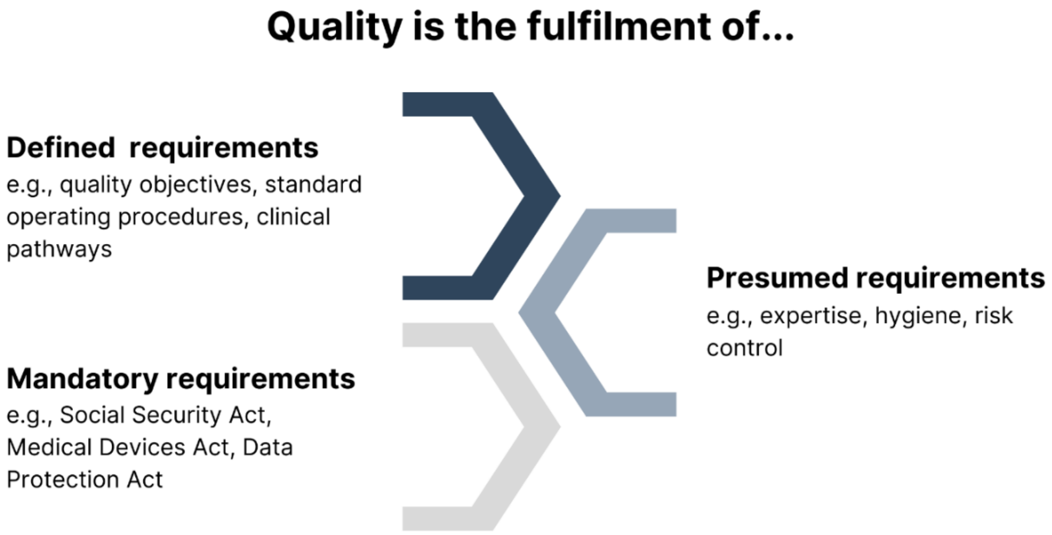


**Figure 1.** Definition of requirements for quality in healthcare based on [79, 80].

In healthcare, a wide range of definitions for quality have been established. Donabedian's definition of quality of care is objective, specifying that quality refers to 'the extent to which actual care conforms to predetermined criteria for good care' [81]. Quality in healthcare can be broadly described as the provision of adequate and suitable healthcare to improve the chances of desired outcomes for individuals and the population. The term 'adequate and suitable' refers to care that prioritises patient needs, quality of life, professional qualifications, and economic efficacy [79]. Donabedian was the pioneer of quality classification, known as quality dimensions [82]. As a means of defining quality and rendering it operational for quality management, these dimensions have been endorsed for many years in the social and health sectors. He identifies three layers of quality that can impact one another [79, 82]:

- **Structural quality** encompasses the features of facility, such as the quantity and calibre of organisational and financial resources, staff number and training, patient accessibility, etc.
- **Process quality** encompasses all service delivery facets provided by a medical institution or practice such as diagnosis, therapy, administration, and laboratory services.

- **Outcome quality** appertains to health status modifications in connection with previous service provision. It can be gauged through both objective changes, for instance, improvement in disease status, complication rates, and patient numbers, and subjective criteria such as patient satisfaction.

Quality management refers to the comprehensive handling of all aspects related to product or service quality. The aim is to improve the quality of products and services by implementing coordinated activities to steer and manage the organisation [76, 79, 83]. Management and control may involve incorporating the quality policy into business objectives, defining quality objectives and responsibilities, engaging in quality planning, control, assurance, and improvement. To achieve optimal results, quality management should follow certain principles as shown in Figure 2. Improvement and optimisation of structures and processes are crucial aspects of typical management activities aimed at enhancing the quality of products and services [84]. While every level of execution is responsible for quality management, top management should provide leadership. Implementing this principle necessitates involvement from all members of the organisation.

**Figure 2.** The principles of quality management based on DIN ISO 9000:2015 [85].

To ensure objectivity in quality, a healthcare organisation's quality management system must define quality requirements for healthcare products and services. This necessitates considering various perspectives and aspects from a wide range of sources [77]. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) published quality criteria in 1988 which describe the typical characteristics of high-quality medical care used globally [86]. The following quality criteria are included:

- Accessibility of care,
- Adequacy of care,
- Continuity/coordination of care,
- Efficacy of care (effectiveness under ideal conditions),
- Efficiency of care (effectiveness in practice),
- Patient orientation of care,

- Safety of care environment,
- Timeliness of care.

Based on these quality standards, specific quality objectives can be established to define the desired level of fulfilment for particular aspects. In order to assess the quality, the target state is regularly measured against the actual state as demonstrated in Figure 3.

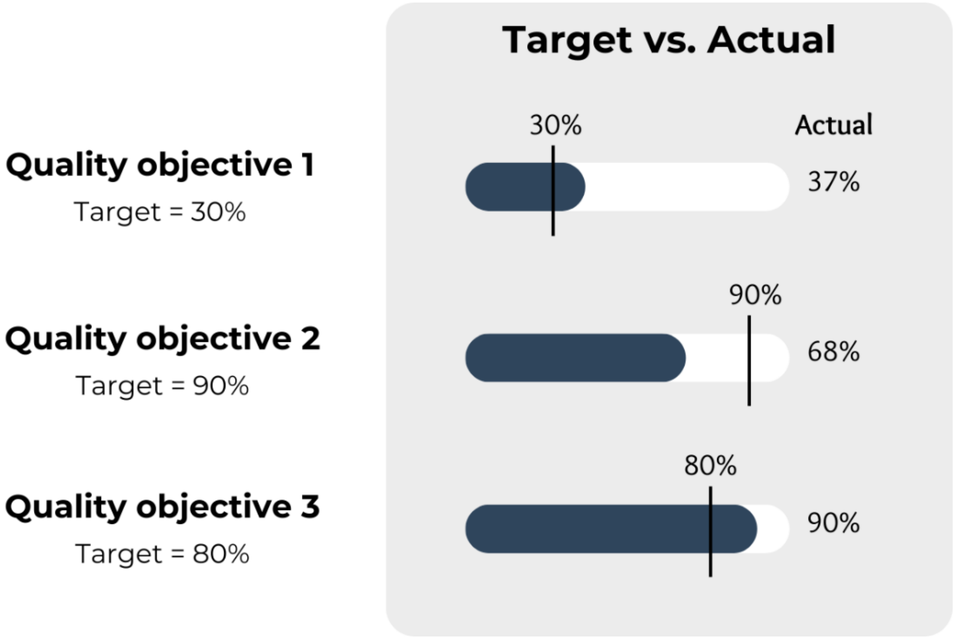
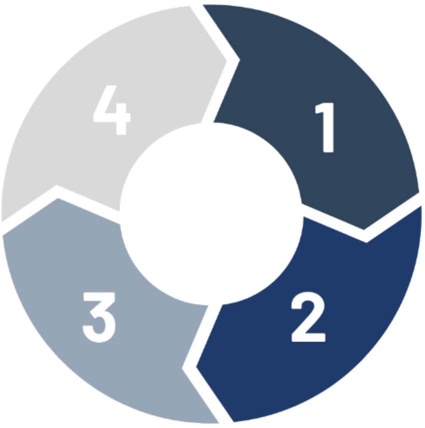


**Figure 3.** Example of a target-performance analysis**.**

Based on such target-performance analyses, improvement needs can be identified and necessary actions initiated. The Plan-Do-Check-Act (PDCA) cycle, introduced by Deming (1986), is one of the most widely recognised concepts for continuous quality improvement [87]. As illustrated in Figure 4, the PDCA cycle is a standard four-stage process that is implemented in daily operations and serves as the foundation of the quality management system [88]. The daily routine **(Do)** should be based on the development of concepts, guidelines and standards **(Plan)**, which should be reviewed on a regular basis **(Check)** and improved accordingly **(Act)** [73, 88]. The planning phase entails identifying potential areas for improvement and optimisation, setting objectives, and devising processes. The execution and implementation of these processes, and optimisation measures, form the ‘Do’ phase. The ‘Check’ phase involves measuring and evaluating the processes against the predetermined specifications and requirements. Finally, in the ‘Act’ phase, measures are implemented for continuous quality improvement based on the results of the audit or correction of processes.



**1. Plan**
- Analyse cause and corrective change measure and notice disturbances
- Objectives, customer expectations, process planning, manual, organisation chart, process map

**2. Do**
- Implement pilot measure
- Implement processes
- Work activities and documentation

**3. Check**
- Review achievement of objectives and impact of interventions/ measures
- Analyse data and review results
- Internal audits/reviews, management evaluation

**4. Act**
- Integrate into routine
- Implementing change
- Team meetings, quality circles, projects

**Figure 4.** The Plan-Do-Check-Act (PDCA) cycle in quality management based on [79, 85].

In addition to the PDCA cycle as a fundamental aspect of quality management, a comprehensive quality management system comprises a range of elements including standards, models, and tools [77–79]. Quality assurance is an essential part of quality management that seeks to instil confidence among stakeholders by ensuring that defined quality requirements are met, for example, through the utilisation of quality reports or certifications [78, 85]. The term quality assurance can refer to both external quality comparisons and ensuring a precise level of quality [27]. To influence the quality of care through quality management, it is crucial to define specific requirements and to accurately measure the provided quality, enabling identification of opportunities for improvement. A maximum number of individuals within an organisation who collaborate in achieving a superior level of quality while optimising processes can yield an appropriate level of added value and diverse advantages. Accordingly, quality management is concerned with governing the interplay of these elements to reach optimum quality.

## 3.2. The New Form of Care 'Integrated, Cross-Sectoral Psycho-Oncology (nFC-isPO)'

The term 'New Forms of Care (NFC)' pertains to pioneering or unconventional means of delivering healthcare and support services that intend to enhance healthcare quality and efficiency, while adapting to evolving societal and medical requirements [89, 90]. Healthcare in Germany is bifurcated into the inpatient (hospital) and outpatient sectors and new forms of care are introduced to foster collaboration between these sectors and surmount their segregation. For instance, psycho-oncological care is frequently provided in hospitals and rehabilitation centres within the inpatient sector. However, there may be added pressure on outpatient counselling centres due to rising cancer cases. This highlights the requirement for advancing care models [44, 89]. In response, the 'New Form of Care Integrated, Cross-Sectoral Psycho-Oncology (nFC-isPO)' has been created, implemented, and assessed in Germany from 2017-2022 [44]. This approach seeks to accomplish the objectives outlined in the NCP by providing psycho-oncological care tailored to the unique health needs of all cancer patients. The objective was to establish a stepped care approach to psychotherapy and psychosocial support aimed at mitigating anxiety and depression in adult cancer patients [44].

The nFC-isPO comprises six components: a care concept, clinical pathways, a psycho-oncological care network, a care process organisation plan, an IT-supported documentation and assistance system 'Computer-Aided Assistance System Psycho-Oncology (CAPSYS)', and a quality management system [44]. The nFC-isPO clinical care programme provides psycho-oncological services to individual cancer patients within 12 months of enrolment following their cancer diagnosis. The programme is based on the concepts of care and clinical pathways [44]. The remaining components encompass the formal-administrative features of the nFC-isPO, established to fulfil the legally binding prerequisites for patient care in the German healthcare framework. The nFC-isPO was initially developed over the course of one year from October 2017 onwards, and underwent a continuous quality improvement process. Subsequently, in 2019, the nFC-isPO was put into operation in four local psycho-oncological care networks located in the federal state of North Rhine-Westphalia, Germany [44]. In accordance with state law, the implementation of the nFC-isPO was contingent upon a legal foundation securing 'special care' through a contract with the German statutory health insurance funds (§ 140a SCB V). Quarterly internal and cross-network quality assurance and improvement measures have been established to guarantee an ongoing quality enhancement process, sustaining the quality of the nFC-isPO for further dissemination across the German healthcare system [44]. As part of the project, the nFC-isPO underwent evaluation by an independent institution, the Institute for Medical Sociology, Health Services Research, and Rehabilitation Science (IMVR), at the University of Cologne, Germany [44, 91].

To systematically develop the nFC-isPO and enable external evaluators to assess its quality, effectiveness and efficiency under routine care, this research incorporates methods from translational psycho-oncology, practice-based health services research, and programme theory. To establish a methodical, community-based novel treatment model, a specific programme theory, the stepped-care approach, and evidence-based guideline recommendations were used [44]. The practice-based health services research and translational research serve as the fundamental scientific framework for closing the gap between laboratory experiments and clinical applications in daily practice. This translation of clinical trial findings into patient care is illustrated in Figure 5 [3, 44, 92–95].

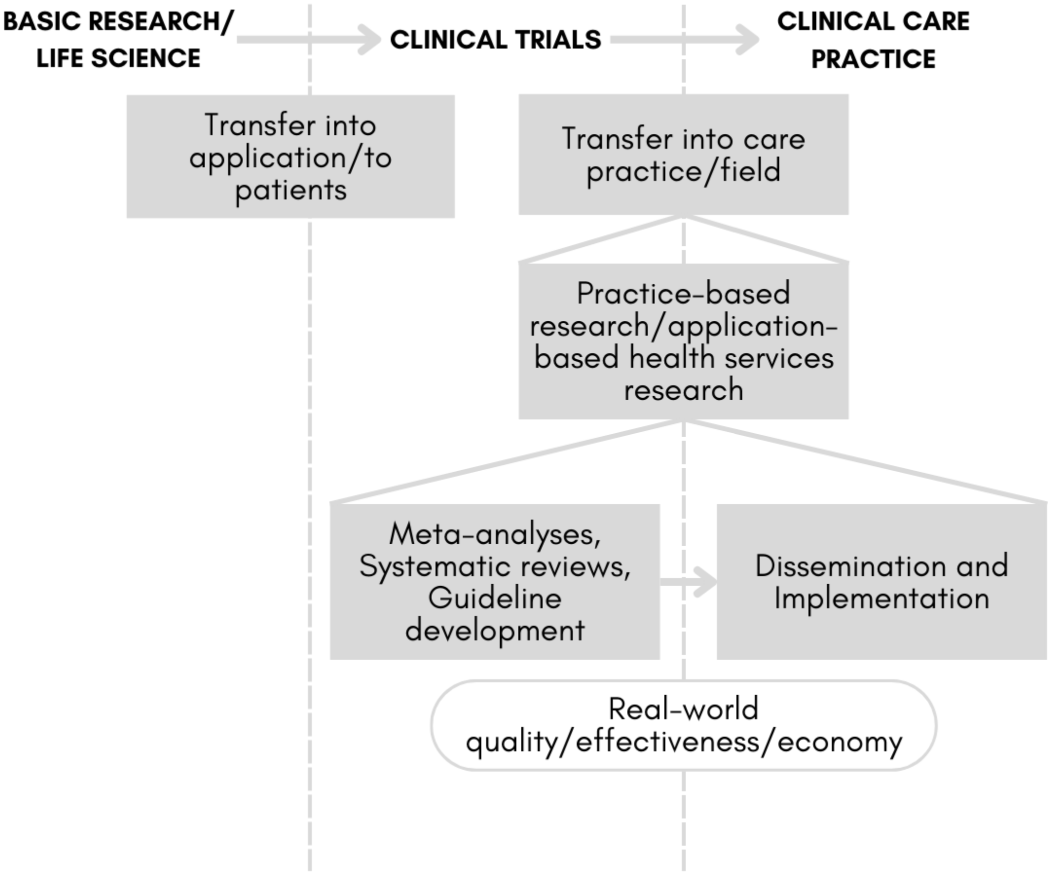


**Figure 5.** Concept of translational research based on [3].

Based on Pfaff's throughput model illustrated in Figure 6 [94], evidence-based healthcare innovations can be created (‘input’) and assessed during their integration in the healthcare system (‘throughput’) concerning their performance (‘outputs’) and health impacts (‘outcomes’) [94, 96].

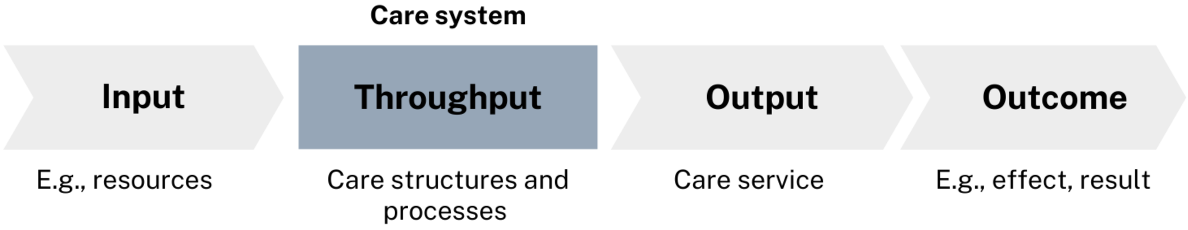


**Figure 6.** Theoretical model of care systems based on [94].

The novel care system was established using Issel's programme theory as a framework for the structured advancement of health programme components [97]. Issel's programme theory employs techniques and approaches that are suitable for the design and evaluation of a care programme, as indicated in Figure 7.

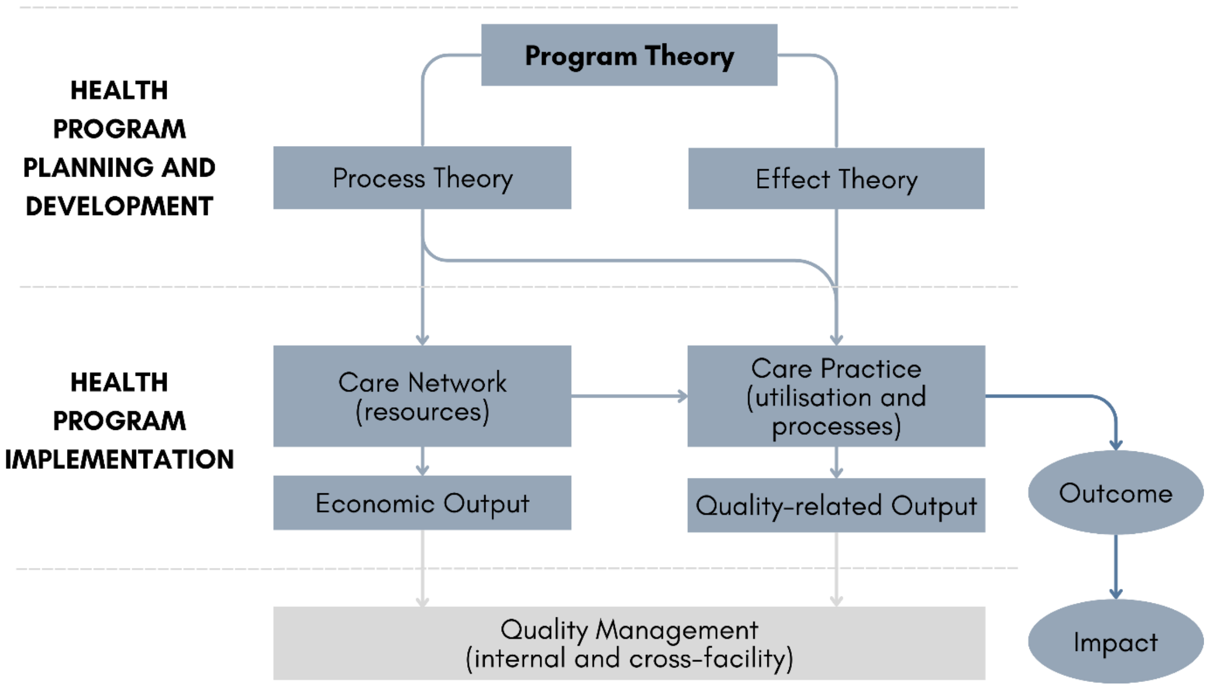


**Figure 7.** Model of programme theory based on [44, 97].

The concepts were adjusted to reflect the context of psycho-oncology including the development, implementation, and evaluation of psycho-oncological care services [44, 58, 98, 99]. The detailed scientific concept of nFC-isPO is described in Kusch and Labouvie (2015) [3, 44]. This research was funded by a grant from the Innovation Fund of the German Federal Joint Committee (grant number: 01NVF17022). The study was registered beforehand in the German Clinical Trials Register with the registration number DRKS00015326, on October 30th, 2018 [44, 100, 101].

# Chapter 4

## Aim and Objectives

The purpose of this project was to address existing challenges in providing high-quality psycho-oncological services, and subsequently to improve the quality of care for patients by focusing on an appropriate quality management system. This cumulative dissertation aims to contribute to nFC-isPO by developing, implementing, and assessing a comprehensive quality management system for a cross-sectoral new form of care in Germany.

The research projects are guided by the following objectives:

1. To develop a comprehensive set of quality indicators for a psycho-oncology care programme in Germany. This objective involves a rigorous process of identifying appropriate quality indicators that can efficiently measure and evaluate key aspects of psycho-oncology care. A thorough literature review, expert consultation, and consideration of existing guidelines and best practices will contribute to the development of this set of quality indicators.
2. To implement a participatory quality development approach as a means of ensuring and enhancing quality. This objective centres on engaging stakeholders, such as healthcare professionals, patient representatives, scientists, and project partners in the development and refinement of the quality management system. By actively involving these key stakeholders, their invaluable perspectives and ideas will be integrated, resulting in a more comprehensive and user-centric system.
3. To evaluate the effectiveness of implementing the quality management system in clinical practice, the assessment will include an examination of various factors, including adherence to established protocols and agreements, integration of the system into routine clinical practice, and gauging performance. This assessment will provide valuable insights

into the strengths and areas for improvement of the quality management system currently in place.

By pursuing these objectives, this cumulative dissertation will contribute to the further development of quality management systems and the advancement of psycho-oncological care in Germany. Developing a set of quality indicators will establish a framework for monitoring and steering the quality of care. Implementing a participatory quality development approach will integrate the viewpoints and requirements of all stakeholders within the system. The assessment of the implemented quality management system will furnish evidence of its effectiveness and direct further improvements. These objectives strive to enhance the quality of psycho-oncological care, with the ultimate objective of improving patient outcomes and provider experience through quality management.

# Chapter 5

# Methods

This amalgamation of approaches is a typical characteristic of mixed methods research. Mixed methods entail the incorporation of qualitative findings and quantitative data within a research project. The methodology employed in this dissertation is an embedded mixed methods design with a focus on quantitative methods [102–104]. As research projects have varying objectives, distinct methodological approaches have been employed to tackle the particular objective and research question. As several additional tools and elements have been created and integrated into the quality management system in the context of this dissertation, it is vital to comprehend the methodological prerequisites. Clinical pathways were developed as part of quality management and to provide a visualised basis for further research. The chapter includes two additional subchapters that explain the methodological foundation for a quality management system (Chapter 5.1) and the techniques used for clinical pathway development (Chapter 5.2), in addition to the techniques utilised in the three research projects. Chapter 5.3 concludes with the methods employed in the three research projects.

## 5.1. Elements of a Quality Management System

As quality management is a vast discipline, encompassing a multiplicity of methods and tools, this dissertation has made strides in developing and implementing multiple quality management tools and aspects beyond those presented in the aforementioned publications. This was accomplished following an orientation model of a quality management system, as depicted in Figure 8.

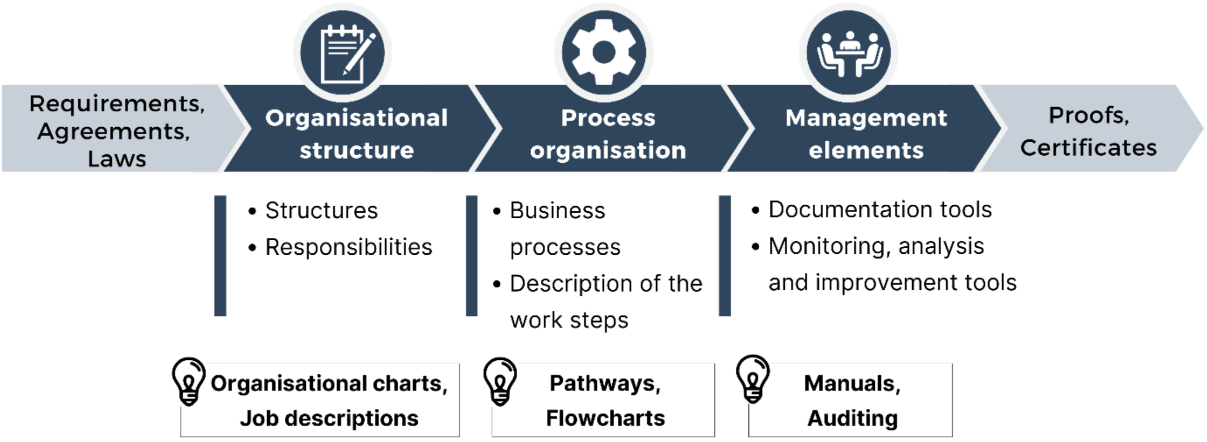


**Figure 8.** Orientation model of a quality management based on [83, 105].

The essential components of an effective quality management system encompass pre-existing frameworks and accountabilities for all quality-related activities. Moreover, defining service delivery procedures- in particular, those related to core services- and implementing tools for recording and tracking quality management systems are imperative [105]. Tools for managing these requirements include organisational charts, pathways, or manuals that document all quality-related structural features and processes and present them transparently both internally and externally [79]. An effective quality management system ensures that the performance and quality of an organisation are continually reviewed and improved, meeting internal and external requirements, such as DIN EN ISO standards [106]. The provision of healthcare should be continuously and systematically developed, taking into consideration advancements and insights [74, 107]. The central question is whether processes, individual work steps, or services are executed correctly in accordance with the quality objectives of nFC-isPO. The appropriateness of resource allocation is a crucial element of the nFC-isPO quality management approach, which revolves around the continuous improvement process following the PDCA cycle.

## 5.2. Development of Clinical Pathways

There are various definitions and denominations of clinical pathways which all share the same fundamental feature - describing the sequence, timing, content, and responsibilities of crucial care components for specific patient groups. Clinical pathways embody the treatment consensus of all involved healthcare professionals, allowing for transparency and comparability. Additionally, they can serve as a tool to educate new staff and familiarise patients and their relatives with the treatment process [108–110]. The core component of a clinical pathway is the timeline on which care elements are organised. Additionally, the purposes and origins of clinical pathways can be diverse, such as for expense tracking, process improvement and interface management, quality assurance, or comprehensive care [109]. Clinical pathways should rely on guidelines that are grounded in evidence. Guidelines provide a valuable source of synthesised evidence in ensuring that clinical pathways adhere to medical standards [109]. The nFC-isPO follows the structure depicted in Figure 9 when developing clinical pathways, while modelling after the 'Model of Integrated Patient Pathways' at Katonsspital Aarau [111].

**Figure 9.** Development of planned treatment processes based on [109, 112].

Because integrated care structures were insufficient to require a state analysis [113], the processes were algorithmically designed through user-story creation and endorsed by interdisciplinary experts. The BIC Design software (GBTEC Software and Consulting AG, Bochum) was utilised to visualise clinical pathways, which were modelled in the established reference modelling language 'event-driven process chain (EPC)' [114]. The clinical pathways underwent continuous evaluation and development through a target-performance comparison in routine clinical practice, within the framework of participatory quality development. The development and implementation of the pathways were integrated into the cycle of continuous quality improvement to facilitate their integration into everyday clinical practice [109]. The success of clinical pathways relies on how users customise the offered path to fit their needs [109]. This necessitates the involvement of all professional groups [110]. Consequently, clinical pathways were initially discussed frequently in internal quality circles and cross-facility quality workshops at the outset. The incorporation of clinical pathways into the quality management and assurance of the nFC-isPO can lead to several quality-enhancing outcomes. These include the establishment of a consistent quality standard that considers the entire treatment process across different sectors, the development of a platform for interdisciplinary communication between the involved professional groups, and the recognition of opportunities for enhancing the treatment process. Deficiencies in care can be swiftly identified in the nFC-isPO through interactive flowcharts, offering valid data for process control [115]. This facilitates staff induction, training, and necessary changes [115]. The IT-supported assistance programme CAPSYS stores standard operating procedures (SOP) and other relevant documents in the digital version of the clinical pathways. Furthermore, clinical pathway functionality may include linking to other clinical pathways and retrieving or printing documents.

### 5.3. Research Projects

To develop quality indicators for a cross-sectoral programme for psycho-oncological care (Publication 1) [68], the commonly used RAND/UCLA Appropriateness Method was used in combination with the Delphi method [68, 116–120]. This approach is beneficial for synthesising scientific evidence and expert opinions acquired through the consensus technique [68, 116]. The iterative approach comprises a systematic review of the literature, an anonymous two-stage survey (Delphi rounds), a questionnaire-based re-evaluation of the quality indicators, and a face-to-face expert panel discussion [68, 119, 121, 122]. To identify existing quality of care indicators and domains in cancer patients with emotional distress or mental disorders, a systematic literature review was carried out. A predefined search strategy was applied to systematically search six databases for scientific articles [68]. Additionally, relevant secondary publications and grey literature (such as reports of quality assurance projects), relevant organisations' websites (such as medical societies that have developed or are using quality indicators), and evidence-based guidelines proposing quality indicators were reviewed by manual search [68]. All identified quality indicators underwent evaluation and rating through a two-round Delphi process involving participants from diverse fields of health services research and psycho-oncological care, all operating within the care programme. Consensus determined an quality indicator's acceptance with at least 75% of the ratings in category 4 or 5 on a five-point Likert scale [68, 120, 123]. During the interim period, expert panels evaluated and deliberated over the initial quality indicators for relevance, data availability and feasibility by utilising a short assessment form [68, 124–126].

The objective of the second research project was to design and implement a participatory approach for quality development and to examine the extent of stakeholder participation (Publication 2). ‘Participatory quality development’ pertains to all individuals who are directly or indirectly impacted by or interested in the operations of nFC-isPO (i.e., stakeholders). Stakeholders involved in the nFC-isPO comprised healthcare professionals from four distinct care networks located in North Rhine-Westphalia, Germany, scientific partners such as health services research, medical informatics, health economics, and project partners like health insurance firms and non-profit patient advocacy organisations. As part of the four-stage continuous quality improvement process, multiple participatory tools were developed and implemented within a well-structured control loop. For the purpose of evaluation, a longitudinal survey using flash polls was carried out twice to gauge the viewpoints of participants on needs assessment, planning and implementation, evaluation, collaboration, and participation in quality development [127]. The initial round occurred in October 2019 via written questionnaire, while the succeeding round took place on a digital platform using 'Limesurvey' in July 2021 due to the pandemic of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). Survey respondents were systematically selected by purposive sampling and enlisted from the interdisciplinary, cross-facility quality workshops. Data were gathered through a survey consisting of 22 questions, including both single and multiple-choice items, rating scales, and free-text fields. All questions were either multiple choice or rated on a 5-point Likert scale. Additionally, respondents were requested to indicate their perceived level of involvement and to propose ideas for enhancing the development of quality participatory processes. Descriptive statistical analysis was performed using IBM SPSS Statistics 26. An open-ended query on ways to improve the development of quality was examined via content structuring analysis [128]. Peer debriefing was utilised to corroborate the interpretation of the open-ended text. Flash polls have a relatively long-standing history in participatory quality development and act as a suitable instrument to assess the standard of collaboration and participation of various stakeholders [125, 129].

Utility analysis, also known as scoring analysis, can aid in decision-making, evaluation, and ranking. It is an objective method that provides valuable insights without subjective evaluations. The analysed aspects are broken down and their descriptive criteria are weighted. The degree of fulfilment is evaluated, and the evaluations per criterion are then combined to form an overall score [130]. An utility analysis assessed the extent to which the multidisciplinary care programme and its quality management were implemented during routine clinical practice (Publication 3) [131]. Systematic evaluation and decision-making were facilitated through fragmentation, de-emotionalisation and objectivisation [130, 131]. The care programme was divided into various fragments and assessed based on structure, process, and outcome quality. The evaluation criteria were pre-defined and categorised with weighted point values assigned to different levels of implementation. Evaluation cases pertain to particular scenarios, structures, or situations that are analysed for diverse objectives, and assessed based on distinct criteria aligned with a particular issue or problem. These evaluation cases were created based on the quality indicators and quality characteristics derived from the requirements and quality aspects of the nFC-isPO system [131]. The nFC-isPO was comprehensively evaluated through the categorisation of eight areas representing different evaluation domains (e.g., joint agreements, care concepts, care management, quality management, quality assurance and development, IT-based documentation and support systems, human resources, and quality indicators). A total of 200 evaluation cases were established to provide a comprehensive evaluation of various aspects of the nFC-isPO. These cases were classified according to quality dimensions and criteria [69, 131, 132]. To streamline the evaluation process, a unique identifier was assigned to each thematic block within the evaluation domain for tracking and organisation. Several steps were taken during the utility analysis process to determine the overall value by combining individual values with specific weights: (1) Rigorous evaluation criteria were established to assess various aspects of the quality of the nFC-isPO. (2) Each evaluation criterion was then allocated a point value reflecting its significance in the overall evaluation. (3) The factor values for the individual criteria within each evaluation area were subsequently summed to derive a total value, which provides a comprehensive assessment of the particular dimension [131]. Quantities, ratings, and intervals were assigned to specific values on a pre-determined 5-point scale. Scores below the mean value of 3 were considered to indicate areas of potential concern. The analysis was conducted using descriptive statistics with IBM SPSS Statistics 26 [131].

# Chapter 6

## Results

This subsequent chapter details the discoveries of this dissertation. Initially, Chapter 6.1 gives a concise summary of the tools and elements of the quality management system. This is followed by the research projects published within this cumulative dissertation. Chapter 6.2 analyses the peer-reviewed scientific publication 'Developing quality indicators for cross-sectoral psycho-oncology in Germany: combining the RAND/UCLA appropriateness method with a Delphi technique'. The second publication, 'Participatory health research in cross-sectoral psycho-oncology: implementation and results of participatory methods in quality development', describes the implementation and results of participatory methods for quality development in Chapter 6.3. The third publication, 'Assessing the implementation of a comprehensive quality management system for cross-sectoral psycho-oncology in Germany', provides an assessment of the implementation of the comprehensive quality management system in the same field (Chapter 6.4).

### 6.1. Quality Management System

The quality management system presented in this dissertation comprises various tools, aspects, and approaches tailored for the nFC-isPO. Initially, a comprehensive **quality policy** (i.e., a concise statement of an organisation's purpose, mission, and strategic direction) was developed, agreed, and implemented, including a **mission and vision** statement as illustrated in Figure 10. **Organisational charts**, encompassing responsibilities and authorities within and between institutions, along with **job descriptions** were developed and conceptualised. These instruments were collaboratively designed with the project lead, fine-tuned with representatives of all stakeholders within quality workshops using creative methods, and authorised by, or exhibited to, all participants in the quality workshops (refer to Appendix 1).

**01** **Needs-Based Care**

- We respect and support the dignity and autonomy of people with cancer.
- We advise, treat and support people with cancer through all stages of the disease, providing them with quality information and psycho-oncological care that meets their needs.

**02** **Expertise and Quality**

- Our interdisciplinary approach aims to provide the best possible integrated, cross-sectoral and multidisciplinary psycho-oncology care for those affected.
- Our expertise is based on the latest scientific findings and is directly geared to quality assured psycho-oncological patient care.
- We emphasise continuous quality improvement and the creation of standards for optimising patient care through the approach of participatory quality development.

**03** **Resources**

- We stand for responsible, appropriate and rational care according to the needs of the person with cancer.
- We are aware of our responsibility in the use of economic resources consciously.
- We are committed to the appropriate use of human resources for the benefit of our treatment team.

**04** **Stronger Together**

- We support those affected by providing appropriate care, professional communication and a wide range of information.
- We value a positive working environment, mutual acceptance and commitment for the benefit of patients and the healthcare team.
- We promote interdisciplinary cooperation and the competence of each individual through structured knowledge exchange, training and constructive, open communication.
- Networks in different locations ensure a comprehensive range of care services to guarantee access for patients close to home in their region.

**Figure 10.** Quality policy of the nFC-isPO.

A thorough IT-based **document management** system has been put in place, with all documentation managed through the web-based management system, Pergamon. This allows for the routine checking, updating, approval and distribution of instructions, forms, and checklists. Additionally, a **qualification matrix** has been integrated into the quality management system to control the planning and monitoring of education, training, and professional induction for all nFC-isPO stakeholders. To effectively deliver both clinical and formal-administrative services of the nFC-isPO, the core services (i.e., doing the right thing) and core processes (i.e., doing the right thing right) have been clearly defined [44]. A detailed **process map** has been developed which outlines the management, operational and supportive processes, as illustrated in Figure 11. Care services are managed and controlled through cross-sectoral processes, exemplified by the **clinical pathways** in Figure 12. The clinical pathways have been connected to the document management system and incorporated into the IT-based support programme.

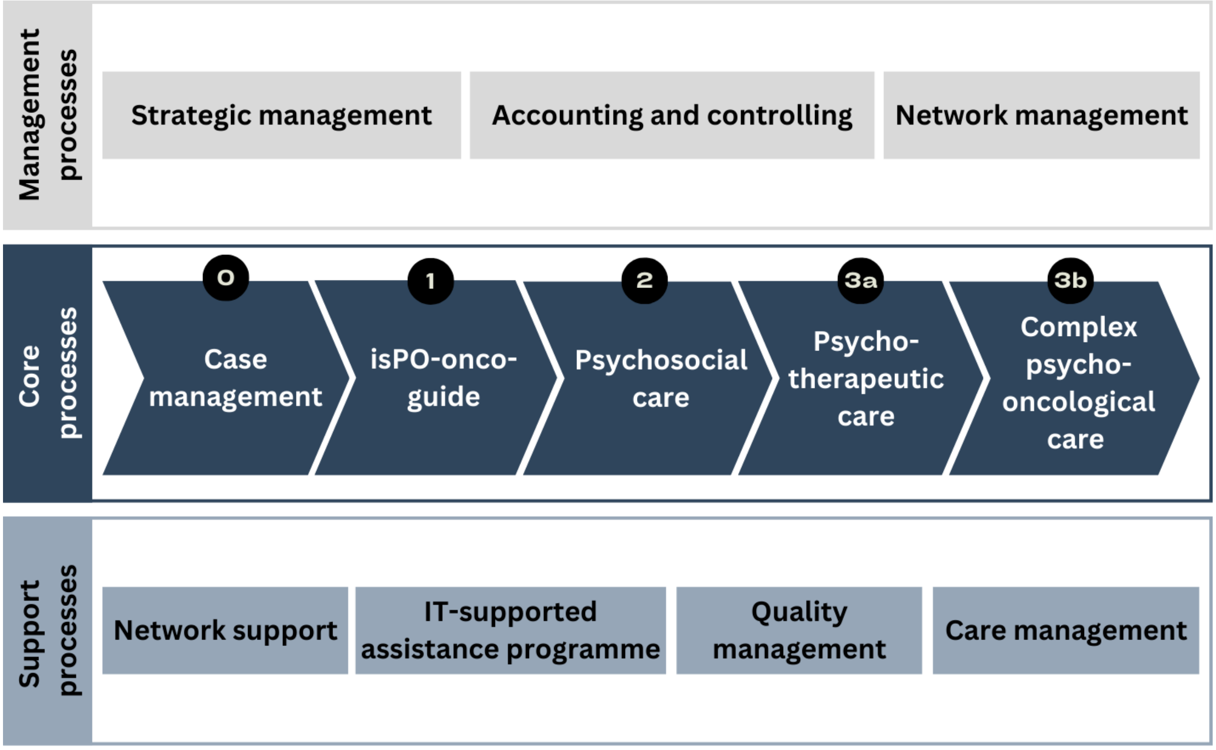


**Figure 11.** Business processes of the nFC-isPO.

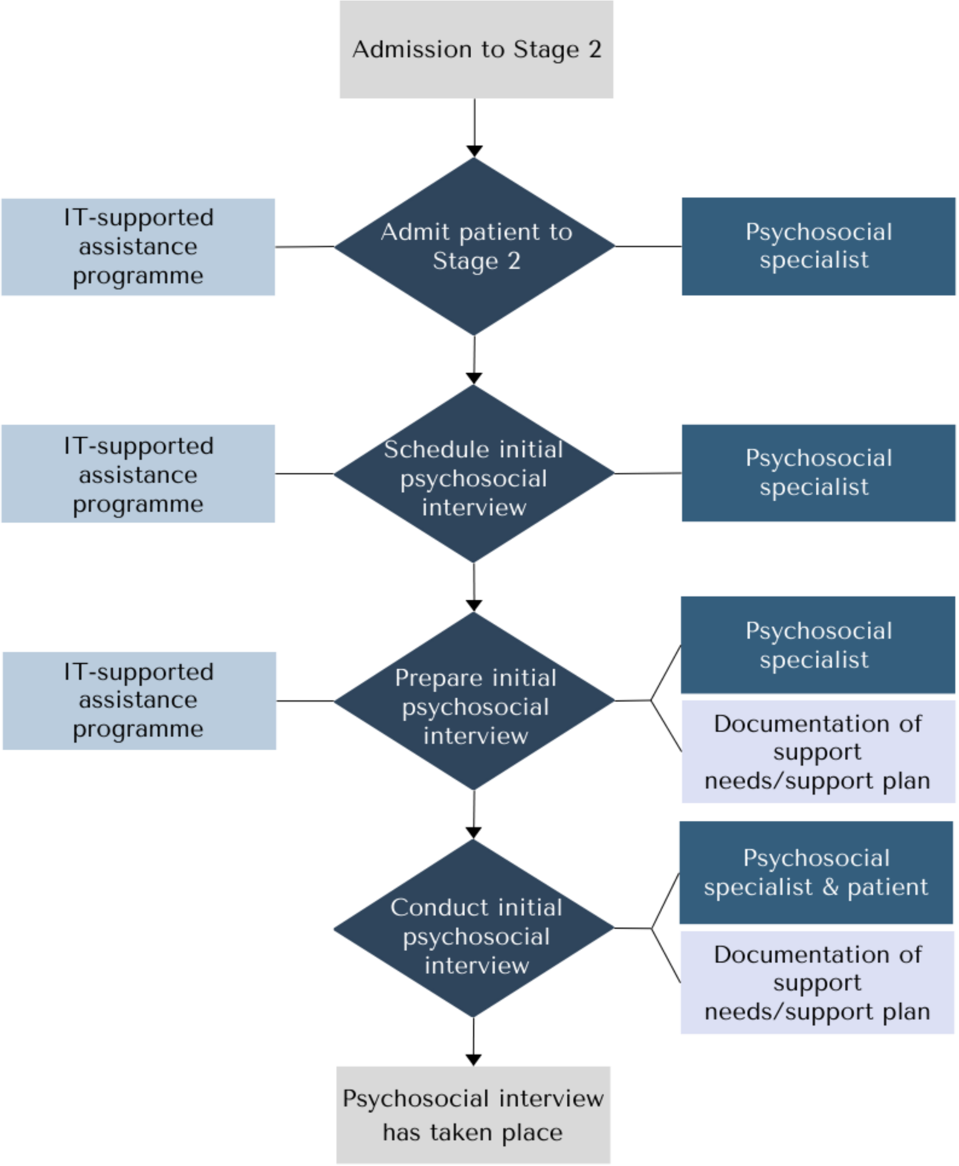


**Figure 12.** Extract from a nFC-isPO level 2 clinical pathway.

**Standard operating procedures (SOPs)** were developed from the clinical pathways, and **quality indicators** were defined to assess performance along the same pathways [68]. The utility analysis investigated the quality characteristics and quality indicators (Appendix 2f). Appendix 4ff present specific results and outliers. As part of the ongoing improvement of nFC-isPO, quarterly multidisciplinary **quality circles** were established within facilities. These include the continuous analysis and review of processes, structures, and results. In addition, **quality workshops** across facilities were implemented. The implementation is depicted in

Figure 13. These workshops and circles were intended as practical and structured team meetings with a thematic focus, designed to benefit the local care network teams. Cross-facility quality workshops and internal quality circles have proved beneficial for ensuring a logical progression in the flow of information. These meetings were aimed at systematically analysing and evaluating the optimisation and adaptation processes during the implementation phase, with the goal of deriving actionable measures for improvement. The meetings were rooted in the SOPs, clinical pathways, and results of the reporting system from the care system. To advance and enhance care quality in a participatory manner, each quality workshop was facilitated by two trained experts who utilised different problem-solving techniques to aid the group in creating and executing resolutions to recognised issues. These one-day sessions were conducted every quarter, with the quality circle convening roughly one week prior to the quality workshop. The conclusions of these gatherings were assessed. A collaborative agreement restricted the number of attendees to a maximum of three representatives from each project partner in the twelve mandatory quality workshops ($n \approx 20$). Additionally, a comprehensive and standardised reporting system complemented the system of continuous improvement.

All aspects of quality management have been detailed and documented in a comprehensive **manual**. The manual aims to provide a summary of the essential elements of the nFC-isPO quality management system, acting as an overview and introduction to the system. Additionally, the quality management system has been integrated as a module within an IT-based support programme.

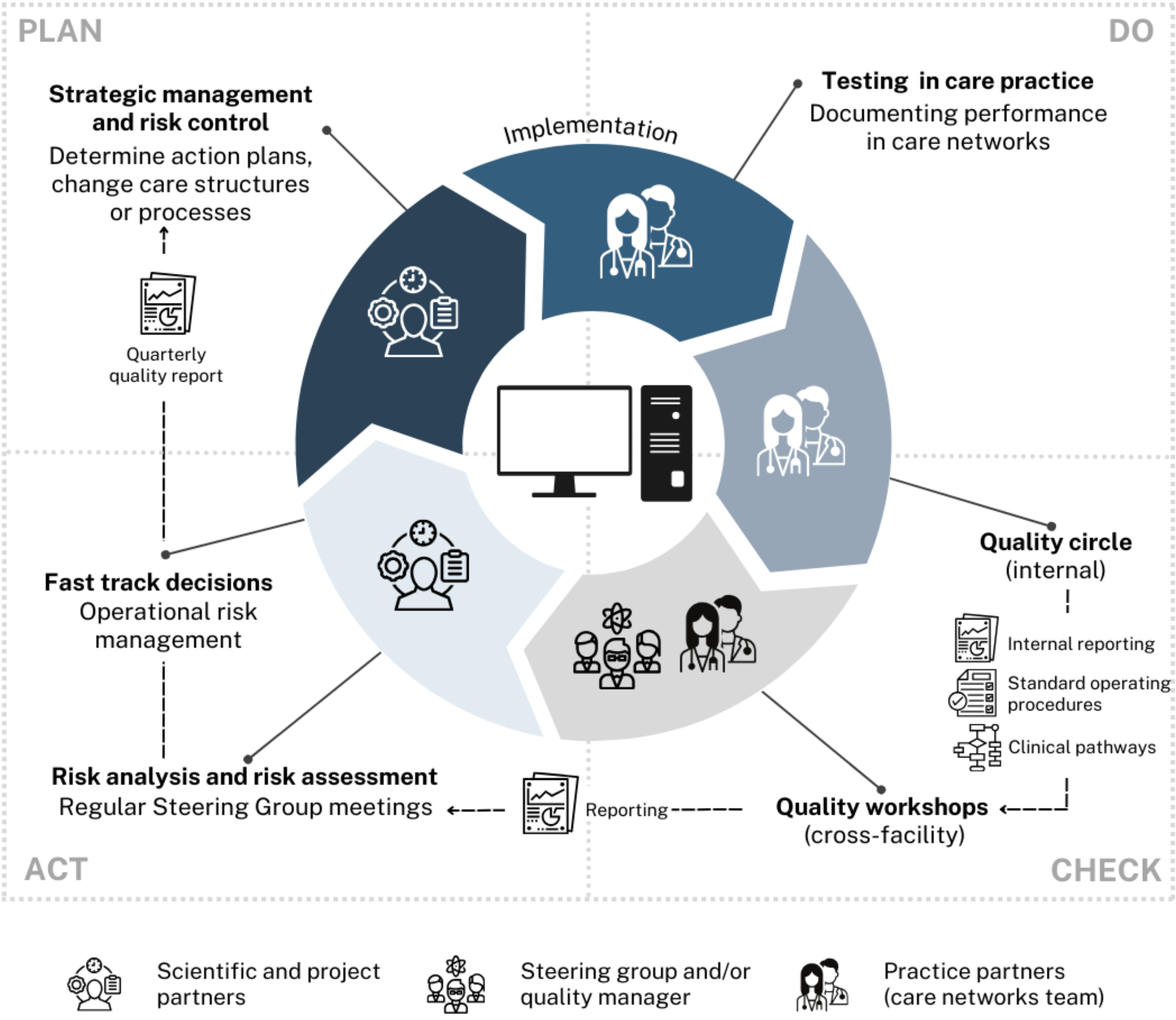


**Figure 13.** Participatory continuous improvement process in nFC-isPO.

## 6.2. Publication 1: Quality Indicators

Published as:

### Developing quality indicators for cross-sectoral psycho-oncology in Germany: combining the Rand/UCLA appropriateness method with a Delphi technique

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BMC Health Services Research

**RESEARCH** **Open Access**

# Developing quality indicators for cross-sectoral psycho-oncology in Germany: combining the RAND/UCLA appropriateness method with a Delphi technique

Lisa Derendorf[1*], Stephanie Stock[1], Dusan Simic[1] and Clarissa Lemmen[1]

## Abstract

**Background** Internationally, the need for appropriately structured, high-quality care in psycho-oncology is more and more recognized and quality-oriented care is to be established. Quality indicators are becoming increasingly important for a systematic development and improvement of the quality of care. The aim of this study was to develop a set of quality indicators for a new form of care, a cross-sectoral psycho-oncological care program in the German health care system.

**Methods** The widely established RAND/UCLA Appropriateness Method was combined with a modified Delphi technique. A systematic literature review was conducted to identify existing indicators. All identified indicators were evaluated and rated in a two-round Delphi process. Expert panels embedded in the Delphi process assessed the indicators in terms of relevance, data availability and feasibility. An indicator was accepted by consensus if at least 75% of the ratings corresponded to category 4 or 5 on a five-point Likert scale.

**Results** Of the 88 potential indicators derived from a systematic literature review and other sources, 29 were deemed relevant in the first Delphi round. After the first expert panel, 28 of the dissented indicators were re-rated and added. Of these 57 indicators, 45 were found to be feasible in terms of data availability by the second round of expert panel. In total, 22 indicators were transferred into a quality report, implemented and tested within the care networks for participatory quality improvement. In the second Delphi round, the embedded indicators were tested for their practicability. The final set includes 16 indicators that were operationalized in care practice and rated by the expert panel as relevant, comprehensible, and suitable for care practice.

**Conclusion** The developed set of quality indicators has proven in practical testing to be a valid quality assurance tool for internal and external quality management. The study findings could contribute to traceable high quality in cross-sectoral psycho-oncology by providing a valid and comprehensive set of quality indicators.

**Trial registration** "Entwicklung eines Qualitätsmanagementsystems in der integrierten, sektorenübergreifenden Psychoonkologie—AP "Qualitätsmanagement und Versorgungsmanagement" zur Studie "integrierte, sektorenübergreifende Psychoonkologie (isPO)" a sub-project of the "integrierte, sektorenübergreifende Psychoonkologie (isPO)",

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was registered in the German Clinical Trials Register (DRKS) (DRKS-ID: DRKS00021515) on 3rd September 2020. The main project was registered on 30th October 2018 (DRKS-ID: DRKS00015326).

**Keywords** Quality measurement, Quality indicator, Quality improvement, Quality improvement methodologies, RAND/UCLA Appropriateness Method, Delphi Technique, Psycho-oncology, Cancer, Complex intervention, Integrated care model

## Background

The incidence of cancer is increasing significantly worldwide [1, 2], with nearly 500,000 new cases diagnosed in Germany each year [3]. Cancer patients are affected by emotional distress and often by psychological disorders [4–9]. In Germany, the implementation of cross-sectoral psycho-oncological support is considered an important strategy to improve quality of cancer care for patients of all cancer entities. The German National Cancer Plan (NCP) strongly recommends to further develop "oncological care structures and quality assurance" [10, 11]. The implementation of psycho-oncological care structures along with quality management are not only complex and considered an integral part of oncology care [12, 13], but must also meet the demands for needs-based and accessible care, while being subjected to legally binding quality assurance terms [14].

Monitoring and improving quality in health care is of crucial importance, even if quality itself is not directly observable and measurable. Therefore, quality-related indicators are employed to make health care measurable [13, 14]. A quality indicator is a quantitative measure that can be used to monitor and assess the quality of governance and management, as well as clinical and support functions that impact patient outcomes in a process of care. They do not measure quality directly, but are rather a performance assessment tool that can draw attention to potential performance issues that may require more intense review within an organization [15]. Quality indicators have notably gained momentum because they systematically point out potential for improvement in a functioning quality management system [16, 17]. Indicators in health care are often applied for quality measurement and improvement (e.g., plan-do-check-act cycles (PDCA)), but also, for example, for comparison with other service providers (e.g., benchmarking), public disclosure (e.g., quality reports), or quality-based remuneration of services (pay for performance) as well as for research purposes [18–21].

To improve routine care of cancer patients in cancer centres in Germany, an intervention called "*new form of care integrated, cross-sectoral psycho-oncology*" (nFC-isPO) has been developed and piloted. In Germany, the health care system is divided into an inpatient and an outpatient sector. Treatment and diagnostics conducted during a hospital stay belong to the inpatient sector, whereas all treatment and rehabilitation activities outside of the hospital belong to the outpatient sector. "New forms of care" (nFC) are care models that improve cross-sectoral care, optimise intersectoral interfaces, or overcome the separation of sectors [22–24]. In the inpatient sector, psycho-oncological care is often provided in acute hospitals and oncological rehabilitation facilities. Although cancer counselling centres are well established in the outpatient sector, they will not be able to meet the demand in the medium term due to the demographic trends and the associated increase in the number of new cases [3, 25, 26]. A detailed examination of the psycho-oncological care structures in Germany by the Federal Ministry of Health (2018) showed that the degree of coverage of inpatient psycho-oncological care by psycho-oncological services in Germany can vary considerably depending on the sector and region. For example, more than half of the regions in the outpatient sector and about 40% in the inpatient sector have a coverage of less than 50% [27].

The nFC-isPO has bridged the gap from bench to bedside by providing a high quality, translational psycho-oncological care program for cancer patients [22, 28–31]. To ensure that care is delivered as stipulated, an appropriate and reliable set of quality indicators was needed for comprehensive quality management [22, 32]. The aim of this study was to develop, implement and evaluate a set of suitable indicators to systematically measure, manage, and improve the quality of care for a cross-sectoral psycho-oncological care program for cancer patients in routine care in several cancer centres in Germany.

## Methods

### Design

A procedure of linking the RAND/UCLA Appropriateness Method (RAM) with elements of the Delphi technique was used to develop a set of quality indicators to measure the quality of care regarding structures, processes, and outcomes of a cross-sectoral psycho-oncology care program [33, 34]. This methodology was useful to combine scientific evidence and expert opinion obtained through consensus technique. The iterative approach included a systematic literature review, a two-stage anonymous survey (Delphi rounds), a questionnaire-based reassessment of indicators and a face-to-face expert panel discussion (see Fig. 1) [17, 34, 35]. This project was registered in the German Clinical Trials Register (DRKS) (DRKS-ID: DRKS00021515) on 03/09/2020.

### Systematic literature search and selection of potential quality indicators

In June 2018, a systematic literature search was conducted to identify an initial set of quality indicators and domains of quality of care for cancer patients with emotional distress or mental disorder. Initially, six databases (PubMed, PsychINFO, Livivo, PSYNDEX, SpringerLink, Cochrane Library) were systematically searched for scientific articles. A predefined search strategy was used (see Additional file 1). In addition, bibliographies of relevant secondary publications and grey literature (e.g., reports on quality assurance projects), websites of relevant organizations that have developed or were using quality indicators (e.g., medical societies), and evidence-based guidelines recommending quality indicators were reviewed by hand search. The authors also identified indicators from the four care networks cooperating in the project. Study selection and screening were performed independently by two researchers (LD and CL). Duplicate indicators were removed (see Additional file 2). The identification of potential indicators was done by consensus between the two authors (LD and CL). Subsequently, the results were categorised based on Donabedian's quality dimension (structure-, process- or outcome quality) [33, 36], and the recommended quality criteria of Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (accessibility, appropriateness,

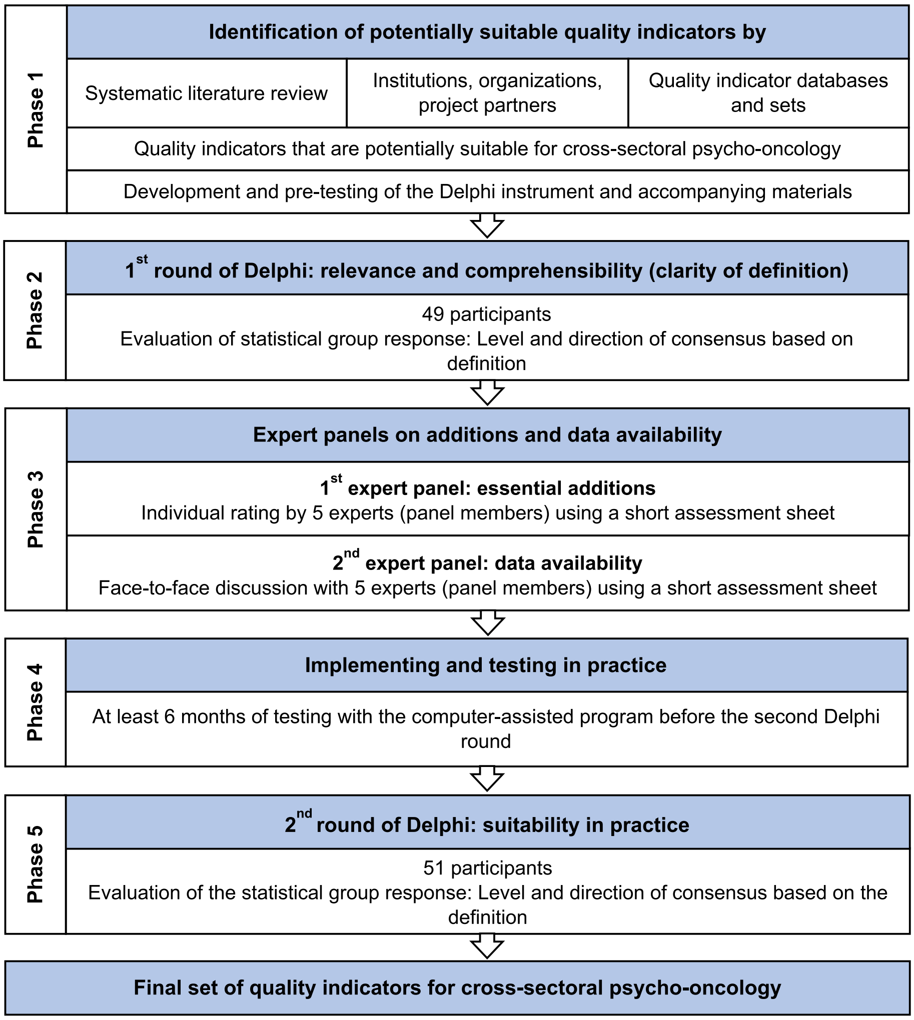

**Fig. 1** Modified process of developing quality indicators for cross-sectoral psycho-oncology

continuity, efficiency, efficacy, patient perspective, safety, timeliness) [37, 38]. A preliminary set of indicators was selected to start the expert consensus and rating process (phase 1).

### Selection of survey participants and panel members

In a Delphi, the selection of the panel is based on the members' knowledge of the particular topic. Therefore, a purposive sampling strategy was was used to select the experts [39, 40]. The inclusion criterion was that the panel members had to be involved in the nFC-isPO team, as they had the background information on the development, implementation and testing of the nFC-isPO. The participants needed to be able to assess the project-specific requirements of the nFC-isPO for the development of indicators and for the availability of data. The Delphi rounds involved participants from different fields of health services research and psycho-oncological care who all operated in the care program (e.g., health care professionals, health insurance companies, patient representatives etc.). Although the first and second round of Delphi (phase 2 and 5) had a closed group of participants, participants who did not participate in the first round were allowed to take part in the second Delphi round (e.g., due to staff turnover) [41]. The multidisciplinary expert panel consisted of five nFC-isPO representatives from the fields of psycho-oncology, quality management, health services research and medical statistics.

### Rating the indicators

Based on the results of the literature search (phase 1), the survey items for the first Delphi round (phase 2) were developed and set up in the online survey tool “Limesurvey”, before being tested for functionality and comprehensibility. In order to assess the relevance and comprehensibility of the indicators, two assessment questions were developed for each indicator instead of a single global rating. At first, participants were asked to rate the relevance on a verbally named five-point Likert Scale (5 = relevant, 4 = rather relevant, 3 = partly relevant, 2 = rather not relevant, 1 = not relevant). Relevance was defined as the extent to which the characteristics of the indicator are appropriate for the concept being assessed [34]. Secondly, the authors asked for comprehensibility of the indicators, i.e. clarity of definition, by using a binary decision question (yes/no). Additional free-text options enabled the participants to comment on the need for change in definition or to suggest missing indicators based on their professional judgement. This structure allowed to consider specific adjustments when revising and optimizing the indicators in the following process. Phase 2 resulted in an overview of consented and dissented indicators. The results of the Delphi rounds were made available to the participants in the quality circles and the quality workshops.Based on the results of the first Delphi round, the expert panel evaluated the dissented indicators again individually with regard to relevant additions, taking special account of the free-text comments using an assessment sheet. The panel members then individually discussed and rated the operability and feasibility (i.e., data availability) of the preliminary indicator set using a short assessment sheet [42]. The face-to-face discussion took place at the “Centrum für Integrierte Onkologie (CIO)” at University Hospital of Cologne (phase 3). In phase 4, the indicators assessed as feasible were operationalised and systematically implemented into practice. The testing took place over a period of at least six months in four different health care networks.

The implemented and tested indicators were re-rated in the second Delphi round (phase 5) with regard to their practical suitability for assessing and managing the quality of care in the care program. In addition to the rating on the 5-point Likert scale, the participants had the opportunity to leave comments in a free-text box.

### Definition of consensus and statistical analysis

The consensus rule for assessing agreement and disagreement of the indicators in the Delphi process was established a priori. For descriptive statistical analysis, the authors used a proportion within a limited range [43]. The determined threshold of consensus is at 75% agreement, summed for categories 4 and 5 (agreement) or 1 and 2 (disagreement) [44].

- An indicator was considered to have a "moderate consensus" rating if the percentage of ratings of "relevant (5)" or "rather relevant (4)" (+) reaches at least 75% consensus out of all valid responses.
- An indicator was considered to have a "strong consensus" rating if the percentage of ratings of "relevant (5)" or "rather relevant (4)" (++) reaches at least 90% consensus out of all valid responses.
- Evaluated as "moderate rejection" (-) if the proportion of evaluations with "not relevant (1)" and "rather not relevant (2)" reaches at least 75% consensus out of all valid responses.
- Evaluated as "strong rejection" (--) if the proportion of evaluations with "not relevant (1)" and "rather

not relevant (2)" reaches at least 90% consensus out of all valid responses.

- All other indicators that had no unanimous group response (neither agreed nor disagreed), were considered dissent.

## Results

An overview of the identified and evaluated indicators can be seen in Fig. 2.

### Participation in the study and characteristics of participants

For the first round of the Delphi, 49 participants were invited. Of the 49 participants in the first round (100% response rate), 27 properly completed the questionnaire (55% completion rate). 21 (41.2%) of the participants of the first round also participated in the second round. Here, especially the care network teams were asked to share the survey in-house with the relevant individuals in nFC-isPO. A total of 51 people participated, 35 (68.6%) completed the second survey in full, 11.8% (6 records) were missing. 24 (47.1%) of the participants in the second round did not partake in the first round. The structure of the participants covered a variety of occupational fields related to psycho-oncological care. Table 1 describes the characteristics of the participants.

### Consensus after round 1

Participants reached a strong consensus for 9 out of 88 (10.2%) indicators and a moderate consensus for another 20 (22.7%) indicators regarding relevance,

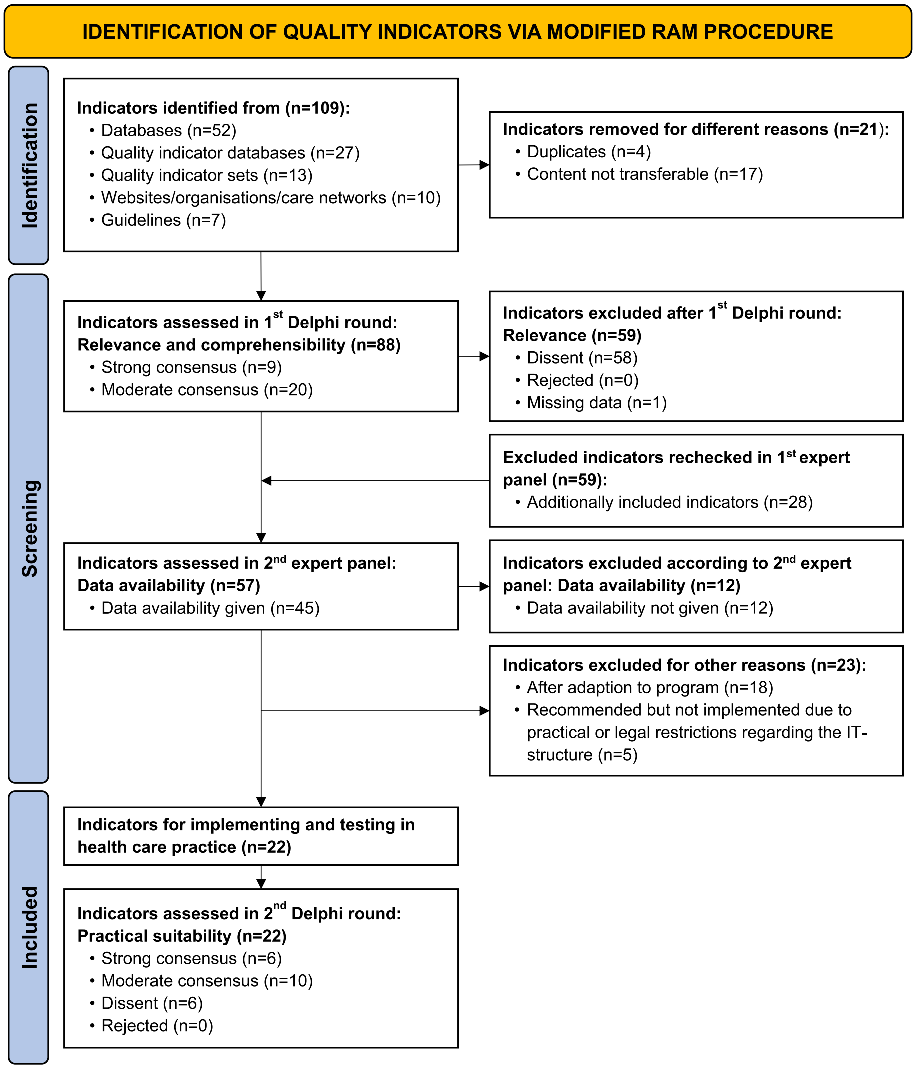

**Fig. 2** Results of the modified RAM procedure

**Table 1** Participant characteristics

**Characteristics of the participants from various fields of psycho-oncological care**

| | Round 1 | | Round 2 | |
|---|---|---|---|---|
| **Quality management touch points** | **N** | **%** | **N** | **%** |
| Yes | 20 | 40.8% | 35 | 68.6% |
| No | 7 | 14.3% | 11 | 21.6% |
| Missing | 22 | 44.9% | 5 | 9.8% |
| Total | 49 | 100.0% | 51 | 100.0% |
| **Working experience in years** | **N** | | **N** | |
| Valid | 27 | | 46 | |
| Missing | 22 | | 5 | |
| Mean ± SD | 13.22 | ± 11.01 | 12.24 | ± 11.19 |
| Median | 10 | | 8 | |
| Min | 0 | | 1 | |
| Max | 40 | | 49 | |
| Quartile | | | | |
| 1st | 4 | | 3 | |
| 2nd | 10 | | 8 | |
| 3rd | 20 | | 18.5 | |
| **Professional role** | **N** | **%** | **N** | **%** |
| Project worker | 7 | 18.4% | 17 | 28.3% |
| Psychotherapist | 6 | 15.8% | 10 | 16.7% |
| Case manager | 5 | 13.2% | 4 | 6.7% |
| Physician in the Oncology Centre | 4 | 10.5% | 5 | 8.3% |
| Nurse practitioner | 3 | 7.9% | 3 | 5.0% |
| Network coordinator | 3 | 7.9% | 3 | 5.0% |
| Psychosocial specialist | 3 | 7.9% | 2 | 3.3% |
| Quality manager | 1 | 2.6% | 7 | 11.7% |
| Patient representative | 1 | 2.6% | 2 | 3.3% |
| isPO-onco-guide | 1 | 2.6% | 0 | 0.0% |
| Social worker | 1 | 2.6% | 0 | 0.0% |
| Physician in private practice | 0 | 0.0% | 0 | 0.0% |
| Other | 2 | 5.3% | 2 | 3.3% |
| Not reported | 1 | 2.6% | 5 | 8.3% |
| **Total** | **38** | **100.0%** | **60** | **100.0%** |

i.e. the significance of the quality characteristic captured by the quality indicator for the care system. A total of 29 indicators were classified as relevant for the psycho-oncological care program. There was dissent for 58 (67.0%) indicators. No indicator was rejected. Data was missing for one indicator due to a technical error. 10 (11.36%) indicators were fully understandable and clear in definition to all survey participants. The remaining 78 (88.6%) indicators were rated comprehensive and clearly defined by at least 82.4% of the respondents. The results can be seen in Additional file 3.

### Results of the expert panels

In total, 28 indicators were added to the set by the authors while rechecking the indicators rated with dissent. In the second round, the members of the expert panel met in person under guidance of a moderator, discussed and evaluated the identified and the complemented indicators regarding data availability. A total of 57 indicators (29 strongly or moderately endorsed plus 28 additions) were evaluated. In 12 cases, implementation in health care practice was rejected due to lack of data availability regarding technical and legal aspects (e.g., data protection, lack of documentation, etc.). Subsequently, the preliminary set was adjusted to reflect care reality, several indicators were combined and the definitions were sharpened by the authors. 45 (79%) indicators were combined into 27. Five of these 27 were deferred as recommendations due to legal and technical uncertainties. The expert panel ended their work with 22 indicators to be implemented and tested in care practice.

### Implementation and piloting

The final set of 22 indicators has been operationalised in the information technology (IT)-supported documentation and assistance system (CAPSYS). CAPSYS was developed to record core data of patient care and contractual service provision, and to support the planning, management and monitoring of the pathway-guided and quality-assured patient care in the nFC-isPO [22]. In addition, a quality management module was developed within CAPSYS. Based on the documented data in CAPSYS, the quality indicators could be calculated and queried as a structured and standardised quality report. The quality report could be generated and retrieved internally for any selectable time period. Before the second round of the Delphi survey, the indicators included in the quality report were tested in practice for at least six months in four care networks in internal and cross-facility quality management.

### Consensus after round 2

In the second round, participants were asked to assess the 22 indicators in terms of their practicality. Consensus was reached for 16 (72.7%) indicators, thereof 6 (27.3%) with strong consensus and 10 (45.5%) with moderate consensus. There was dissent on 6 (27.3%) indicators. No indicator was rejected. Table 2 shows an overview of the results.

## Discussion

In this study a feasible and practical set of quality indicators was developed, operationalized in a quality report and pilot tested for a cross-sectoral psycho-oncological

**Table 2** Overview of results for the assessed quality indicators for Delphi round 2

| | Statistical results of the 2nd round of delphi assessing practical suitability | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Distribution | | | | | Measures of central tendency | | | | Consensus | | |
| | Short title | not relevant | rather not relevant | partly relevant | rather relevant | relevant | Mean ± SD | Median | Quartile | | Direction | | Level of consensus |
| | | (1) | (2) | (3) | (4) | (5) | | | 1st | 3rd | Consensus | Rejection | |
| **1** | Enrolments | 2.9% | 14.3% | 17.1% | 25.7% | 40.0% | 3.86 ± 1.192 | 4 | 3 | 5 | 65.7% | 17.2% | dissent |
| **2** | Assignment to care level | 25.7% | 14.3% | 2.9% | 2.9% | 54.3% | 3.46 ± 1.804 | 5 | 1 | 5 | 57.2% | 40.0% | dissent |
| **3** | isPO-onco-guide consultation | 5.7% | 5.7% | 25.7% | 25.7% | 37.1% | 3.83 ± 1.175 | 4 | 3 | 5 | 62.8% | 11.4% | dissent |
| **4** | Withdrawals | 2.9% | 0.0% | 20.0% | 28.6% | 48.6% | 4.2 ± 0.964 | 4 | 4 | 5 | 77.2% | 2.9% | moderate (+) |
| **5** | Reasons of withdrawals | 8.6% | 0.0% | 8.6% | 22.9% | 60.0% | 4.26 ± 1.197 | 5 | 4 | 5 | 82.9% | 8.6% | moderate (+) |
| **6** | Report of critical events | 2.9% | 0.0% | 2.9% | 37.1% | 57.1% | 4.46 ± 0.817 | 5 | 4 | 5 | 94.2% | 2.9% | strong (++) |
| **7** | Report of critical events—Involvement of additional caregivers | 2.9% | 0.0% | 5.7% | 42.9% | 48.6% | 4.34 ± 0.838 | 4 | 4 | 5 | 91.5% | 2.9% | strong (++) |
| **8** | Number of initial services | 2.9% | 0.0% | 5.7% | 28.6% | 62.9% | 4.49 ± 0.853 | 5 | 4 | 5 | 91.5% | 2.9% | strong (++) |
| **9** | Number of consultations | 2.9% | 0.0% | 2.9% | 14.3% | 80.0% | 4.69 ± 0.796 | 5 | 5 | 5 | 94.3% | 2.9% | strong (++) |
| **10** | Average number of consultations per patient | 2.9% | 2.9% | 5.7% | 42.9% | 45.7% | 4.26 ± 0.919 | 4 | 4 | 5 | 88.6% | 5.8% | moderate (+) |
| **11** | Average duration of consultations | 5.7% | 5.7% | 5.7% | 40.0% | 42.9% | 4.09 ± 1.121 | 4 | 4 | 5 | 82.9% | 11.4% | moderate (+) |
| **12** | Time for organizing access | 0.0% | 2.9% | 14.3% | 22.9% | 60.0% | 4.4 ± 0.847 | 5 | 4 | 5 | 82.9% | 2.9% | moderate (+) |
| **13** | Time to receive services | 0.0% | 0.0% | 5.7% | 22.9% | 71.4% | 4.66 ± 0.591 | 5 | 4 | 5 | 94.3% | 0.0% | strong (++) |
| **14** | Time between consultations | 0.0% | 2.9% | 20.0% | 40.0% | 37.1% | 4.11 ± 0.832 | 4 | 4 | 5 | 77.1% | 2.9% | moderate (+) |
| **15** | Time for organizing assessments | 0.0% | 8.6% | 17.1% | 28.6% | 45.7% | 4.11 ± 0.993 | 4 | 3 | 5 | 74.3% | 8.6% | dissent |
| **16** | Time between service and documentation | 2.9% | 11.4% | 25.7% | 40.0% | 20.0% | 3.63 ± 1.031 | 4 | 3 | 4 | 60.0% | 14.3% | dissent |
| **17** | Mean difference of HADS total scores | 0.0% | 0.0% | 5.7% | 25.7% | 68.6% | 4.63 ± 0.598 | 5 | 4 | 5 | 94.3% | 0.0% | strong (++) |
| **18** | Percentage of improvements in anxiety and depression over time points T1 to T2 | 0.0% | 2.9% | 8.6% | 14.3% | 74.3% | 4.6 ± 0.775 | 5 | 4 | 5 | 88.6% | 2.9% | moderate (+) |
| **19** | Average reduction in anxiety and depression over time points T1 to T2 | 0.0% | 2.9% | 11.4% | 17.1% | 68.6% | 4.51 ± 0.818 | 5 | 4 | 5 | 85.7% | 2.9% | moderate (+) |
| **20** | Percentage of improvements in anxiety and depression over time points T1 to T3 | 0.0% | 2.9% | 11.4% | 20.0% | 65.7% | 4.49 ± 0.818 | 5 | 4 | 5 | 85.7% | 2.9% | moderate (+) |
| **21** | Average reduction in anxiety and depression over time points T1 to T3 | 2.9% | 5.7% | 5.7% | 17.1% | 68.6% | 4.43 ± 1.037 | 5 | 4 | 5 | 85.7% | 8.6% | moderate (+) |
| **22** | Patient satisfaction isPO-onco-guide consultation | 8.6% | 14.3% | 14.3% | 25.7% | 37.1% | 3.69 ± 1.345 | 4 | 3 | 5 | 62.8% | 22.9% | dissent |

**Threshold for consensus:** "strong consensus (++)" ≥ 90% in category 5 and 4; "moderate consensus (+)" ≥ 75% in category 5 and 4; "strong rejection (--)" ≥ 90% in category 2 and 1; "moderate rejection (-)" ≥ 75% in category 2 and 1; dissent: no unanimous group response care program in the setting nFC-isPO. To date, few indicators related to cross-sectoral care of cancer patients have been integrated into the context of psycho-oncological routine care in Germany [11, 12]. The development of practice guidelines began internationally around 2008. In Germany, since around 2014, every institution has been obliged to develop and implement a written concept for psycho-oncological patient care in terms of a quality feature [10, 45–47]. Although there have been important milestones in the last decade, the road from evidence to implementation is still challenging [13, 26, 27, 48].

This research demonstrates the development, piloting, and finally definition of 16 trackable quality indicators. These 16 indicators reflect a relevant and comprehensive set covering psycho-oncology care across sectors, as well as Donabedian's quality dimensions and numerous quality criteria according to JCAHO. A particular challenge was to overcome the sectoral boundaries in a shared set. In Germany, many cross-sectoral care programs are coordinated, e.g., through shared diagnostics or to save resources. This makes it difficult to apply quality indicators across sectors [49]. To avoid performance measurement for individual providers in the nFC-isPO and to ensure a holistic understanding, nFC-isPO quality indicators are always collected for an entire care network consisting of outpatient and inpatient providers. The nFC-isPO indicator set therefore emphasizes the psycho-oncological care program as a whole. Similar to Großimlinghaus [50], the indicator set consists of cross-sectoral and diagnosis-specific aspects. Despite the diagnosis-specific aspects, many of the indicators such as "average number of consultations per patient" or "time to receive services" could be transferred to other disease patterns with mentally distressed patients and similar organizational care structures. The set allows adaptations for different diagnoses, contextual differences, or even for different countries [50, 51].

Although no indicator was unanimously rejected, some aspects were perceived as significantly more irrelevant (rejection between 20 and 30%). In particular, indicators that go beyond the services provided by the nFC-isPO (e.g., "regular attendance of self-help group", "number of relatives' consultations") and indicators related to documentation (e.g., "average time between data collections and documentation") were rejected more strongly. One point of discussion on the expert panel was the relevance of the indicators for theoretical psycho-oncological care in general compared to the relevance for the concrete nFC-isPO. While some of the assessed quality demands were inherent in the structure of the nFC-isPO, it would be pointless to operationalize them in this setting. For example, "information availability for patients" would be unnecessary to record, as patient information is automatically given to the patient in the form of a supplementary sheet at enrolment in nFC-isPO. Nevertheless, it might generally be an important measure of the quality of psycho-oncology care. Another example was that the expert panel seemed to lean more towards emphasizing the relevance of the indicator "number of relative's consultation" in the discussion, but voted only 55% in favour and 27% against (with a mean of 3.41 and standard deviation of 1.476). The wide dispersion suggests that the indicator might be relevant in general but not important for the nFC-isPO due to the structural organization. These aspects need to be considered, when revisiting and adjusting the set for other settings.

The results of this study contribute to national and international demands for improving psycho-oncological care structures. Defining and operationalizing psycho-oncological variables pursuing a uniform, cross-sectoral documentation goes far beyond the seven defined core variables of the first German evidence-based guideline on psycho-oncological diagnosis, counselling and treatment of adult cancer patients [12]. In this respect, the results support the goals of integrated and high-quality, psycho-oncological care [10, 11, 52]. The quality indicators developed can quantitatively cover the formulated goals of the NCP; the identification of psychosocial support needs as well as mental disorders in cancer patients and the provision of the necessary psycho-oncological care in inpatient and outpatient settings [11]. Particularly supportive measures for coping with the cancer (e.g., number of consultations, isPO-onco-guide counselling), relief of psychological and psychosomatic symptoms (e.g., mean difference of HADS total scores) as well as treatment adherence (e.g., reasons of withdrawal, time between services) are reflected in the set. In the medium term, there are considerations to supplement the set with indicators related to psycho-oncological care for relatives, quality of life and social reintegration. The feasibility of data collection and analysis was also tested area-wide as part of the nFC-isPO as required by the NCP [11]. By including inpatient and outpatient caregivers as well as cancer self-help groups (isPO-onco-guide), the set is cross-sectoral and might improve out-of-hospital psycho-oncological care by quantifying process and outcome quality (e.g., isPO-onco-guide consultations and patient satisfaction isPO-onco-guide consultations) [11].

Quality assurance through quality indicators can indirectly contribute to improving quality of care by making effects and outcomes visible [45, 53, 54]. As the lack of integration of indicators into information systems can be an immediate barrier in everyday use [55], this study aimed to link applicable quality indicators with standardized electronic documentation. Großimlinghaus et al. emphasize that the more use is made of existing, electronically available documents that can be extracted and evaluated with as little effort as possible, the better the feasibility of indicators [16, 55]. The strength of this research was that electronic implementation was part of the development process, i.e., evaluating data availability (phase 3) and testing validity in form of a quality report for at least six months (phase 4). Großimlinghaus et al. also emphasize that uniform data collection beyond the data already collected for billing purposes is essential for indicator projects. Therefore, the computerised documentation andassistance program (CAPSYS) [22] developed specifically for the nFC-isPO serves, among other things, as a standardized documentation system. Particularly with regard to numerous, cross-sectoral sites at which the nFC-isPO is carried out, standardized, consistent (electronic) documentation appears to be useful in order to record quality-relevant care data [16, 17]. The consented quality indicators were integrated into CAPSYS in the form of a quality report and enable quality comparisons [22]. By embedding the indicators digitally, the results can be accessed flexibly regardless of location and time. Thus, potentials for quality improvement can be quickly identified and used. The rapid transferability of quality assessments into practice and the linkage with quality improvement measures have been realized, which is important for a systematic approach to continuous quality improvement [56].

Team size was limited by the nature of the project, and there was inevitable turnover in the teams over the four years of the research. Participants were selected on the basis of their knowledge of the topic. Willingness to participate was assumed as all participants were project partners and already committed to the study. The clear inclusion criteria resulted in a relatively small pool of participants with high response rates, but low completion rates (55% and 68.6% respectively). Several studies have shown that the response rates for web surveys are much lower than for traditional surveys [34, 57, 58] and that the higher the number of items, the lower the completion rate [59]. This may explain why many experts abandoned the time-consuming web-based survey, especially in the first round. However, preliminary work on the size of expert panels has shown that a minimum of 20 participants is statistically relevant and can produce a valid expert opinion [60, 61]. In addition, recent studies have shown that small panels can produce reliable results and stable responses, especially when there are only a limited number of experts available in a field [62–64]. The high response rates of the small sized panel in this study are consistent with those observed in previous studies due to direct contact with participants [59].

Although consensus on the correct standard of methodological rigour is still lacking, the methodological changes may partially compromise the validity of this study [65]. The authors are aware that the specific sample of participants may threaten the external validity. Internal validity may be affected by the selection of the panel experts and the fact that the results are not necessarily replicable with comparable other groups [61]. In addition, the successive rounds of the survey resulted in 'natural losses' due to respondents dropping out. For pragmatic research reasons, dropouts and changes in the expert panel were inevitable as people left their jobs and the research project and/or new positions were filled. The professional heterogeneity of the panel is seen as a strength, as the participation of multi-perspective stakeholders is recommended and can increase the acceptability of quality indicators [34]. In contrast to a classical Delphi approach, only 41% of the participants in the second Delphi round were also present in the first round. Similar to the findings of Boulkedid et al. (2011), this may be equivalent to conducting distinct Delphi procedures, in which case it may be difficult to reach consensus.

Although the methodological design had to be modified due to the clinical practice setting, this study was developed and reported according to several guidelines and recommendations [34, 66–68]. Studies have shown that the selection of quality indicators based on consensus techniques is subject to great methodological variability [34, 69], and to date there is no 'one-size-fits-all' approach to identifying quality indicators for different settings. This study follows the methodological approach of the RAND/UCLA Appropriateness Method, combined with a modified consensus method, which is the first choice for identifying credible and valid indicators based on the opinion and experience of stakeholders with knowledge of the issue [34]. However, the further applicability and scientific evidence of the set of quality indicators should be demonstrated in subsequent studies to validate and update them in different care settings [61].

## Limitation

This study may have limitations. The indicator set was developed and applied specifically for a cross-sectoral psycho-oncological care program in the setting of nFC-isPO. These indicators proved feasible and appropriate for this purpose. With regard to the transferability of the indicator set to other settings, some adjustments certainly need to be made, but synergies are possible, especially for diseases with mental distress and cross-sectoral care approach [34, 51, 70]. Although no fixed reference ranges were defined in the beginning, initial empirical values for the indicators observed in everyday clinical practice could be determined. These values, in addition to evidence-based ones, can serve as an initial guide for setting a preliminary target range in the course of continuous revision of the set [16, 49]. Because of the SARS-COV-2 pandemic, direct patient involvement was not possible, but patient representatives were included. The research team tried to minimize the additional psychological burden and increased risk of infection for patients by reducing and postponing scheduled face-to-face interviews. The results of the patient interviews are still pending, but will be included into the set in the future [71]. Due to the small sample size and the low completion rate, this study lacks generalisability. Another limitation influencing panellists' ratings is the level of evidence available for the indicators [55]. In the context of this study with potential indicators retrieving from very different sources, level of evidence was not presented to the participants from widely diverse work contexts to avoid bias. Although the lack of high level of evidence might reduce the generalizability of the findings [55], this is widespread in many health care settings and is the reason for using an expert panel methodology [72]. In addition, the lack of a gold standard for indicator development has been noted in several comparable studies [34, 73]. Counteracting this, the established RAM procedure provides a certain methodological quality by combining several systematic methods and concrete quality criteria [74]. This method presents indicators that are valid and described in sufficient detail so that their results are reproducible, comprehensive and classifiable. The development and use of indicators should be understood as a process, although an important milestone has been reached by creating a set of quality indicators for cross-sectoral, psycho-oncological care. Nevertheless, continuous further development is necessary [56].

## Conclusion

This study contributes to improving quality in cross-sectoral psycho-oncological care by providing a valid, comprehensive and feasible set of 16 quality indicators for cancer patients affected by mental disorders and emotional distress. Operationalizing the theoretical concept of quality into a set of quality indicators and integrating it into a standardized and digitized quality management system makes it possible to go beyond a purely descriptive presentation of performance. The practical test has shown that quality assurance and controlling based on a set covering cross-entity and entity-specific aspects of care is successful in this specific psycho-oncological setting. Further work is needed to continuously improve the set and check if these indicators can be transferred to similar settings.

### Abbreviations

| | |
|---|---|
| NCP | German National Cancer Plan |
| PDCA | Plan-Do-Check-Act cycle |
| nFC-isPO | New form of care integrated, cross-sectoral psycho-oncology |
| RAM | RAND/UCLA Appropriateness Method |
| JCAHO | Joint Commission on Accreditation of Healthcare Organizations |
| CIO | Centrum für Integrierte Onkologie |
| HADS | Hospital Anxiety and Depression Scale |

## Supplementary Information

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**Additional file 1.**

**Additional file 2.**

**Additional file 3.**

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### Authors' contributions

Conceptualization, LD and CL.; methodology, LD and CL; formal analysis, LD; writing—original draft preparation, LD; writing—review and editing, CL; supervision, CL and SSt; project administration, LD; funding acquisition, DS and SSt. All the authors have read and agreed to the published version of the manuscript.

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### Availability of data and materials

All data generated or analysed during this study are included in this published article and its supplementary files.

## Declarations

### Ethics approval and consent to participate

"*Entwicklung eines Qualitätsmanagementsystems in der integrierten, sektorenübergreifenden Psychoonkologie—AP "Qualitätsmanagement und Versorgungsmanagement" zur Studie "integrierte, sektorenübergreifende Psychoonkologie (isPO)"* a sub-project of the "*integrierte, sektorenübergreifende Psychoonkologie (isPO)*", was registered in the German Clinical Trials Register (DRKS) (DRKS-ID: DRKS00021515) on 3rd September 2020. The main project was registered on 30th October 2018 (DRKS-ID: DRKS00015326). The project was approved by the Ethics Commission of the Faculty of Medicine of Cologne University (18–092) on 15th October 2018. Informed consent was obtained from all subjects and/or their legal guardian(s). The participants agreed to take part in the modified Delphi process at the start of phase 2. All methods were carried out in accordance with relevant guidelines and regulations.

### Consent for publication

Not applicable.

### Competing interests

The authors declare no competing interests.

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## Publisher's Note

## 6.3. Publication 2: Participatory Quality Development

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### Stakeholder Participation in Quality Management: Implementation and Results of Participatory Methods in Quality Development

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# Stakeholder Participation in Quality Management: Implementation and Results of Participatory Methods in Quality Development

[Beteiligung von Interessengruppen im Qualitätsmanagement: Umsetzung und Ergebnisse partizipativer Methoden in der Qualitätsentwicklung]

*Lisa Derendorf, Stephanie Stock, Michael Kusch, Hildegard Labouvie, Clarissa Lemmen*

## Abstract

**Introduction.** Involving all stakeholders is an important factor in health research to achieve high-quality care. However, many stakeholders are often not involved in the translation of clinical trial results into patient care. While the benefits of involving stakeholders in research are well-established, challenges persist in achieving sustained and meaningful participation in daily practice. Participatory quality development (PQD) aims to implement sustainable participation in a continuous quality improvement process by stabilising and improving the structures that have been established. The study aims to gather initial results on a complex intervention that employs participatory methods to facilitate continuous optimisation and to investigate the degree of stakeholder involvement.

**Methods.** The research employs a structured four-stage control loop, incorporating elements such as needs assessment, planning, implementation, and evaluation. Several participatory tools were implemented as part of a continuous quality improvement. A longitudinal survey was conducted to assess stakeholder perceptions at two different time points. The survey used rapid assessments including multiple choice questions, open-ended questions, and 5-point Likert scales.

**Results.** A sustainable PQD process integrated into the quality management (QM) of a cross-sectoral intervention is feasible. The results indicate that stakeholders' perceptions have evolved from mere inclusion to shared decision-making throughout the project. However, the results also highlight challenges for stakeholder participation, emphasizing the significance of individual motivation, project phases, and transparency. Various discourses have emerged regarding the motivation of stakeholders and their roles. Some stakeholders chose not to participate more actively due to other professional obligations. Another theme was the impact of project phases on participation levels. Transparency and pre-agreed commitments can strengthen the development of roles and relationships, facilitating participation.

**Discussion.** The research provides insights that can guide future projects aimed at promoting sustainable participation in QM and development. The presented modular tools and experiences can be adapted to different settings, offering valuable lessons for participatory approaches in health services research and complex interventions. The study highlights that assessing and promoting stakeholder participation in QM is an ongoing and adaptable process.

**Conclusion.** Sustainable stakeholder participation in QM requires flexibility. Tacit knowledge can be used in standardised processes to achieve inclusion and shared decision-making. However, balancing stakeholder needs is crucial. To achieve desirable participation in quality development, it is important to encourage diverse approaches without imposing rigid structures. The presented aspects can be viewed as a successful approach to participation in complex interventions, as well as a modular set of experiences and methods.

## Zusammenfassung

**Einleitung.** Die Einbeziehung aller Beteiligten ist ein wichtiger Faktor in der Gesundheitsforschung, um eine qualitativ hochwertige Versorgung zu gewährleisten. Allerdings sind viele Beteiligte häufig nicht an der Umsetzung der Ergebnisse klinischer Studien in die Patientenversorgung beteiligt. Während die Vorteile der Einbeziehung von Interessengruppen bekannt sind, besteht die Herausforderung darin, eine dauerhafte und sinnvolle Beteiligung in der täglichen klinischen Praxis zu erreichen. Die partizipative Qualitätsentwicklung (PQE) zielt darauf ab, eine nachhaltige Beteiligung an einem kontinuierlichen Qualitätsverbesserungsprozess zu implementieren, indem sie die bereits etablierten Strukturen stabilisiert und verbessert. Das Ziel der Studie besteht darin, erste Ergebnisse einer komplexen Intervention zu sammeln, die partizipative Methoden einsetzt, um eine kontinuierliche Anpassung und Optimierung zu ermöglichen. Des Weiteren wird untersucht, inwieweit sich die Stakeholder tatsächlich in den PQE-Prozess eingebunden fühlen. Diese Zielen sollen durch die Entwicklung eines partizipativen Ansatzes zur Qualitätssicherung und -verbesserung, seine Umsetzung in einem Versorgungsforschungsprojekt und die Bewertung der Beteiligung der Akteure an der neuen Versorgungsform 'integrierte, sektorübergreifende Psychoonkologie' (nFC-isPO) erreicht werden.

**Methoden.** Diese Arbeit nutzt für PQE einen strukturierten Regelkreis in vier Schritten (Plan-Do-Check-Act-Zyklus), der Elemente wie Bedarfsermittlung, Planung, Umsetzung und Bewertung umfasst. Im Rahmen eines strukturierten Prozesses zur kontinuierlichen Qualitätsverbesserung wurden verschiedene partizipative Instrumente und Methoden entwickelt und umgesetzt. Eine Längsschnittbefragung wurde durchgeführt, um die Wahrnehmungen der Beteiligten zu zwei Zeitpunkten während des Projekts zu erfassen. Für die Umfrage wurden Blitzbefragungen mit Multiple-Choice-Fragen, offene Fragen und 5-Punkte-Likert-Skalen verwendet.

**Ergebnisse.** Es ist möglich, einen nachhaltigen PQE-Prozess in das Qualitätsmanagement einer sektorübergreifenden Intervention zu integrieren. Die Ergebnisse zeigen, dass sich die Wahrnehmung der Beteiligten im Laufe des Projekts von einer bloßen Einbeziehung zu einer gemeinsamen Entscheidungsfindung entwickelt hat. Die Ergebnisse zeigen jedoch auch die Herausforderungen für eine nachhaltige Beteiligung der Stakeholder auf. Dabei wird die Bedeutung der individuellen Motivation, der Projektphasen und der Transparenz betont. Es sind verschiedene Diskurse hinsichtlich der Motivation der Stakeholder und ihrer Rolle entstanden. Einige Stakeholder wollten sich aufgrund ihrer beruflichen Verpflichtungen nicht stärker an dem Projekt beteiligen. Ein weiteres Thema war der Einfluss der Projektphasen auf den Grad der Beteiligung. Transparenz und im Voraus vereinbarte Verpflichtungen können die Entwicklung von Rollen und Beziehungen stärken und die Beteiligung erleichtern.

**Diskussion**. Die Ergebnisse können für zukünftige Projekte zur Förderung einer nachhaltigen Beteiligung am Qualitätsmanagement und an der Qualitätsentwicklung nützlich sein. Die vorgestellten modularen Instrumente und Erfahrungen können an unterschiedliche Rahmenbedingungen angepasst werden und bieten wertvolle Erkenntnisse für partizipative Ansätze in der Versorgungsforschung und bei komplexen Interventionen. Die Studie betont, dass die Bewertung und Förderung der Beteiligung von Interessengruppen im partizipativen Qualitätsmanagement ein fortlaufender und anpassungsfähiger Prozess ist. Es ist wichtig sicherzustellen, dass die Beteiligten kontinuierlich in den Prozess einbezogen werden.

**Fazit.** Um die Versorgungsqualität nachhaltig zu verbessern, ist eine flexible Beteiligung mehrerer Interessengruppen am Qualitätsmanagement erforderlich. Lokales Wissen kann in standardisierten Prozessen genutzt werden, um eine Einbeziehung und gemeinsame Entscheidungsfindung zu erreichen. Dabei ist es jedoch von entscheidender Bedeutung, die Bedürfnisse aller Beteiligten in Einklang zu bringen. Um eine wünschenswerte Beteiligung an der Qualitätsentwicklung zu erreichen, ist es wichtig, verschiedene Wege zu fördern, ohne starre Strukturen zu schaffen. Die vorgestellten Aspekte können als erfolgreicher Ansatz für die Beteiligung an komplexen Interventionen und Projekten sowie als modularer Satz von

Erfahrungen und Methoden betrachtet werden. Zukünftige Forschung kann je nach Kontext auf geeignete Elemente zurückgreifen.

**Keywords**

Participation, stakeholder engagement, quality improvement, participatory quality development, participatory health research, health services research

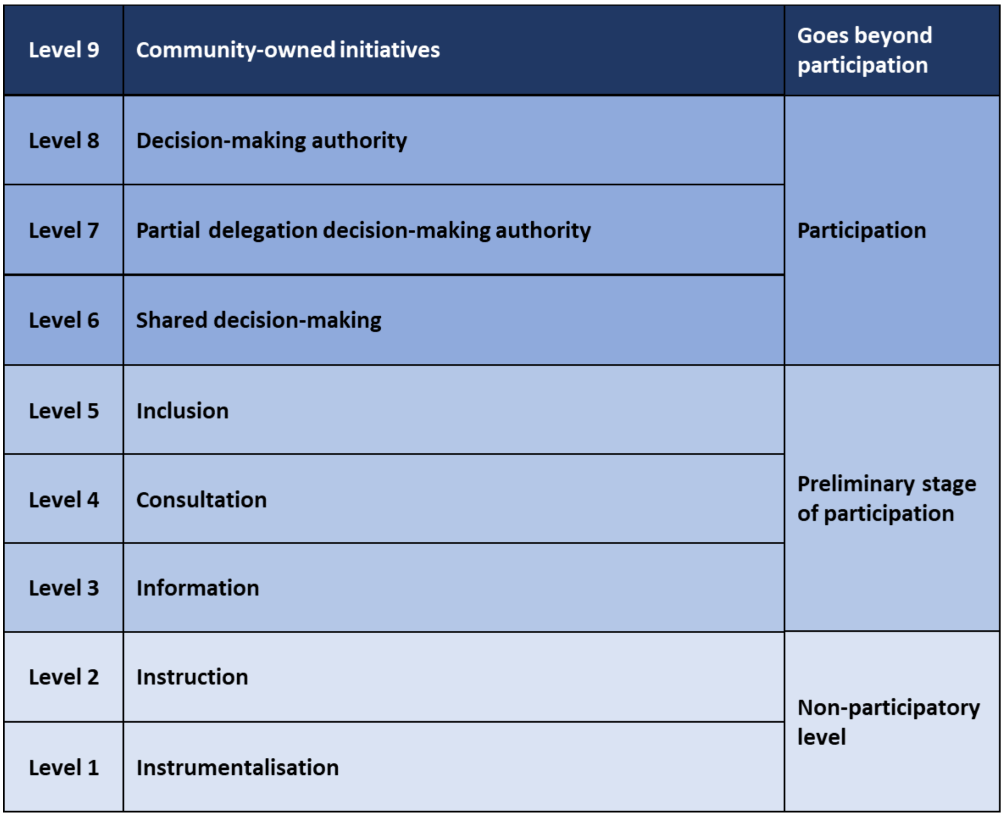
**Schlüsselwörter**

Partizipation, Stakeholder Einbindung, Qualitätsverbesserung, partizipative Qualitätsentwicklung, partizipative Gesundheitsforschung, Versorgungsforschung

## 1. Introduction

Participation is one of the central quality criteria in health research [1,2]. Involving people whose working or living conditions are the subject of research – hereafter referred to as stakeholders – in the research process can have several benefits. For example, patients can help to define patient-relevant priorities and endpoints, design research and thus tailor health care to their needs [3,4]. Involving practitioners in research can improve healthcare services and processes, and practitioners tend to report higher levels of satisfaction and competence in their work [5–7]. Sustainable stakeholder participation can succeed if those affected and responsible are involved as directly and continuously as possible in the process of planned organisational change [8,9]. However, many stakeholders are not adequately involved when research addresses relevant areas of their private or working lives [10,11]. Failure to involve stakeholders in research approaches may be due to various reasons, such as lack of knowledge and insufficient understanding of the purpose and ways of conducting participatory research. Lack of resources and skills, as well as insufficient incentives, can also be barriers to appropriate stakeholder involvement [12,13].

The concept of participatory health research (PHR) emphasises the involvement of various stakeholders, such as patients, practitioners, and researchers, in a collaborative research process. This approach aims to ensure that all parties participate on an equal footing. In particular, participatory quality development (PQD), which is based on PHR, focusses on stabilizing and improving these established structures [14]. With the help of PQD, the different interests of stakeholders can be systematically identified and negotiated through networking and collaboration (such as roundtables). Furthermore, PQD involves continuous improvement of interventions through equitable, collaborative partnerships between science, practice partners and patients [1,15]. Two central features of PQD include the direct use and expansion of local, mostly tacit knowledge of stakeholders [1,2]. Tacit knowledge, often deeply rooted in personal experience, intuition, insights, and practical know-how, refers to knowledge that is challenging to formalise, articulate, or express in a way that is easy to communicate or document [16,17]. This knowledge can be made explicit by applying participatory methods of data collection and analysis (e.g., focus groups, rapid assessments, etc.). The gain in knowledge is directly related to the development of new possibilities for action to promote change in a targeted way [1]. PQD can contribute to quality improvement through the repeated use of certain methods such as voting and reflecting, or by integrating it into an existing quality management system [1,15]. In this context, participation is understood as involvement and co-determination. As can be seen from figure 1 (and Supplementary Material 1), the extent of participation is described by several levels [18]. Each stage, apart from instrumentalization, has its justification depending on the situation and context, and not every participant in a project claims the same decision-making power [9]. The stage model can enhance transparency regarding the expected participation of stakeholders. It is designed to encourage discussion among stakeholders about the desired and current level of participation. All participants should be enabled to formulate their own needs and to bring them into the participation process according to their level of participation [1,19].



| | | |
|---|---|---|
| **Level 9** | **Community-owned initiatives** | **Goes beyond participation** |
| **Level 8** | **Decision-making authority** | **Participation** |
| **Level 7** | **Partial delegation decision-making authority** | |
| **Level 6** | **Shared decision-making** | |
| **Level 5** | **Inclusion** | **Preliminary stage of participation** |
| **Level 4** | **Consultation** | |
| **Level 3** | **Information** | |
| **Level 2** | **Instruction** | **Non-participatory level** |
| **Level 1** | **Instrumentalisation** | |

**Figure 1.** Levels of participation, Source: own representation adapted from Wright et al. (2011) [18].

However, it is important to lay the foundations of participation early on, such as providing tools and training, to involve stakeholders authentically and effectively [20].

### 1.1. Aims and objectives

To the best of our knowledge, there is limited research on the PQD and its implementation, especially in the context of health services research or complex interventions. Therefore, the aims of this study were (I) to collect preliminary findings on an intervention (and its realisation) using participatory methods in the context of quality development in order to enable ongoing and continuous adaptation and optimisation of the complex intervention, and (II) to explore how all participants felt involved in the participatory quality development process. To achieve this, the specific objectives of this study were

(1) to develop a participatory approach to quality assurance and improvement,

(2) to implement the participatory approach into a health services research project,

(3) and to assess the extent of stakeholder participation

for the new form of care ‘integrated, cross-sectoral psycho-oncology’ (nFC-isPO).

This research provides practical insights and initial findings on the application of participatory methods and research in complex interventions, particularly in the context of quality management beyond the project planning phase. This is relevant for researchers seeking to optimise stakeholder engagement in health service research. Furthermore, it caters to professionals experienced in quality management who aim to establish sustainable quality development by actively engaging stakeholders. The participatory quality development process exemplified by the nFC-isPO, along with the knowledge derived from this study, is designed to be adaptable and modular. It can be seamlessly transferred and customized, either individually or in combination, to suit diverse settings, thereby serving as a versatile resource for those embarking on similar initiatives.

### 1.2. Study setting and design of nFC-isPO

In Germany, nearly 500,000 new cases of cancer are diagnosed each year, while this number is expected to increase [21]. Cancer patients are regularly affected by emotional distress and psychological disorders such as anxiety, depression, or both [22,23]. Previous studies suggest that between 28% and 55% of cancer patients use psychological or social services [24–26]. The implementation of cross-sectoral psycho-oncological support structures is considered an important strategy to improve quality of cancer care for patients. Growing evidence-based knowledge has led to increased demands on health policy makers to transfer scientific findings into clinical practise nationally and internationally [22,27]. Further development of oncological care structures and quality assurance is strongly recommended, and institutions are required to develop and implement a written concept for psycho-oncological patient care as a quality feature [28,29]. These requirements are not only complex, but must also meet the demands for needs-based and accessible care, and are also subject to legally binding quality assurance terms [29,30]. Quality-assured, nationwide, and needs based psycho-oncological care is still far from being achieved [31].

The project, known as nFC-isPO, underwent a multi-phase process in Germany, encompassing its design and development from 2017 to 2018, implementation from 2018 to 2020, and comprehensive evaluation and consolidation from 2020 to 2022. The overall aim was to establish a stepped psychosocial and psychotherapeutic care approach to reduce anxiety and depression in adult cancer patients and to promote treatment adherence [22]. As a subproject in order to establish stakeholder participation, a PQD approach carried out within and across different care networks was designed and tested to achieve sustainable quality assurance and continuous improvement with the highest possible level of involvement of all stakeholders [1,22]. Therefore, a number of PQD elements have been developed and implemented in a structured, four-stage control loop (Plan-Do-Check-Act cycle (PDCA cycle)) (see Supplementary Material 2). Thus, the tacit knowledge of the stakeholders in the four phases is used for continuous quality improvement. Phases include (1) a needs assessment, where the participating target group identifies its own needs, followed by (2) a planning phase, where the interventions or actions to meet the needs are jointly agreed and defined. In the (3) implementation phase, the defined action plan is implemented. The intervention or actions are (4) evaluated during and after implementation. In this context, participation and collaboration are core principles of the PQD. In order to assess the participation of all stakeholders, a longitudinal survey in the form of rapid assessments was conducted at two points during the project. The use of rapid assessments has a relatively long tradition in PHR framework and is suitable to survey the quality of collaboration and participation of the different stakeholders [9,32]. NFC-isPO and its components (including quality management) were developed according to Issel's 'program theory' [33,34], translational psycho-oncology [34,35], and methods of application-oriented health services research [34].

## 2. Material and Methods

### 2.1. Selection of participants

PQD addresses all persons who are directly or indirectly affected by or have an interest in the activities of nFC-isPO (i.e. stakeholders). The term stakeholders in this context includes practice (i.e. treatment teams in four different care networks in North Rhine-Westphalia, Germany), scientific and project partners. Scientific partners are an interdisciplinary team from health services research, health sciences, medical informatics, psycho-oncology and psychotherapy, statistics, health economics and quality management. Project partners are three participating health insurance companies and two nationwide non-profit associations for patient representation (Cancer Society North Rhine-Westphalia (KG-NRW) and House of the Cancer Patient Support Associations of Germany (HKSH-BV)). The selection of the survey participants for the rapid assessment followed a purposive sampling [36,37]. All respondents were recruited from the multidisciplinary cross-facility quality workshops as all stakeholders involved were equally represented. Cross-facility quality workshops and internal quality circles (only for the local care network teams) were practical, theme-based, and systematic team meetings to analyse and methodically evaluate the optimisation and adaptation processes in the implementation phase and to derive measures for improvement. Two trained facilitators moderated the quality workshop and guided the group using various problem-solving techniques to develop and implement solutions to identified problems. These one-day meetings were held on a quarterly basis (quality circle about a week before the quality workshop) and the results were evaluated. A cooperation agreement limited the number of participants in the twelve mandatory quality workshops to a maximum of three representatives per project partner. On average, 20 people attended each quality workshop. The respondents gave their consent to participate in the survey.

### 2.2. Development of the questionnaire, data collection and analysis

In order to identify the perceived level of stakeholder participation, a structured rapid assessment questionnaire was designed according to the conceptual framework of PQD and was tested in advance for functionality, comprehensibility, and processing time [1]. The rapid assessments took place at two points in time. The first round took place in October 2019 using a written questionnaire within the 4th quality workshop. Due to the SARS-CoV-2 pandemic, the quality workshops were converted to a digital format. Therefore, the second round of the survey was conducted digitally in July 2021 as part of the 11th quality workshop using the online survey tool ‘Limesurvey’. At both times, participants were asked to evaluate the last twelve months retrospectively. Descriptive statistical analysis was performed with IBM SPSS Statistics 26. Data were collected using 22 single- and multiple-choice questions, rating scales, and free text fields. The questionnaire was thematically divided into needs assessment, planning and implementation, evaluation, collaboration, and participation (see Table 1). The first questions concerned information about which structures and offers for quality development were used and perceived as effective. Participants were then asked to rate statements on the planning, implementation and evaluation of quality development activities, as well as on participation and collaboration using a 5-point Likert scale ranging from ‘strongly agree’ to ‘strongly disagree’. Finally, participants could indicate at which level of participation (see Figure 1) they see themselves and answer one open question on ideas for improving the quality development process. The responses were screened using content structuring analysis [38]. The evaluation of the free texts was checked by peer debriefing.

**Table 1.** Results of the rapid assessments.

**STATISTICAL RESULTS IN 2019 AND 2021**

| **Statement** | **Year** | **Distribution %** (n) | | | | | |
|---|---|---|---|---|---|---|---|
| | | Strongly agree | Agree | Neither agree nor disagree | Disagree | Strongly disagree | **Total* (n)** |
| **Planning and implementation** | | | | | | | |
| Actions in nFC-isPO are carried out according to the urgency of your needs. | 2019 | 26 (6) | 35 (8) | 35 (8) | 4 (1) | 0 (0) | 23 |
| | 2021 | 29 (4) | 29 (4) | 36 (5) | 0 (0) | 7 (1) | 13 |
| The processing time of the defined actions for the (further) development of nFC-isPO is reasonable. | 2019 | 22 (5) | 44 (10) | 26 (6) | 9 (2) | 0 (0) | 23 |
| | 2021 | 14 (2) | 21(3) | 43 (6) | 21 (3) | 0 (0) | 14 |
| My knowledge is appropriately considered for the (further) development of nFC-isPO. | 2019 | 35 (8) | 30 (7) | 30 (7) | 0 (0) | 4 (1) | 23 |
| | 2021 | 21 (3) | 21 (3) | 43 (6) | 14 (2) | 0 (0) | 14 |
| I feel adequately informed about the processing status of the (further) development of nFC-isPO. | 2019 | 35 (8) | 30 (7) | 22 (5) | 9 (2) | 4 (1) | 23 |
| | 2021 | 29 (4) | 29 (4) | 43 (6) | 0 (0) | 0 (0) | 14 |
| I feel appropriately involved in the (further) development of nFC-isPO. | 2019 | 30 (7) | 35 (8) | 22 (5) | 9 (2) | 4 (1) | 23 |
| | 2021 | 29 (4) | 36 (5) | 29 (4) | 7 (1) | 0 (0) | 14 |
| **Evaluation** | | | | | | | |
| The results of the evaluation of the internal quality circles were presented in an understandable way. | 2019 | 64 (7) | 36 (4) | 0 (0) | 0 (0) | 0 (0) | 11 |
| | 2021 | 50 (3) | 50 (3) | 0 (0) | 0 (0) | 0 (0) | 6 |
| The results of the evaluation of the external quality workshop were presented in an understandable way. | 2019 | 53 (10) | 47 (9) | 0 (0) | 0 (0) | 0 (0) | 19 |
| | 2021 | 57 (4) | 43 (3) | 0 (0) | 0 (0) | 0 (0) | 7 |
| The quality report on the quality workshop (minutes, recommendations for action, etc.) was presented in an understandable way. | 2019 | - | - | - | - | - | - |
| | 2021 | 33 (3) | 67 (6) | 0 (0) | 0 (0) | 0 (0) | 9 |
| The protocol for the quality workshop was presented in an understandable way. | 2019 | 45 (9) | 50 (10) | 5 (1) | 0 (0) | 0 (0) | 20 |
| | 2021 | - | - | - | - | - | - |
| Recommendations for action on the quality workshop were presented in an understandable way. | 2019 | 46 (5) | 46 (5) | 9 (1) | 0 (0) | 0 (0) | 10 |
| | 2021 | - | - | - | - | - | - |
| The weekly report (including case numbers, referral numbers, and graphs) | 2019 | - | - | - | - | - | - |
| | 2021 | 55 (6) | 18 (2) | 18 (2) | 9 (1) | 0 (0) | 11 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| was presented in an understandable way. | | | | | | | |
| The controlling report was presented in a comprehensible way. | 2019 | 50 (6) | 33 (4) | 17 (2) | 0 (0) | 0 (0) | 12 |
| | 2021 | 33 (2) | 33 (2) | 33 (2) | 0 (0) | 0 (0) | 6 |
| The IT-based structured quality report from CAPSYS was presented in an understandable way. | 2019 | - | - | - | - | - | - |
| | 2021 | 57 (4) | 43 (3) | 0 (0) | 0 (0) | 0 (0) | 7 |
| The participatory quality development was presented in an understandable way. | 2019 | 46 (5) | 46 (5) | 9 (1) | 0 (0) | 0 (0) | 11 |
| | 2021 | - | - | - | - | - | - |
| **Collaboration** | | | | | | | |
| The collaboration between the nFC-isPO stakeholders is respectful. | 2019 | 30 (7) | 65 (15) | 4 (1) | 0.0 | 0.0 | 23 |
| | 2021 | 62 (8) | 23 (3) | 8 (1) | 8 (1) | 0.0 | 13 |
| There is equal collaboration between all nFC-isPO stakeholders. | 2019 | 22 (5) | 44 (10) | 30 (7) | 4 (1) | 0.0 | 23 |
| | 2021 | 23 (3) | 23 (3) | 39 (5) | 8 (1) | 8 (1) | 13 |
| **Participation** | | | | | | | |
| As an nFC-isPO stakeholder, I can influence decisions for the (further) development of the nFC-isPO. | 2019 | 5 (1) | 55 (12) | 27 (6) | 14 (3) | 0.0 | 22 |
| | 2021 | 23 (3) | 15 (2) | 39 (5) | 23 (3) | 0.0 | 13 |

- = The report did not exist at the time of the survey in 2019, or was subsumed under cumulative quality report in 2021.
- * Totals may vary due to different target groups for tools and reports and missing values.

## 3. Results

### 3.1. Participatory quality development integrated in the PDCA cycle

Figure 2 illustrates some of the main characteristics of the structure and processes of the quality management implemented under the premise of PQD for nFC-isPO. Based on the PDCA cycle, guided working groups in which participants define problems, causes, and solution strategies themselves (internal quality circles and cross-facility quality workshops) were implemented and tested in care practice. The local care network teams hold structured, quarterly internal quality circles to identify challenges in care practice by discussing administrative and clinical SOPs, IT-based quality reports and process analyses. Participants are expected to independently develop and implement appropriate solutions. The results of the various internal quality circles are discussed jointly in the following quarterly cross-facility quality workshop consisting of two representatives of each party. In this way, all stakeholders can equally exchange information about needs, challenges, and solutions and benefit from mutual experience and knowledge.

This procedure intensified and consolidated collaborations and network structures, not only locally but also across all networks. Furthermore, the practice partners participating in the quality workshops are important multipliers for care network teams on site. The results and decisions of the quality workshop are summarized and reviewed by quality managers, recorded in a quality report, and forwarded to the steering group. Urgent concerns could be decided directly during the quality workshop via fast-track procedure. With the transfer of results into practice, the project management was active in its steering function. In this concretisation, the relevance of the challenges and the solutions developed by the practice partners can gain in importance in practical implementation and be translated into materials for quality development. A comprehensive reporting system has been implemented to increase transparency and provide feedback to all stakeholders throughout the project. The reporting includes various quality reports, evaluations of the quality workshops and recommendations for action, as well as controlling and recruitment reports.

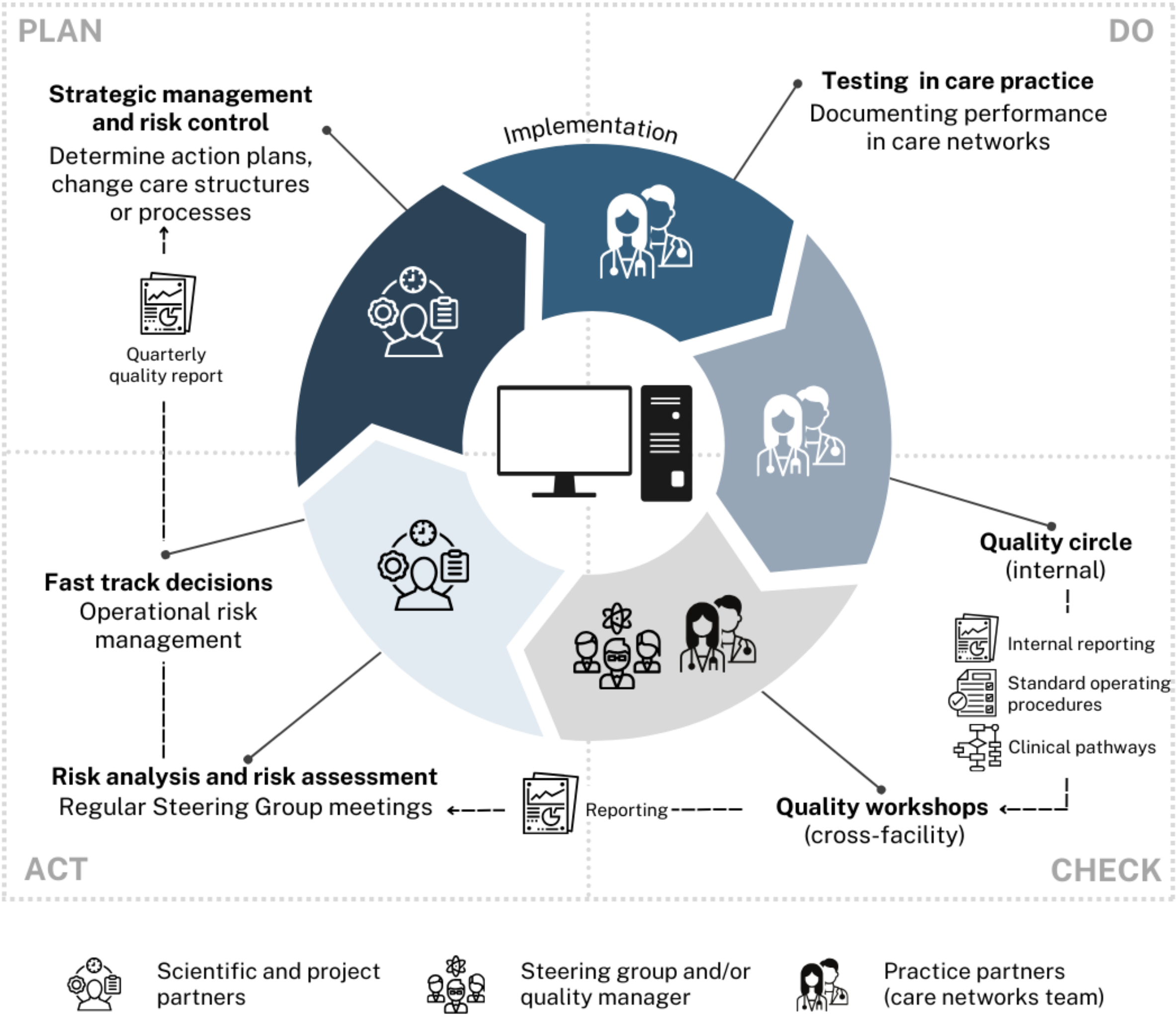


**Figure 2.** Implementation of the participatory quality development and its instruments in nFC-isPO.

In addition, several other tools were implemented to encourage participation and support the local teams in delivering the intervention. A digital helpdesk was set up where all stakeholders could ask questions and receive a timely response from the network support. The KG NRW supported the local care networks in the implementation of the intervention in their role as network support. Regular meetings were offered to share knowledge between the different care networks. All project stakeholders were able to contact each other throughout the project. The tools were evaluated in terms of their perceived effectiveness in the rapid assessment survey.

### 3.2. Participants of the rapid assessment survey

23 people participated in the first round in October 2019. One participant worked as a project partner, twelve were scientific partners, and ten were practice partners (e.g., network coordinators, case managers, psychotherapists). In July 2021, 15 respondents participated in the second survey. Two respondents belonged to the group of project partners, eight were scientific partners and five were practice partners.

### 3.3. Results of the rapid assessment survey

In 2019, 18 out of 22 (82%) participants felt at least included or even able to (jointly) decide on the (further) development of the intervention: 82%; one value was missing (see Figure 3). In 2021, this was the case for 10 out of 13 participants (77%; two values were missing). During the project, stakeholders felt more empowered to participate in shared decision-making (increase of 12%), while others evolved into more consultative roles (increase of 9%). Although stakeholders increasingly used the tools of ‘quality workshop’ and ‘direct contact’ with the project lead and project partners, they only felt that ‘direct contact’ with the project management or the project partners was increasingly effective (see Figure 4). As can be seen in Table 1, the degree of (strong) agreement in the area of planning and implementation decreased slightly over the course of the project regarding the processing times of defined measures, expertise used and feeling of being sufficiently informed. However, the perception of being adequately involved in the (further) development of the nFC-isPO remained constant. All evaluations, reports, and measures were rated mostly understandable. Most of the respondents (strongly) agreed that the collaboration between all stakeholders throughout the project as respectful, with 96% (n=22) in 2019 and 85% (n=11) in 2021. Nevertheless, it can be seen from the data in Table 1 that there has been a slight decrease in the percentage of respondents reporting equal collaboration between all stakeholders from 65% (n=15) in 2019, to 46% (n=6) in 2021. Furthermore, the results reveal that there has been a sharp decline from

59% (n=13) in 2019 to 39% (n=5) in 2021 among stakeholders who felt able to influence decisions for the development of the intervention.

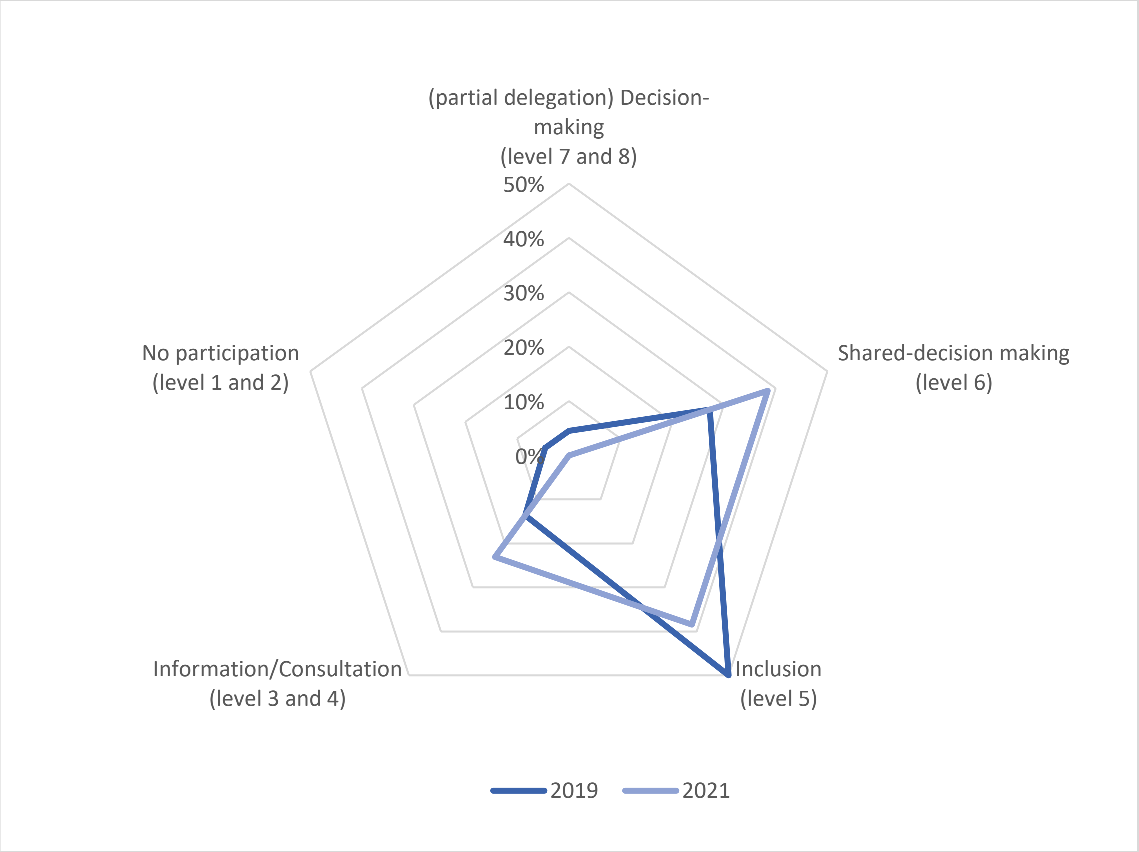


**Figure 3**. Perceived level of participation in the participatory quality development (PQD) in nFC-isPO based on Wright et al. (2011) [18].

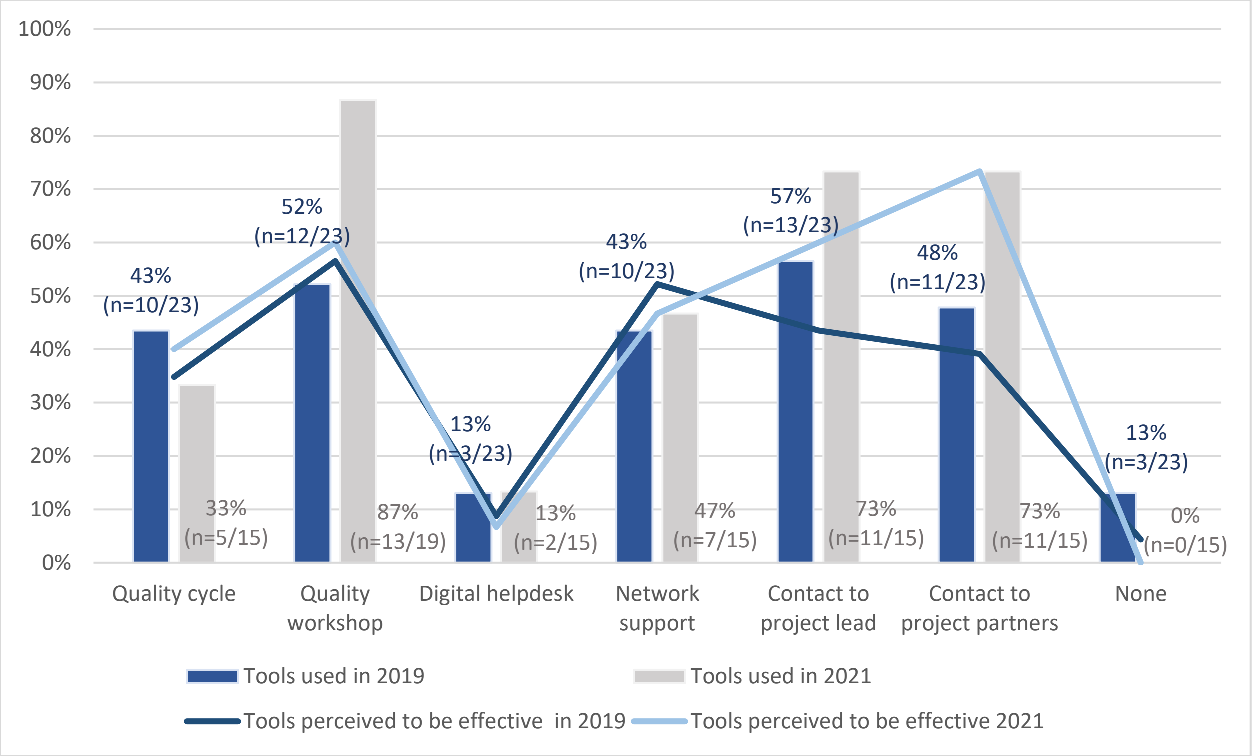


**Figure 4.** Used and perceived to be effective tools in nFC-isPO.

The open question on ideas for improving the quality development process was analysed and categorised according to its content. Eleven comments were made in 2019 and six in 2021. The categories identified were 'exchange between care networks', 'transparency and feedback', 'atmosphere of meetings', 'participation' and 'other'. Three respondents wished for more exchange and interaction, especially for care providers in local care networks. Nine comments related to transparency and feedback for the ongoing development and improvement processes, about which participants wished to be better informed. This requirement has been met through a comprehensive structured reporting system. One participant stated that there should be optimisation without blame ('meeting atmosphere'). Comments on the concept of 'participation' were made in two comments. Two comments dealt with clinical aspects ('other').

## 4. Discussion

This study identified several major challenges for sustainable and successful stakeholder participation in quality management: individual motivation, different project phases, and transparency and liabilities.

At the beginning, it was not possible to draw on existing collaborations and relationships between stakeholders. What is striking, however, is the strong improvement in perceived respectful collaboration between all stakeholders. While in 2019 only 30% strongly agreed that there was respectful collaboration, by 2021 this had increased to 62%. These results support the idea that considering basic principles and enabling factors such as trusting collaboration, time, financial, and structural resources, and individuals willing to participate and take responsibility are essential for the successful continuation of participatory projects [1,39]. In particular, the individual's attitude towards the project might play an important role. Quality workshops were increasingly used as PQD tool by all participants (from 52% in 2019 to 87% in 2021). Despite the 36% increase in use, over time only 3% (2019: 57%; 2021: 60%) more of the respondents rated the quality workshops as purposeful. The situation is different for the direct exchange with the project management and the project partners. Although the use of these structures increased by 16% and 25% respectively from 2019 to 2021, respondents' perception of the purposefulness of these structures also increased by 17% and 34% respectively. The results indicate that direct and personal contact is important to stakeholders. However, there may be changes in personnel and thus changes in relationships and collaboration. Similar to Wright et al., the constellation of stakeholders (e.g. the composition of teams, staff turnover) changed to some extent, which influenced the dynamics and openness towards the participants and the project [40]. This finding is consistent with that of Kümpers et al. who confirm that roles in participatory projects evolve contextually, i.e. depending on resources, competences, and personal and professional interests and specifications [41]. One interesting finding is that there was a discrepancy in the degree of influence on decisions regarding the (further) development of the nFC-isPO, which increased from 2019 to 2021. In 2021, 23% of respondents still reported having no influence on decisions, which is an increase of almost 10%. Meanwhile, the percentage of respondents who reported having influence on decisions increased by 5% to 23%. Furthermore, the results indicate a shift in participants' perceptions from mere inclusion to shared decision-making. In 2019, all levels of participation (including non-participation) were represented, whereas in 2021, respondents' perceptions were distributed only among shared decision-making, involvement, and consultation. The percentage of individuals who reported feeling only consulted rose from 14% to 23%. However, the percentage of respondents who felt represented at the level of shared decision-making also increased by 11% to 38%. It is possible that some practice partners had difficulty accepting project-related activities, while others were highly motivated and committed to the project. Previous studies have also noted that the extent of stakeholder participation depends on how strongly they identify with their role and the scope for action they have or perceive [39,41]. However, due to the small number of respondents in this study, additional research is required to assess the influence of motivation and role identification on stakeholder participation.

Another finding was that besides individual motivation such as role identification or commitment, participation can also vary in different project phases. The further the intervention was defined and implemented, the fewer aspects could still be effectively changed. The flexibility of co-design was greater in the development and implementation phases than in the consolidation phase. The consolidation phase may have contributed to the fact that the processing time of the defined actions for improving nFC-isPO was not perceived as adequate by the stakeholders. As care structures and processes were optimised over time and integrated into routine care, they could no longer be changed as flexibly as at the beginning. At the beginning there was creative freedom for all participants to develop structures, simply because there were no existing structures yet. PQD elements embedded at an early stage, such as networking, cooperation agreement, and multi-perspective quality workshops, made it possible to quickly achieve practicable results [1]. Furthermore, local tacit knowledge [17,42] could be made visible and usable in a timely manner and expanded and consolidated over time through various collaborations. Interestingly, 13% of the stakeholders in 2019 felt insufficiently informed about the processing status in the PQD. In 2021, on the other hand, none of the respondents felt uninformed, which may be due to the comprehensive reporting structure established at the end of the project. It can therefore be assumed that the dynamic changes in the project phases can also change stakeholders' perception of being involved [14].

In order to make participatory collaboration transparent and binding, the implementation of and participation in the quality circles and quality workshops was regulated in advance in a cooperation agreement. Similar to Kümpers et al., this created clarity about power relations, possibilities of influence, and levels of reflection and scope for action, as no instructions or permissions had to be given by superiors [41]. The results of the open question showed that stakeholders particularly value transparency and feedback as well as (personal) exchange and interaction. Therefore, sufficient feedback and information mechanisms should be made available to all stakeholders (e.g., regular reports and updates). In addition, smaller face-to-face meetings and working groups should be offered that create a space for transparency and participation.

Overall, these insights can help to better understand that not all stakeholders are able or willing to participate equally at all phases of a project, so the level of participation may also vary over the life of the project [9,43]. Nevertheless, it is clear that in addition to the benefits to the group, such as improved collaboration, communication, and learning effects, the overall development of the staff (e.g. skills) in this process should not be underestimated [44,45]. This study indicates that participatory projects require great flexibility in organisation and implementation to ensure the greatest possible participation of all stakeholders. This finding was also reported by previous studies [1,15,46,47]. Since the implementation of participatory methods is not subject to rigid requirements, they should be constantly tested and can be adapted as needed [15,47].

### 4.1. Implications for policy, practice, and research

This research can be seen as a practical guide to participatory approaches in health services research or complex interventions. To the best of our knowledge, there is little literature on this topic of growing interest and need. The implications for practice, policy, and research are profound and interconnected:

In practice, the research emphasizes the critical importance of considering stakeholder participation right from the project's initiation. The actual implementation of stakeholder participation is a balancing act and can consume time and resources, especially at the beginning [1,48]. The interdisciplinary nature of health services research and the collaborative environment in psycho-oncology highlight the importance of involving all stakeholders for successful and sustainable project implementation [30,49–51]. Additionally, the research recommends planning participatory designs with expertise in various participatory approaches, encompassing diverse methods and perspectives. This underscores the significance of early integration of participatory tools into the quality management control loop, fostering an intuitive and efficient optimisation process without constant consideration of roles or hierarchies. Therefore, it is recommended to appoint an experienced individual with high methodological competence and expertise in participation to the project initiator or manager's role. This underscores the critical role of leadership in ensuring effective stakeholder involvement [12]. In addition, comparison of the findings with those of other studies confirms that it makes sense to establish criteria for assessing the presence of participation, the quality and impact of participatory processes for each project phase [9,15].

From a policy perspective, there is a call for resource allocation, recognizing that implementing participation can be a resource-intensive process. Policymakers are urged to prioritise the allocation of resources, emphasising the importance of dedicating time and support, especially in the initial stages of a project. On the research front, there is a clear indication of the need for future studies evaluating the effectiveness of stakeholder involvement on health care services, patient outcomes, and job satisfaction. It is essential to understand the impact and benefits of participatory approaches in diverse healthcare settings.

In conclusion, the lessons learned from this research emphasise the need for a comprehensive and inclusive approach to stakeholder involvement in the healthcare design, processes, and evaluation. The use of participatory quality development methods and offering various participatory tools in a structured manner, depending on the project's context, is recommended. This approach is in line with the wider objective of improving transparency, collaboration, and the overall quality of research through participatory methods in healthcare settings. A recent study by Rackerseder et al. (2022) describes the effective use of participatory methods and tools in the development of patient and stakeholder information in the outpatient setting of cancer counselling centres in Germany [52]. Providing quality workshops or working groups will increase trust and collaboration and reduce feelings of lack of transparency.

### 4.2. Limitations

Being limited to the project stakeholders, this study lacks a representative sample size. The occurrence of the SARS-CoV-2 pandemic made it difficult to establish structures and collaborations by putting an additional burden on all stakeholders, especially the practice partners. Thus, the established communication formats had to be cancelled in presence, but could be successfully continued digitally. However, the digital formats were perceived as less binding. Notwithstanding this limitation, the clear and transparent structures that had been established in advance in a cooperation agreement proved to be advantageous during this time due to binding regulations.

## 5. Conclusions

This study provides an insight into the practical implementation of participatory research and was conducted to develop a sustainable integrated participatory quality management and to evaluate the level of stakeholder participation. The findings show that involvement and joint decision-making of multi-perspective stakeholders could be achieved by using tacit knowledge in standardised structures and processes for quality-oriented improvement. However, respecting and implementing stakeholder needs is a balancing act that should not be underestimated in terms of resources and time. As roles and project phases change dynamically, participatory methods must be adapted flexibly. The highest possible level of participation should be aimed for, even if sometimes only preliminary stages are feasible. While there is no patent recipe for participatory research projects, many paths can lead to the desired participation. In order to stabilise and sustain participatory processes after the end of the project, criteria for assessing the degree of participation and the quality of participatory processes should be defined and regularly evaluated in the sense of a quality management cycle. Participatory research offers a wide range of methods and there is no one-size-fits-all solution. The different aspects presented here can be seen together as a proven and successful approach to participation in complex interventions and projects, but also as a modular set of experiences and methods. Future research can draw on those elements that are appropriate to the context. Overall, this study strengthens the idea that the assessment the level of participation is a continuous process and flexibility in this context is a basic requirement for participatory quality management.

## Declarations

### Ethics approval and trial registration

The project was approved by the Ethics Commission of the Faculty of Medicine of Cologne University (18-092) on 15th October 2018. Informed consent was obtained from all subjects and/or their legal guardian(s). The participants agreed to take part in survey. All methods were carried out in accordance with relevant guidelines and regulations. This study was registered in the German Clinical Trials Register (DRKS) (DRKS-ID: DRKS00021515) on 3rd September 2020. The main project was registered on 30th October 2018 (DRKS-ID: DRKS00015326).

### Consent for publication

Not applicable.

### Data statement

All data generated or analysed during this study are included in this published article and its supplementary files.

### Declarations of interest

None.

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## Author Contributions

Conceptualization, LD, MK, HL and CL.; Data curation, LD and CL; Methodology, LD and CL; Investigation; LD, CL and HL; Formal analysis, LD; Software, LD; Validation, LD and CL; Resources, LD, CL and MK; Writing—original draft preparation, LD; Writing—review and editing, CL, MK, SSt; Visualization, LD; Supervision, CL and SSt; Project administration, LD; Funding acquisition, MK and HL. All the authors have read and agreed to the published version of the manuscript.

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## APPENDIX. Supplementary Material

The datasets supporting the conclusions of this article are included within the article and its supplementary Material.

Supplementary Material 1: Definition of the levels of participation.

Supplementary Material 2: Elements of the quality management and participatory quality development within the PDCA cycle.

Supplementary Material 3: SQUIRE Statement.

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## 6.4. Publication 3: Programme Adherence

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# Assessing the implementation of a comprehensive quality management system for cross-sectoral psycho-oncology in Germany

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ORIGINAL ARTICLE

# Assessing the implementation of a comprehensive quality management system for cross-sectoral psycho-oncology in Germany

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**KEYWORDS**
Evaluation;
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**Abstract**

*Introduction:* Quality management in healthcare is essential for safe, effective, and patient-centered services. Quality management systems (QMS) monitor and improve healthcare quality. Integrating QMS is crucial for optimal quality of care, but previous studies show gaps in integration. This study aims to assess program adherence to a QMS in cross-sectoral psycho-oncological care and to develop strategies for better integration, ultimately improving healthcare quality.

*Materials and methods:* The study used a utility analysis to assess the program adherence of a cross-sectoral psycho-oncology care program using a 5-point scale. The evaluation process involved breaking down the program into distinct areas, and used key figures and developed indicators to assess adherence. Descriptive statistics were used.

*Results:* The study conducted a comprehensive assessment of program adherence in a complex care program, analysing 4460 evaluation cases based on 128 quality indicators. The results showed a score of 4.2 out of 5 points (84%), indicating a highly effective implementation of the QMS. Notably, the study observed successful implementation of top-down elements, while encountering more challenges in integrating bottom-up aspects.

*Conclusion:* The study demonstrates effective implementation of a comprehensive QMS. Successful integration was observed in areas such as care concept, care management, quality assurance, and IT-based documentation, while challenges remain in quality development and indicators. Active leadership involvement, staff training, data collection, and a learning culture are essential for successful implementation. Future research should assess the impact and cost-effectiveness of QMSs and develop tailored approaches to sustain healthcare professionals' motivation in quality improvement efforts.

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**PALABRAS CLAVE**
Evaluación;
Adhesión al programa;
Gestión de la calidad;
Garantía de calidad;
Mejora de la calidad;
Psicooncología

## Evaluación de la implementación de un sistema integral de gestión de la calidad para la psicooncología intersectorial en Alemania

### Resumen

*Introducción:* La gestión de la calidad en la asistencia sanitaria es esencial para prestar servicios seguros, eficaces y centrados en el paciente. Los sistemas de gestión de la calidad (SGC) controlan y mejoran la calidad de la asistencia sanitaria. La integración de los SGC es crucial para una calidad óptima de la atención, pero estudios anteriores muestran lagunas en la integración. Este estudio tuvo como objetivo evaluar la adherencia de los programas a un SGC en la atención psicooncológica intersectorial y desarrollar estrategias para una mejor integración, mejorando en última instancia la calidad asistencial.
*Materiales y métodos:* El estudio utilizó un análisis de utilidad para evaluar la adherencia al planteamiento de un programa de atención psicooncológica intersectorial utilizando una escala de 5 puntos. El proceso de evaluación consistió en desglosar el programa en áreas diferenciadas, y se utilizaron ratios e indicadores desarrollados para evaluar la adherencia. Se utilizaron estadísticas descriptivas.
*Resultados:* El estudio realizó una evaluación exhaustiva de la adherencia al programa en un programa asistencial complejo, analizando 4.460 casos de evaluación basados en 128 indicadores de calidad. Los resultados mostraron una puntuación de 4,2 sobre 5 puntos (84%), lo que indica una implementación muy eficaz del SGC. En particular, el estudio observó una implementación satisfactoria de los elementos descendentes, mientras que encontró más dificultades en la integración de los aspectos ascendentes.
*Conclusiones:* El estudio demuestra la implementación eficaz de un SGC exhaustivo. Se observó una integración satisfactoria en áreas como el concepto de atención, la gestión de la atención, la garantía de calidad y la documentación basada en tecnologías informáticas, mientras que sigue habiendo dificultades en el desarrollo y en los indicadores de calidad. La implicación activa de la dirección, la formación del personal, la recogida de datos y una cultura de aprendizaje son esenciales para el éxito de la implementación. Las investigaciones futuras deberán evaluar el impacto y la rentabilidad de los SGC y desarrollar enfoques adaptados para mantener la motivación de los profesionales sanitarios en los esfuerzos de mejora de la calidad.

## Introduction

Quality management in healthcare plays a pivotal role in ensuring the delivery of safe, effective, and patient-centered services.[1–4] Quality management systems (QMS) can be defined as a dynamic set of interrelated activities, methods and procedures designed to monitor, regulate and improve the quality of healthcare, such as board-led quality monitoring, the establishment of quality policy documents, formal protocols, and the in-depth analysis of key figures.[5,6]

In the context of psycho-oncology, where addressing the psychosocial and emotional needs of cancer patients is of utmost importance and complexity, the effective implementation of quality assurance tools becomes even more challenging.[7,8] Cross-sectoral psycho-oncological services in Germany, encompassing diverse healthcare sectors, necessitate a systematic approach to quality management to ensure seamless care and improved patient outcomes.[9] The effective implementation of quality assurance tools and QMS is a critical aspect of ensuring optimal patient outcomes and delivering high-quality care.[10] However, studies have indicated that planned quality assurance tools or management systems are often not fully integrated into clinical everyday practice, leading to potential lapses in quality and compromised patient care.[11,12] The absence of complete implementation and presence of inefficient, error-prone processes and systems can have far-reaching consequences, including suboptimal patient experiences, increased healthcare costs, and compromised patient safety.[11,13]

'Adherence' refers to the degree to which individuals or participants follow or comply with the prescribed components, guidelines, or protocols of a particular program or intervention.[14] In the context of this study, program adherence relates to the extent to which the implemented care program meets pre-defined requirements and how well caregivers adhere to the recommended quality assurance tools. Such evaluations can help identify barriers and facilitators to implementation, allowing for targeted interventions and improvements to ensure comprehensive integration.[15]

This study aimed to evaluate the level of program adherence of a QMS within the context of a cross-sectoral psycho-oncological care program. For this purpose, strategies and assessment tools were developed to analyze the comprehensive QMS in clinical workflow. The results of the work are described and evaluated in this paper.

## Material and methods

The methodological framework employed in this study involves a utility analysis to assess the internal program adherence of the 'new form of care integrated, cross-sectoral psycho-oncology (nFC-isPO)'.[16,17] Designed, implemented, and evaluated in Germany between 2017 and 2022 across four care networks (CN), the nFC-isPO program aimed to establish a comprehensive stepped psychosocial and psychotherapeutic care approach for adult cancer patients. The primary objective was to reduce anxiety and depression levels while simultaneously promoting treatment adherence among this patient population. The program's translational nature ensures the provision of high-quality psycho-oncological care, enabling effective and tailored support for cancer patients throughout their journey.[9] Detailed information for a deeper understanding of the structure of nFC-isPO and its QMS can be found in Kusch et al. (2022)[9] and Supplementary Material A.1. This approach aims to systematically evaluate the implementation of the program and is underpinned by the principles of fragmentation, de-emotionalization, and objectivization, facilitating rational assessments and evidence-based decision-making.[16] The complexity of cross-sectoral services demands a structured and systematic approach to evaluation. Fragmentation involves breaking down the program into smaller, manageable segments, allowing for in-depth analysis and evaluation of each component. De-emotionalization entails distancing from subjective biases, ensuring an objective assessment of the program's effectiveness. By avoiding emotional involvement, the evaluation remains rooted in factual evidence and impartiality. Objectivization emphasizes the use of measurable and quantifiable indicators to assess program adherence.[16] This enables a rigorous and transparent evaluation process, reducing ambiguity and enhancing reliability. The scoring process employed direct ranking for all evaluation cases, except for the quality indicators (QI), whose significance was assessed using the analytical hierarchy process (AHP) as an inspiration.[16,17] In this context, **evaluation cases** are understood as specific instances, structures or situations that are studied and analyzed for different purposes and evaluated or compared according to different aspects or criteria related to a particular subject or problem. Evaluation cases were formulated based on developed indicators and quality characteristics derived from relevant requirements and quality aspects of the nFC-isPO. The evaluation cases were organized into eight distinct areas, representing the different **evaluation domain**. These domain were:

1. Joint agreements
2. Concept of care
3. Care management
4. Quality management
5. Quality assurance and development
6. IT-supported documentation and assistance system
7. Human resources
8. Quality indicators

A total of 200 evaluation cases were defined to ensure a comprehensive evaluation of the nFC-isPO program's various aspects. The thematic blocks of evaluation domain were coded with unique identifiers (IDs) to facilitate tracking and organization during the evaluation process.

Each evaluation case was categorized into one of the three quality dimensions according to Donabedian.[2] To ensure the implementation of recognized psycho-oncological quality standards, evaluation items were linked to eight binding **quality criteria** based on the 'Joint Commission on Accreditation of Healthcare Organizations (JCAHO)' recommendations.[18] Supplementary Material A.2 provides comprehensive definitions of terms used throughout the evaluation process, ensuring clarity and consistency in the analysis.

The utility analysis procedure included the following steps to calculate the total value from the weighted sum of individual values:

- **Definition of evaluation criteria:** Rigorous evaluation criteria were established to measure the various aspects of the nFC-isPO program's quality.
- **Weighting of evaluation criteria:** Each evaluation criterion was assigned a defined point value, reflecting its relative significance in the overall assessment.
- **Summation of factor values:** The factor values of individual criteria within each evaluation domain were aggregated to derive a total value, providing a holistic evaluation of that particular dimension.

The evaluation criteria can be seen in Table 1. These criteria provide benchmarks against which the performance of each evaluation case can be measured. A predetermined assignment of specific point value regarding quantities, ratings, and intervals to certain scale values was established prior to the evaluation. Answers were scored on a five-point scale. This standardization ensures consistency and comparability in the assessment process, enhancing the reliability and validity of the results.[16]

## Statistical analysis

The assessment was conducted through descriptive statistics. Various analyses were performed using IBM SPSS Statistics. Metrics were scored using a 'red flag' threshold, where a score below the mean of 3 (rounded mean minus one standard deviation) was considered to indicate potential areas of concern.

## Results

In this study, 4460 individual assessment decisions were made based on 128 quality indicators across eight quarters and four care networks, along with 72 quality characteristics with varying degrees of specification (see Supplementary Material A.3).

The majority of evaluation cases were related to quality (91.8%, $n = 4096$), quality management (3.2%, $n = 144$), joint agreements (1.4%, $n = 64$) and quality assurance and development (1.3%, $n = 56$). The process quality gained the highest distribution of evaluation cases (85.2%, $n = 3800$), followed by structural quality (11.2%, $n = 500$), and outcome quality (3.6%, $n = 160$). Fig. 1 shows that the quality cri-

**Table 1** Definition of the evaluation criteria.

| Evaluation criteria | Explanation |
|---|---|
| ID | Each evaluation item has an individual identifier by category and subcategories. |
| Evaluation domain | Each evaluation case was assigned to one of the following categories: **Joint agreements, care concept, care management, quality management, quality assurance and quality development, IT-supported documentation and assistance system, human resources and quality indicators.** |
| Care networks | Each evaluation case was assigned to one of the four care networks or to the overarching care program. |
| Quality dimension[2] | Each evaluation case was assigned to a quality dimension: **structural quality, process quality, outcome quality** |
| Quality criterion[18] | Each evaluation case was assigned to quality criterion: **accessibility, appropriateness, continuity, effectiveness, efficiency, patient perspective, safety, timeliness** |
| Assessability | Is the evaluation case assessable, e.g., whether there is information or data that can be used as a basis for evaluation: **Yes/No**<br>*Example: For quality Indicator No. 81021, no data from the structured quality reports of the care networks are available for quarter 2 in 2020. Consequently, this evaluation criterion is to be recorded as 'not assessable'.* |
| Degree of implementation | Is the evaluation case fully implemented e.g., theoretically developed, implemented in care practice:<br>**- 5 points = Fully implemented in care practice (> 80%)**<br>**- 3 points = Partly implemented in care practice (80−51%).**<br>**- 1 point = Not implemented in care practice (< 50%).**<br>*Example: 3/8 (37.5%) quality workshops conducted were evaluated. As a result, the evaluation item is awarded one point (37.5% < 50% = Not implemented).* |
| Quarter | Each evaluation case was assigned to one of the eight corresponding quarter (3 months) in the period from 01/01/2019 to 31/12/2020. |
| Quarterly value | Capture of the value associated with the evaluation case and quarter on a metric scale level with absolute numbers.<br>*Example: In care network 1, 60 patients were enrolled in Q1 2019 for ''QI 81001 New enrolment: enrolment in contract according to 140a SGB V''. (Quarterly value = 60)* |
| Trend over time | The change of the evaluation case over time was assessed, if applicable:<br>**'The collected data shows a positive trend over the last 2 years'**. Values or data series contain no more than one outlier and/or show a clear ''positive trend,'' i.e., are continuously improving (e.g., shortening of waiting times).<br>**'The collected data is stable and/or largely meets the targets'**. The values or data series contain a maximum of two outliers, but on the whole meet the requirement for the quality aspect.<br>**'The collected data is stable, but has potential for optimization'**. The specified values or data series contain several 'red flag' outliers or are subject to a 'negative trend', i.e., deteriorate continuously but without major outliers (e.g., prolongation of waiting times).<br>**'The collected data is unstable'**. The values or data series given are subject to strong fluctuations or contain large outliers that cannot be logically explained.<br>**'No (sufficient) data available'**. No or insufficient data or information is available as a basis for evaluation. |
| Influence of Covid-19 | Does the Covid-19 pandemic appear to affect the series or specific values? **Yes/No** |

teria ''timeless'' was the most prevalent area with 38.5% (*n* = 1728). ''Continuity'' of care comprised 27.1% (*n* = 1216), and appropriateness of care made up 15.7% (*n* = 704) of the evaluations. Process quality evaluations primarily involved assessment items related to timeliness, safety of the care environment, continuity, and appropriateness of care. On the other hand, evaluation cases focusing on effectiveness and patient perspective were more commonly associated with outcome-oriented evaluations. The majority of structural quality evaluation cases related to access to care, or in some cases no quality criterion could be assigned (see Fig. 1).

The overall assessment indicated that 99.2% (*n* = 4423) of the evaluation cases were assessed as at least implemented. Summing the factor values, the assessment of the nFC-isPO program adherence resulted in the following ratings (see Table 2).

The results shed light on the implementation status and effectiveness of different components.

**Joint agreements** were mostly in place, with 86% of the necessary contracts being successfully established. However, there were three aspects, including the internal quality report for quality assurance and the external quality report for quality workshops that were implemented in only one

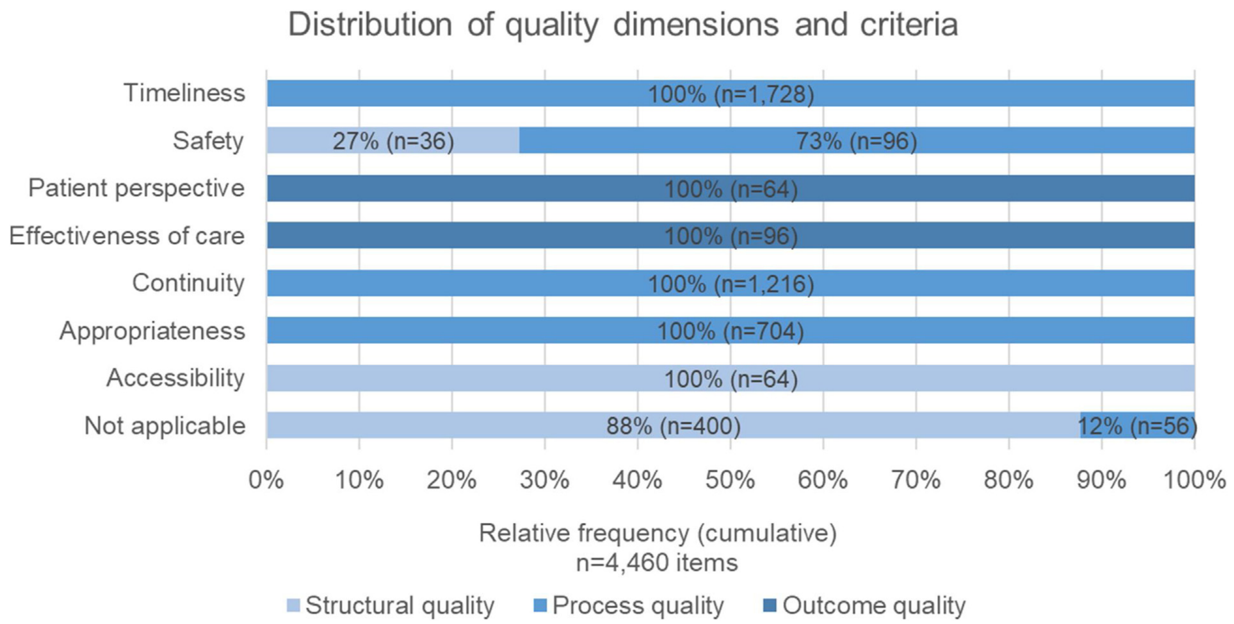

**Figure 1** Distribution of quality dimensions and criteria in evaluation cases.

**Table 2** Results of the scoring procedure.

| Evaluation domain | Assessment | |
|---|---|---|
| | % | Point value |
| Joint agreements | 86 | 4.3/5 |
| Concept of care | 100 | 5/5 |
| Care management | 100 | 5/5 |
| Quality assurance | 98 | 4.9/5 |
| Quality development | 70 | 3.5/5 |
| IT-supported documentation and assistance system | 100 | 5/5 |
| Human resources | 82 | 4.1/5 |
| Quality indicators | 76 | 3.8/5 |
| **Overall** | **84** | **4.2/5** |

care network due to data protection regulations. Additionally, the withdrawal of patients under the § 630 BGB IV Contract for Special Care was only present in one care network.

Regarding the **care concept**, all its components were developed and implemented successfully across the different care networks.

**Care management** demonstrated its efficiency, as a well-structured management system for nFC-isPO was established and operational within the organization of the care networks.

The **quality assurance** achieved implementation rates of up to 98%. Notably, the quality policy of nFC-isPO was effectively communicated and agreed upon by collaborating with all stakeholders. The definition and systematic implementation of clinical pathways further exemplified the commitment to quality management. The program also provided necessary knowledge and competences to relevant roles, fostering efficient quality assurance and development actions. The assessment of 87.5% implementation degree was achieved through 28 out of 32 quality circles and 7 out of 8 quality workshops. Despite the challenges posed by the Covid-19 pandemic, where some events had to be initially canceled, alternative solutions such as telephone conferences and digital platforms were introduced to ensure continuous progress.

The evaluation of **quality development** aspects revealed that 70% of the requirements were successfully implemented. Notably, 81% of the quality circles underwent systematic evaluation within the network, though 38% of the quality workshops were unable to do so due to the interim digital circulation process. The program's commitment to continuous quality improvement was evident through the meticulous management and implementation of quality workshop-related action plans in the participatory quality development process.

**IT-supported documentation and assistance system** played a crucial role in the program's success. All IT applications and additional modules, such as the quality management module, were effectively developed and integrated into the organization of the care networks. Regular updates and releases ensured the system's functionality and relevance.

**Human resources** allocation for nFC-isPO reached 82%, with most positions being appropriately filled according to the contract. However, in one care network, the staffing for isPO-onco-guide was missing, while case managers and isPO-onco-guide were absent in two other care networks. One care network managed to cover both roles with a single person, which was considered with half a point value.

The evaluation of **quality indicators** using performance measurements demonstrated the comprehensive nature of the program. A structured quality report incorporated 128 quality indicators and key figures. Over eight quarters and four care networks, a total of 4096 evaluation cases were analyzed regarding their development and target

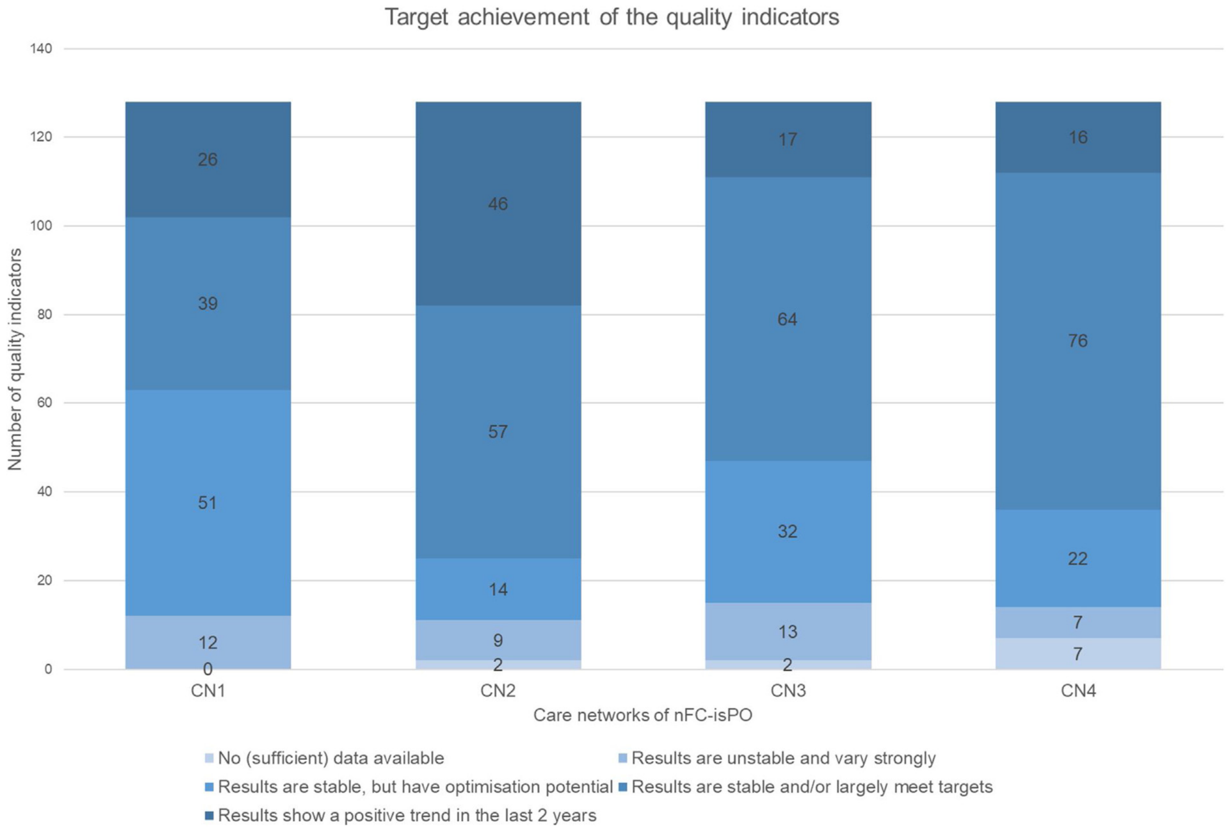

**Figure 2** Results of the assessments of quality indicators.

achievements (see Fig. 2). On average, the results of the quality indicators achieved a score of 3.75 (SD = 0.7).

## Discussion

The overall results of this study demonstrate a high level of implementation and program compliance of the nFC-isPO QMS. The developed strategy, designed evaluation concept and quality assurance tool were tested on the basis of scientific methods and quality criteria. They are usable and applicable for the evaluation and optimization of a comprehensive QMS for cross-sectoral psycho-oncology care.

Numerous studies have focused on developing or implementing quality management and quality assurance tools in healthcare settings. However, there remains a significant gap in our understanding of the effective implementation and program adherence of such measures.[19] Upon analyzing the results, it is evident that the effective implementation of care concept, care management, quality assurance, and IT-supported documentation and assistance system has taken place. A closer look reveals that these aspects are mainly based on theoretical foundations and that the integration of manuals, documents or concepts into health care practice is a focus of the (project) leadership. While various stakeholders contributed to the implementation of individual concepts or documents by management, providers played a crucial role in the actual execution in clinical practice. To effectively implement a QMS, robust leadership support at various levels within the organization is crucial.[6,20] The introduction of such a system brings about significant changes in established mechanisms and practices, leading to structural modifications and fostering streamlined organizational processes.[21]

In contrast, in the domains of quality development, where only 70% of measures were put into action, and quality indicators (76%), the responsibility for executing the measures fell on the caregivers. Introducing regular local quality circles and inter-institutional quality workshops aimed at implementing the PDC/SA cycle and fostering learning effects for all participants. Therefore, lower implementation degrees can be attributed to missing staff participation. These findings are somewhat surprising given the fact that other research indicate the significance of QMS as supportive structural feature in fostering and enhancing teamwork, work satisfaction and safety climate.[6,21] However, in accordance with the findings of this study, Groene et al. (2013)[19] observed that formal structures and responsibilities were implemented to a greater extent than other aspects, such as patient involvement in designing quality improvement interventions or addressing the needs of chronically ill patients.

Though the overall QMS of this study is well-established, systematic reviews suggest that the consistency with quality improvement interventions is insufficiently researched and effects may be context-dependent.[22,23] The study by Taylor et al. (2014)[22] reviewed the Plan-Do-Study-Act (PDSA) method as a quality improvement tool, and only 2.7% of the studies met all the method's characteristics and principles. In contrast, while this study methodologically implemented all aspects of the PDSA cycle, only

50% of participants attended meetings regularly. These finding further support the idea that the success of quality improvement interventions, especially, relies on their compatibility with caregivers' motivation and work practices to achieve maximum effectiveness in implementation. Comparison with other studies confirms that certain factors positively influence successful quality improvement. Trapper and colleagues discovered that effective quality improvement interventions encompass managing clinical workflow and empowering dedicated staff to coordinate specific aspects of patient care, resulting in consistent positive outcomes.[24] Based on the findings from relevant studies, this study applies several drivers for the successful implementation and effectiveness of QMS and quality improvement. These key drivers include active leadership involvement, staff training, empowering practices, data collection and analysis, and cultivating a learning culture.[20,24,25]

Active leadership involvement throughout the entire project period, providing guidance, resources, and fostering a culture of quality improvement, is crucial for successful QMS implementation. Staff trainings and empowering practices are essential drivers for QMS adoption among healthcare professionals, enhancing their understanding and motivation to effectively implement QMS principles, and were mandatory for caregivers and project partners.[20,24] Nurturing a learning culture and conducting regular data collection and analysis play vital roles in fostering continuous improvement and enabling evidence-based decision-making. The QMS compounded regular quality circles and workshops, as well as a digital helpdesk for caregivers in case of urgent questions.[20,25]

While successful implementation relies on various drivers, challenges can impede their effectiveness. Challenges such as resistance to change, time constraints, and ineffectively implemented tools were also encountered during this study and should be addressed to optimize the benefits of QMS.[20,25] A significant hurdle was the resistance to new initiatives and the complexity of QMS, as healthcare professionals may be hesitant to adopt changes they perceive as burdensome. Overcoming this resistance demands open communication, stakeholder involvement in planning, and ample support during implementation.[20,25] Time constraints and competing tasks were recognized as challenges for healthcare staff in integrating the QMS, potentially leading to incomplete or suboptimal implementation; careful planning, considering staff members' realistic time commitments, is essential to address this issue.[20,25]

The study under discussion has several limitations. One key limitation is the absence of a standardized method for assessing the implementation of QMS for new forms of care in health care in line with the predefined requirements and their impact. However, implementation in the practical setting and methodological selection of a utility analysis enabled a systematic and robust approach to evaluate the implemented QMS with predefined requirements and their application for the nFC-isPO.

Nevertheless, there are avenues for further exploration. The impact of the quality management tools employed in the study warrants more in-depth investigation. Numerous studies have consistently indicated that the implementation of quality-assured interventions yields various positive effects on aspects of healthcare delivery and patient outcomes.[6,21] In this respect, the benefit of the nFC-isPO QMS should be examined. Additionally, to assess the overall effectiveness, it is essential to evaluate the cost-effectiveness of this QMS e.g., using the cost-of-quality concept. This concept takes into account costs associated with error prevention, testing, and both internal and external errors.[26] Furthermore, to assess the construct validity, it is crucial to test using alternative approaches, e.g., the 'Quality Management Systems Index'.[27,28]

Even though nFC-isPO has been implemented to a high degree, there is still room for improvement in its implementation, especially with regard to its integration into the daily clinical routine of staff. The recently published study by Lee et al. impressively demonstrates that quality improvement measures can be successfully translated into practice in a minimally invasive way.[29] In Lee et al.'s study (2022), a randomized clinical trial was conducted to evaluate the efficacy, feasibility and acceptability of a communication-priming intervention on electronic health records (EHRs) documented goals-of-care discussions in hospitalized patients with serious illnesses. Similar to the quality management in this intervention, Lee et al. successfully developed an automated and IT-based intervention that did not require much more active involvement, but was based on personal patient- and clinician-specific preferences through integration into the given conditions. The QMS presented here also attempted to involve all stakeholders in the continuous process of quality management and improvement with as little effort as possible for the care providers. However, more use could have been made of existing structures, such as automated patient information based on patient needs derived from IT-based documentation.

## Conclusion

In conclusion, the study highlights the effective implementation of a comprehensive QMS for cross-sectoral psycho-oncology care in Germany. The findings indicate a high level of adherence to the quality management program, with successful implementation observed in areas like care concept, care management, quality assurance, and IT-supported documentation. However, challenges remain in areas like quality development and quality indicators, which necessitate targeted interventions to improve integration into clinical workflows. The study provides valuable insights into the drivers and challenges of implementing QMS in healthcare and underscores the importance of active leadership involvement, staff training, empowering practices, data collection, and fostering a learning culture for successful implementation. Future research should take into account the assessment of the impact and cost-effectiveness of QMS. Additionally, a tailored approach, based on the needs of key stakeholders and informed by prior assessments identifying facilitating factors for successful implementation, should be developed to sustain the motivation and engagement of healthcare professionals in quality improvement efforts. The findings from this study contribute to the advancement of quality healthcare practices and offer opportunities for continuous improvement in patient care.

## Authors' contributions

Conceptualization, LD and CL.; methodology, LD and CL; validation, LD, CL and MK; formal analysis, LD; investigation; LD; writing—original draft preparation, LD; writing—review and editing, CL; supervision, CL and SSt; project administration, LD; funding acquisition, SST and MK. All the authors have read and agreed to the published version of the manuscript.

## Ethics approval and consent to participate

The study was registered in the German Clinical Trials Register (DRKS) (DRKS-ID: DRKS00021515) on 3rd September 2020. The main project was registered on 30th October 2018 (DRKS-ID: DRKS00015326). The project was approved by the Ethics Commission of the Faculty of Medicine of Cologne University (18–092) on 15th October 2018.

## Consent for publication

Not applicable.

## Availability of data and materials

All data generated or analyzed during this study are included in this published article and its supplementary files.

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## Conflict of interest

The authors have no competing interests.

## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.jhqr.2023.10.007.

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# Chapter 7

## Discussion

With the large annual number of new cancer cases and the various requirements of those diagnosed, it is essential to provide high quality psycho-oncological care. The aim of this dissertation is to develop, implement and assess a quality management system appropriate for a novel psycho-oncological care model prevailing across multiple sectors. Various approaches, methods, and tools from the extensive field of healthcare quality improvement and management were adapted for the psycho-oncological and cross-sectoral setting. Additionally, the views of a range of stakeholders were considered, including healthcare professionals, project partners, scientists, patient representatives and health insurers. This chapter will offer significant insights into the discoveries made. Section 7.1 presents a summary and discussion of the principal findings from the three publications. Subsequently, in section 7.2, an assessment of the research projects' strengths and limitations is conducted. Section 7.3 examines the findings within the current state of the field and discusses the potential implications for future research. The chapter concludes with section 7.4, which discusses the findings regarding future challenges and healthcare trends, specifically in relation to psycho-oncology and their impact on quality management.

### 7.1. Key Findings and Discussion of the Publications

Quality-assured psycho-oncological care is inconsistently accessible for many cancer patients nationwide [1, 11, 15, 16, 62]. The presented findings could assist in fulfilling the criteria of the 2008 NCP from the German government, which proposes the development of novel forms of quality-assured psycho-oncological treatment integrated into both inpatient and outpatient sections [24]. Figure 14 displays the key findings of the three publications.

01

**DEVELOPMENT OF QUALITY INDICATORS**

- Unveiling a robust and tangible set of quality indicators.
- Bridging disciplinary and sectoral divides.
- Seamlessly adapt and transfer between different settings.
- Alignment between the set of quality indicators and the formulated goals of the National Cancer Plan.
- All underpinned by essential IT-driven operationalisation and standardised electronic documentation.

02

**PARTICIPATORY QUALITY DEVELOPMENT**

- Flexibility as an elementary requirement for participation.
- Fluctuating participation throughout the life cycle of the project.
- Intrinsic motivation at the individual level as a key catalyst.
- Recognising variations in participation across different project phases.
- The importance of transparent commitments.

03

**IMPLEMENTATION OF QUALITY MANAGEMENT**

- Effortlessly executing top-down, structural quality features.
- Facing bottom-up challenges due to extra commitment.
- Resistance to change due to perceived burden on healthcare professionals.
- Vital: active leadership support and highlighting quality management benefits for healthcare professionals.

**Figure 14.** Key findings of the three publications of this dissertation.

The development of quality indicators to measure and steer the quality of care has yielded significant outcomes (Publication 1) [68]. Initially, the research project contributes to quality measurement in cross-sectoral psycho-oncological care by providing a credible, all-encompassing, and workable set of 16 quality indicators for cancer patients with emotional distress and mental disorders [68]. This fills a gap in cancer research because the number of quality indicators concerning the cross-sectoral care of cancer patients in Germany was low up to now. The available quality indicators were based on national and international guidelines for quality assurance and management established around 2008 [24, 54, 56, 57, 66–68].

Secondly, creating a unified set of quality indicators proved difficult due to sectoral barriers, while simultaneously avoiding individual provider performance measurement and maintaining a universal understanding of the care programme. In Germany, the field of psycho-oncology is highly fragmented due to various services, making it a multidisciplinary domain [133]. Given this, it was crucial to consider the perspectives of all stakeholder while assessing the relevance and feasibility of the set across both inpatient and outpatient providers [68].

Thirdly, quality indicators linked to documentation (e.g., 'average time between data collection and documentation') and services beyond those provided in nFC-isPO (e.g., 'regular attendance of a self-help group') were consistently perceived as less relevant. Although the experts acknowledged the significance of these quality indicators in the wider context of psycho-oncological care during the discussions, they assigned them lesser importance in the project setting than the real world setting (due to the project's construction and the absence of funded implementation [68]).

Fourth, the quality indicators presented also encompass diagnosis-specific aspects of psychological distress. Thus, the set enables adjustment and transfer to alternatives circumstances, contextual variances or even other countries [68, 134, 135]. These aspects should be taken into consideration when revising and adapting the material for other contexts [68].

Fifth, this research surpasses the seven defined and recommended quality indicators of the initial ‘German evidence-based guideline on psycho-oncological diagnosis, counselling, and treatment of adult cancer patients’ [67, 68]. The research project introduces an operationalised and comprehensive set for cross-sectoral care, which quantitatively addresses the objectives of the NCP. The presented quality indicators can indicate the identification of psychosocial support requirements and mental afflictions, along with supportive measures to manage cancer such as the isPO-onco-counselling guide [68]. Furthermore, the ' mean difference in HADS total scores' can indicate reduced psychological and psychosomatic symptoms, and 'reasons for discontinuation' can serve as an indicator of treatment adherence. Incorporating diverse stakeholders - inpatient and outpatient healthcare professionals, alongside self-help groups and patient representatives – could generate a more comprehensive overview while still highlighting betterment in specific areas and outcomes quality (e.g. 'isPO-onco-guide counselling' and 'patient satisfaction with isPO-onco-guide counselling') [24, 68].

Sixth, utilising IT to operationalise quality indicators and integrating them into a structured quality management system goes beyond a descriptive performance presentation [68]. This approach has proven successful in terms of timely visibility of outcomes [51, 68, 136]. To enable the integration of quality indicators into information systems in daily use the project established a linkage between relevant quality indicators and standardised electronic documentation. In addition, the research project demonstrates how efficient such an incorporation of quality indicators into a comprehensive IT-driven reporting framework can be [68, 117, 137]. The computerised documentation and support programme CAPSYS is a crucial element in enhancing feasibility, data quality and timeliness by enabling uniform data collection in various locations and for complex interventions. This is exemplified by its contribution to timely responses, as noted in previous research [68, 121, 137].

The second publication affirms that achieving maximum stakeholder participation requires flexibility in the organisation and implementation of participatory projects. However, a high level of participation is not consistently maintained throughout the lifespan of the project (Publication 2) [129, 138]. Additionally, the publication identifies several pivotal factors for successful stakeholder involvement in quality management, including individual motivation, various project stages, and transparent commitments. The involvement of individuals' motivation and attitudes in participation and participative projects is essential. While participatory processes can enhance cooperation, communication, learning effects, and staff with advanced skills [139, 140], not all stakeholders were equally capable or enthusiastic to take part. To improve stakeholder participation, personal and direct contact was deemed a valuable tool. However, participatory projects can be time-consuming and, for some, incompatible with other professional roles. Given the possibility that changes in the constellation of stakeholders (e.g., due to staff turnover) may impact attitudes towards project-related activities and tasks, it is noteworthy that these findings align with those of Mamede et al. (2017) and Kümpers (2021) et al. The authors highlight that the increase of participation is dependent on individuals' identification with their role and perceived scope for action [141, 142]. These noteworthy findings suggest that roles in participatory projects develop contextually, depending on resources, competences, personal and professional interests [141].

Additionally, it was found that participation may differ across various project stages. The degree of flexibility in co-design was more pronounced during the development and implementation stages than during the consolidation phase. Furthermore, as the intervention became more precisely defined and operationalised, the number of structural aspects that must be altered decreased. The initial utilisation of participatory tools such as multi-perspective quality workshops enabled prompt attainment of practical outcomes, particularly in the implementation or improvement of structures. Subsequently, these tools were employed at the end of the project to apprise stakeholders and optimise local processes. Nonetheless, the local implicit knowledge resulting from engagement with participatory tools was unquestionably valuable throughout every phase of the project, frequently yielding superior and more expeditious outcomes. It is possible that the dynamic changes in the project phases affect stakeholders' perceptions of participation. This research project found that binding rules and transparent commitments positively impact participatory projects. This finding broadly aligns with previous studies that associate clarity about power relations and room for manoeuvre with increased commitment to projects [141]. Supervisors did not need to provide instructions for attendance of the regular, pre-arranged face-to-face meetings. Moreover, the regulation of processes and structures through binding and pre-defined agreements enhanced transparency and enabled various opportunities for influence.

Publication 3 demonstrates the successful implementation of a comprehensive quality management system for cross-sectoral care while considering both internal and external necessities [131]. A noteworthy discovery is that top-down approaches (e.g., the provision of theoretical concepts, legal agreements and the integration of manuals) have yielded positive outcomes in the implementation of structural quality features [131]. These findings indicate that dedicated leadership and active support at various levels are crucial for the successful implementation of quality initiatives. This is consistent with the research of Kristensen et al. (2015) and Abdallah (2014), who also established the importance of active leadership support not only for structural components but also for routine clinical practice [131, 143, 144].

Conversely, the bottom-up aspects posed greater challenges. The healthcare professionals' responsibility to implement certain elements (such as taking part in quality circles within their local network) was weak due to participants' lack of commitment [131]. This conclusion appears to contradict the study conducted by van Harten et al. (2002), which demonstrated that quality management systems can considerably foster and enhance teamwork, job satisfaction and safety climate [131, 144, 145]. These outcomes imply that the implementation of quality management systems is perceived as an extra bottom-up effort, although healthcare professionals can reap meaningful benefits from the application of quality management systems [131].

Indeed, an unexpected obstacle was the resistance to new initiatives and the complexity of the quality management system. Healthcare professionals may be hesitant to adopt changes they perceive as burdensome [131]. This aligns with previous research indicating that implementing quality initiatives is challenging due to resistance to change, limited time, and ineffectively implemented tools, which can reduce their effectiveness [131, 143, 146]. To overcome this resistance, open communication, flexibility in stakeholder involvement and the provision of sufficient support throughout the project lifecycle were consistently promoted. The findings demonstrate similarities with Groene et al. 's (2013) results where formal structures and responsibilities were linked with greater implementation than other factors such as patient participation or responsiveness to patient needs [131, 147].

## 7.2. Methodological Strengths and Limitation

In its quest to advance the understanding of quality management systems in the context of cross-sectoral and complex health care settings, this dissertation has several notable strengths and acknowledges important limitations that are integral to its design and implementation, as demonstrated in Table 1.

| Strengths | Limitations |
|---|---|
| Mixed methods | Lack of evidence-based methods |
| Adherence to guidelines | Sample size and generalisability |
| Transferability and modularity | SARS-CoV-2 pandemic |
| Participatory approach | Direct patient involvement |
| Long introduction and implementation period | |
| Multi-perspective approach | |

**Table 1.** Strengths and limitations.

This research adopts a mixed methods approach, combining qualitative and quantitative methods, which allows for a more comprehensive understanding of the subject matter. The variety of methodological approaches used in the dissertation and its research projects maximises the strengths of the exploratory and confirmatory approaches and methodological triangulation, thereby enhancing the overall validity of the research. It also provides a high degree of flexibility and contextualisation in addressing complex research questions.

This dissertation acknowledges gaps in the existing literature, particularly in evidence-based methods on the topic of developing, implementing, and evaluating quality management systems for new health care models. Despite this limitation, the individual research projects rely on state-of-the-art methods, such as the widely used RAND/UCLA Appropriateness Method for quality indicator development. This enhances the internal validity of the dissertation [122, 148, 149]. In addition, the different projects comply with relevant research guidelines, such as the SQUIRE statement, the PRISMA statement and several recommendations, which ensure that research is conducted in a standardised and transparent manner [150–153].

The relatively small sample size and selection of participants makes the research findings less generalisable, particularly to participatory projects, and may reduce external validity. Further information on selection bias and potential limitations of small sample sizes can be found in publications 1 and 2 [68]. Another limitation of this study is the occurrence of the SARS-CoV-2 pandemic. The pandemic introduced additional barriers and uncertainties that affected stakeholder participation and patient involvement. Despite the challenges posed by SARS-CoV-2, the quality management system was successfully adapted to digital communication, ensuring the continuation of research activities. Therefore, this work provides valuable insights into the transferability of the presented system to (1) fully electronic quality management, but also (2) to other settings. The modular nature of the quality management system suggests a facilitated transferability to other settings with mentally distressed patients. As SARS-CoV-2 affected contact with patients, the collection of Patient-Reported Outcomes Measures (PROMs) and Patient-Reported Experience Measures (PREMs) through patient interviews conducted by the external evaluator was not possible. However, the involvement of patient representatives remained unchanged. In fact, the participatory approach of this dissertation can be seen as a strength, as multi-professionalism had a sustainable impact on the development and implementation of quality management and generally increased the acceptability of the quality management system [122]. In addition, the project's long inception and implementation period strengthens its validity by allowing for different perspectives, addressing challenges such as the SARS-CoV-2 pandemic, and testing the different components in clinical practice. However, the results of the nFC-isPO study acknowledge the need for more time to fully test the benefits and impact of continuous quality development [44, 154]. The respective scientific publications discuss further strengths and limitations related to the specific methodological approaches used.

### 7.3. Relation to Current State of Research

The present dissertation addresses critical gaps in the existing literature on quality management in healthcare, specifically within the context of multidisciplinary care in psycho-oncology. A review of the current literature indicates a prevailing emphasis on single quality endeavours in general, with insufficient focus on the methods, effective implementation, long-term effects and efficient budgeting (i.e. cost-effectiveness) of such interventions [155, 156]. Whilst the methodological designs require modification towards the clinical practice setting and context of health services research, the individual research projects were executed based on the optimal available evidence, such as the RAND/UCLA method, Delphi technique, and utility analysis, as well as guidance from numerous recommended sources, for example, PRISMA statement and SQUIRE statement [122, 129, 147, 150–153].

This dissertation highlights the necessity for standardised tools or frameworks for the implementation and evaluation of quality management systems. Extensive research has concentrated on the creation of quality initiatives and tools to guarantee quality in healthcare environments. Nevertheless, there is a remarkable absence of comprehension of how these measures are implemented and followed efficiently, and their impact can change depending on the scenario [147, 157, 158]. The findings presented in this dissertation suggest that process evaluations can effectively assess success factors in implementing quality initiatives. The results are consistent with the framework proposed by Hulscher et al. (2003), which outlines the characteristics of quality improvement interventions that may affect their success [159]. Based on previous research, certain factors have been identified as positive contributors to the success of quality improvement efforts. These include effective management of clinical workflow and empowering dedicated personnel to coordinate distinct aspects of patient care [157, 159]. These characteristics may require further investigation during the implementation process. In line with existing literature, the research projects pinpointed various key factors for quality management implementation and effectiveness. These include: active participation of leadership, staff training, empowerment strategies, data collection and analysis, and fostering of a learning culture. Relevant sources support these assertions [143, 146, 160].

The present study provides insight into key factors of quality management that can be measured in the short-term. However, long-dated research is necessary to examine the sustainability and effectiveness of the participatory quality development, as well as validate the quality indicator set. Similar to Schubert et al. (2016), a multi-year longitudinal study should analyse the effects of the nFC-isPO intervention on the quality of care based on the developed quality indicators and the structural requirements [161]. Additionally, the quality indicators must undergo continuous evaluation to ensure their relevance and timeliness.

The evidence-based guideline for psycho-oncological diagnosis, counselling and treatment of adult cancer patients was updated in August 2023 [53]. As part of this update, the Quality Indicators Working Group has introduced two new quality indicators: 'QI 8: Human resources' and 'QI 9: Appropriate premises' [53]. One quality indicator has been eliminated from the collection ('QI 5: Psycho-oncological interventions: Concepts and general principles for the indication of psycho-oncological treatment') [53]. As participating sites are contractually obligated to meet requirements for premises and human resources, this set does not include any quality indicators related to these aspects. The guideline should be regarded as fundamental recommendations without any additional quality management system in place.

External comparison of quality management initiatives is crucial in assessing their effectiveness. Quality competitions and benchmarking can serve as valuable tools in subjecting participating organisations' quality management to external evaluation [162–164], while certification according to DIN EN ISO standards can also aid in this assessment [106]. This study highlights the necessity for research into comprehensive quality management systems, considering their development, implementation, and effectiveness. The findings strongly advocate for further elaborating the methods and frameworks used this study. Especially, exploring the impact of quality management on patient outcomes and cost-effectiveness is crucial. Further comparative analysis of existing studies (i.e. by a systematic literature review) and future-oriented research could aid in narrowing the enduring disparity in literature and practice regarding efficient quality management.

### 7.4. Implications for Practice and Policy

After examining the findings in relation to the current state of research, it is recommended to explore future trends and challenges in health care (as exemplified in Appendix 15). This dissertation provides practical and policy implications for nFC-ispo (Chapter 7.4.1), and evaluates the findings for quality management systems in the context of the digital transformation era (Chapter 7.4.2) and evidence-based standards in psycho-oncology (Chapter 7.4.3).

#### 7.4.1. Implications for nFC-isPO

In recent years, the German healthcare system has been confronted with digital changes, particularly notable with the increased adoption of digital healthcare solutions across all age groups, accelerated by the SARS-CoV-2 pandemic [165, 166]. The findings of dissertation research projects 1 and 2 demonstrate that digital integration into all elements of the quality management system was feasible during the SARS-CoV-2 pandemic. As certain stakeholders found the implementation of in-person quality circles and workshops to be burdensome, a digital and shorter alternative proved more effective for the networks. Stakeholders responded positively to digital alternatives, particularly in networks where in-person quality circles were perceived as burdensome. Recent studies emphasize the growing acceptance of digitisation in healthcare [166–168]. The dissertation's quality management system, integrated into CAPSYS, offers distinct advantages, such as stakeholder engagement and digital integration, contributing to a sustainable and scalable solution for ensuring the quality of implementation. Even the smallest psycho-oncological care network within the nFC-isPO is obligated to adhere to identical quality management standards. These standards encompass a spectrum of elements, including legal and contractual requirements, internal quality assurance measures, reporting obligations, and accounting practices [44]. The integration of digital technologies proves instrumental in meeting these standards, ensuring a consistent and uniform implementation across the domains. Digital tools can play a pivotal role in satisfying the multifaceted requirements but also streamlining the overall adherence to the prescribed standards [169, 170]. The primary practical implication involves the development of an 'implementation module' within CAPSYS. This module is designed to streamline and support the structural, legal, and contractual implementation of the care programme. By offering timely, uniform access to information, it plays a crucial role in ensuring compliance with internal and external requirements for each participating institution. This targeted tool is instrumental in facilitating a smooth and efficient implementation process for the care programme.

The dissertation's findings suggest that interoperability of the quality management system is achievable even with different system requirements across care networks. It is imperative for the quality management system to possess a high degree of connectability to other systems, devices, or stakeholders, fostering interoperability across departments and sectors. The seamless exchange of data among diverse systems has not been sufficiently implemented to date, particularly for medical documentation [166]. To enhance the interoperability of the presented quality management system, it is recommended to implement open local interfaces and to agree on common standards between care networks, health insurers, and researchers. However, the mere automation of data collection is insufficient; the collected data have to be aggregated and utilised to inform data-driven decision-making for resource efficiency improvements [166]. The optimal functioning of future digitised systems relies on the collaborative establishment and implementation of medical and technical standards considering the local context.

### 7.4.2. Outlook on the Influence of the Digital Transformation

To take the next step beyond mere digitisation, future quality management systems should take into account the wide-ranging field of intelligent digital technologies, such as the Internet of Things (IoT) networks, artificial intelligence (AI), and big data, which have transformed various domains, including healthcare [171–176]. Since quality management is largely based on repetitive tasks and the collection of data, automation and predictive analyses could be well suited for use. However, when discussing new information and communication technologies, it is important to distinguish between tools used exclusively for organisational processes or quality management, such as those that increase interoperability, and those that support patient care, such as AI-based disease detection and therapy systems.

A gap analysis revealed that approximately 90% of German hospitals have adopted new information and communication technologies. IoT solutions are leading the way with a utilisation rate of 64%, which is a network of physical devices that collect, transmit, and exchange data [172]. Incorporating the quality management system into the IoT could address the resource-intensive development of quality indicators and documentation efforts by healthcare professionals. In addition, it can simplify data collection and transfer, and thereby reducing the manual efforts and minimising waiting times. It may also help to address the issue of duplicate documentation between CAPSYS and local hospital information systems [172, 177]. Simplifying documentation procedures may create an environment where healthcare professionals can concentrate on hands-on patient care without being burdened by extensive physical documentation [178, 179]. This approach of a quality management system leveraging data generated by the IoT, would ensure the generation of more precise and timely quality reports and indicators, contributing to more effective decision-making in healthcare practices. However, Neft et al. found that 54% of participants consider the IoT-structures as outdated, independent on potential benefits due to low costs offered, big data, and mobile health applications [172]. Nevertheless, the ongoing integration of electronic health records in Germany adds a layer of significance as it presents the possibility of accessing health records in real-time and informed decision-making to enhance the quality of patient care, based on cross-sectoral and aggregated data [180]. In complex healthcare fields like psycho-oncology, the digital aggregation of patient care data emerges as a potent tool, enhancing the timeliness and accuracy of care [181, 182]. A recent study delves into the development of an 'Intelligent Quality Management System' that incorporates AI and aligns with DIN EN ISO Standards [183]. This aligns with the foundation of the presented quality management system on DIN EN ISO criteria, paving the way for future certification. Under these circumstances, AI-supported quality management could offer valuable support to participating networks in assessing structural requirements and proactively identifying potential shortcomings, such as staffing shortages, enabling early intervention. The quality management system integrated into CAPSYS, as elucidated in this dissertation, establishes a robust groundwork for upcoming digital applications. Although there is a widespread eagerness to embrace digital transformation, numerous obstacles can hinder its seamless integration into practical healthcare setting. Beyond the necessary temporal and financial considerations for establishing advanced infrastructure [172], there are also various apprehensions among users regarding inadequate data security, the possible loss of authority, and doubts about trustworthy handling of sensitive health data [167, 168]. Consequently, the development and maintenance of advanced cybersecurity frameworks become imperative, ensuring data protection and preserving sovereignty over personal information [167, 168].

Drawing upon technologies used in patient care, it may be possible to connect AI-based disease detection and therapy systems directly to the quality management system. This could potentially aid in the faster recognition and evaluation of quality indicators, ensuring proper documentation and predicting adverse events using algorithms equipped with historical data and real-time electronic health records [182, 184]. Recent studies have showcased the potential and effectiveness of AI in patient care [182, 184–188]. However, although AI shows promise for patient care, it is important to interpret these findings with caution as the use of such methods is still in its early stages. Serious risks and problems to the quality of care are posed by cybersecurity, high complexity, ethical issues, and systematic bias in AI models [167, 172, 189–192]. In a healthcare context, quality management systems must effectively control the risks associated with the use of AI models. The topic is currently under discussion in national and international political spheres [193–195].

Looking ahead, the autonomous collection, aggregation, and analysis of large amounts of data will be pivotal for quality management. The integration of AI into quality management systems emerges as a transformative avenue, holding potential to enhance accuracy, cost reduction, and time savings, while minimising human errors through the analysis of extensive datasets to identify patterns and foster data-driven decision-making that conventional research methods may find challenging to achieve [196]. However, the costs of integrating new technologies have to be carefully evaluated against the benefits (e.g., competitive advantage) to ensure sustainability [171]. Notably, for the successful implementation of innovative technologies competitive advantages, costs but also different user perspectives should be considered [172].

### 7.4.3. Evidence-Based Standards and Psycho-Oncology

Effective management of interfaces within a quality management system is pivotal in the context of digital transformation, particularly within the interdisciplinary collaboration of psycho-oncology healthcare. As healthcare systems become more complex and globalised, internationally binding standards for quality play a crucial role in ensuring consistent and superior care. Therefore, incorporating external interfaces can further enhance the quality management system. Timely integration of national guidelines, regulations, and registries into the system is highly recommended, not only to meet the requirements of various stakeholders but also to ensure that patient care stays updated with the latest advances in psycho-oncology and research through constant exchange, without any significant delays [197, 198]. Ongoing efforts, such as the development of digital guidelines, pave the way for direct comparisons with updated standards [199, 200]. In this regard, the revised version of the S3 psycho-oncology guideline and its quality indicators could be automatically compared with the quality indicators developed here and adjusted accordingly [53]. Linking quality management data with cancer registries and billing data can significantly contribute to scientific investigations, enabling benchmarking, external audits, and quality assessments [201, 202]. Moreover, such a system could facilitate the accommodation of changes in treatment teams across networks, support in-house training and accreditation courses, and provide assistance with legal contracts and the latest evidence for new staff.

The demand for psycho-oncological eHealth interventions is evident, offering promising mediums for improving psychosocial care and enhancing individual disease management [203]. For example, Schobel and colleagues (2021) conducted a feasibility study that aimed to support medical personnel in the field of psycho-oncology by using smart mobile devices, including tablets and smartphones, to collect data from cancer patients [204]. Studies on the implementation of digital screening tools and stress management applications in psycho-oncology are rapidly increasing, demonstrating higher acceptance rates, convenience and usability compared to traditional methods (i.e. paper-based) [204–211]. Pichler et al.'s (2020) study explored the integration of psycho-oncological distress screening as an electronic Patient Reported Outcome Measure (ePROM) into clinical practice, emphasising the interface challenge between ePROM and the hospital information system [212]. The implementation of ePROMs demonstrated various advantages, including reliable data storage, increased acceptance and user satisfaction, enhanced data quality, improved data accessibility, and expedited psycho-oncological support services through real-time evaluation. However, echoing the findings of research project 2, nurses encountered challenges due to the time demands of screening patients in their daily clinical practice [212]. In research project 1, where some quality indicators focused on patient-reported outcomes (PROMs) like the Hospital Anxiety and Depression Scale or Distress (HADS) Scale, and the Cognitive-Emotional Coping with Cancer questionnaire (CECC), the predominant method of collection was paper-based, later transferred to CAPSYS. Despite CAPSYS efficiently managing processes such as automated questionnaire evaluation, case manager screening (replacing nurses), and automated consultation requests to psycho-oncologists, the primary method of collecting PROMs remains mostly paper-based and warrants improvement. To mitigate the need for double documentation, a recommended approach is the implementation of a feasible ePROM system directly filled in by patients using mobile devices or tablets. Additionally, the integration of proposed Patient Reported Experience Measures (PREMs) should be pursued. Meeting the requirements for psycho-oncological eHealth intervention would not only streamline quality management by reducing error-prone and time-consuming paper-based evaluations but would also enhance the quality of care and promote patient-centeredness in psycho-oncology.

The quality management system nFC-isPO, as introduced here, could undergo substantial improvement with minimal disruption and effort by transitioning all paper-based assessments to digital formats. However, as revealed in Publication 2, there is a certain resistance to change, especially from a bottom-up perspective. An interesting intriguing finding from previous research suggests that individuals who had firsthand experience with the digital instrument exhibited higher acceptance levels than those who had not [204, 213]. Therefore, it becomes crucial to address initial reluctance by introducing new technologies at an early stage before widespread use. The digital transformation in quality management not only facilitates informed decision-making but also enables dynamic adaptation to current knowledge, resulting in the delivery of reliable, high-quality patient care. The rise in transparency and competition, exemplified by publicly available quality data, holds providers accountable for care quality [214]. Future research should intensify efforts to explore the potential of quality management in the changing landscape of healthcare, especially in the context of digital transformation. Appendix 16 presents practical implications arising from the digital transformation, according to the principles of quality management. The discussion of policy and practice implications should be extended, with additional insights found in relevant publications.

# Chapter 8

## Conclusion

In conclusion, this dissertation implemented a robust quality management system to address the challenges of enhancing psycho-oncological care in Germany. Achieving key objectives, such as developing a comprehensive set of 16 quality indicators aligned with NCP goals, demonstrated tangible benefits through their integration into CAPSYS. Stakeholder engagement, despite its success, faced challenges in balancing bottom-up dynamics with top-down structures, emphasizing the essential role of active leadership and flexibility. This dissertation adopts a mixed methods approach, providing a comprehensive understanding of quality management systems in healthcare, with strengths including methodological adherence, adaptability, and insights from a prolonged implementation period, despite acknowledged limitations.

As healthcare systems undergo digital transformation, the study underscores the crucial role of quality management, especially with digital solutions in psycho-oncological care. Future research should delve into fully realising and implementing quality management amidst evolving healthcare challenges. However, it is imperative to acknowledge the context-dependent nature of quality management's development. More research is needed to assess the cost-effectiveness of quality management on patient outcomes and fully comprehend the implications of digital transformation. In the complex landscape of psycho-oncology, marked by fragmented structures and regulatory rigor, adherence to quality standards is crucial. This calls for the establishment of robust quality management processes. Yet, financial implications and substantial personnel resources pose challenges, underscoring the need for early stakeholder commitment. While there is no ‘one-size-fits-all’ solution, gaining buy-in is pivotal for successful implementation and overcoming resistance.

Recognising that quality management is not a universal panacea, the potential and limitations of quality management should be objectively evaluated. A balanced approach, which avoids overburdening the parties involved, is essential. Scientific approaches should not overshadow routine care activities, but aim to seamlessly integrate quality management into daily practice for to improve patient care. Looking forward, the goal is for an effective and smart quality management system to envision digital integration, patient and user centricity, data-driven insights, and minimal invasiveness. Continuous self-assessment ought to enhance timeliness, efficiency, and flexibility, forming a seamless integration into routine care, improving overall patient care.

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## Appendices

**Appendix 1.** Results of the inter-facility quality workshop Quarter I/2019 on the guiding principle in the nFC-isPO.

| Auswertung | Anzahl (n) | | Anteil (%) | | 🔴<br>🟠<br>🟢 |
|---|---|---|---|---|---|
| | Stimme zu | Stimme nicht zu | Stimme zu | Stimme nicht zu | |
| **Bedarfsgerechte Versorgung** | | | | | |
| Wir respektieren und unterstützen die Würde und Autonomie des an Krebs erkrankten Menschen. | 14 | 1 | 93 | 7 | 🟩 |
| Wir achten bei unserem Handeln stets auf die Sicherheit und die individuellen Lebensumstände des an Krebs erkrankten Menschen. | 9 | 6 | 60 | 40 | 🟥 |
| Wir unterstützen und beraten den an Krebs erkrankten Menschen durch Informationen und eine bedarfsgerechte psychosoziale und psychotherapeutische Behandlung. | 13 | 2 | 87 | 13 | 🟩 |
| **Kompetenz und Qualität** | | | | | |
| Unser gesamtes Handeln basiert auf der Notwendigkeit einer koordinierten, integrierten und sektorenübergreifenden Versorgung von an Krebs erkrankten Menschen. | 13 | 2 | 87 | 13 | 🟩 |
| Unsere fachlichen Kompetenzen orientieren sich am Stand der Wissenschaft entsprechend der besten Evidenzen und sind unmittelbar auf eine strukturierte, qualitätsgesicherte Patientenversorgung ausgerichtet. | 13 | 2 | 87 | 13 | 🟩 |
| Unsere Prioritäten sind die kontinuierliche Verbesserung der Qualität und die Schaffung von Standards zur Optimierung der Patientenversorgung durch ein partizipatives Qualitätsmanagement. | 12 | 3 | 80 | 20 | 🟩 |
| **Gemeinsam stark** | | | | | |
| Wir sehen den Patienten als Partner, den wir mit professioneller Kommunikation und Kooperation bedarfsgerecht unterstützen. | 12 | 3 | 80 | 20 | 🟩 |
| Wir legen Wert auf ein positives Arbeitsumfeld, gegenseitige Akzeptanz und Engagement zum Wohle der Patienten und Beschäftigten. | 11 | 4 | 73 | 27 | 🟩 |
| Wir fördern die interdisziplinäre Zusammenarbeit und die Kompetenz jedes Einzelnen durch Schulungen und eine konstruktive, offene Kommunikation. | 13 | 2 | 87 | 13 | 🟩 |
| Wir kooperieren mit zahlreichen ambulanten und stationären Netzwerkpartnern um ein flächendeckendes Versorgungsangebot zu gewährleisten. | 11 | 4 | 73 | 27 | 🟧 |
| **Ressourcen** | | | | | |
| Wir stehen für eine verantwortungsvolle und effiziente Versorgung je nach Bedarf des an Krebs erkrankten Menschen zur Sicherung der Wirtschaftlichkeit. | 12 | 3 | 80 | 20 | 🟩 |
| Wir sind uns über die gesellschaftliche Verantwortung im Umgang mit den bereitgestellten Ressourcen bewusst. | 10 | 5 | 67 | 33 | 🟧 |
| Gesamt: Insgesamt ausgewertete Teilnehmer-Bögen | 15 | | | | |

**Appendix 2.** Results of the utility analysis for the quality charateristics in the nFC-isPO.

**PART I: Quality characteristics**

| **Evaluation scheme:**<br>Has the aspect been implemented? | **Yes** | **Partly** | **No** |
|---|---|---|---|
| | 5 points<br>(> 80%) | 3 points<br>(80% - 50%) | 1 points<br>(< 50%) |

| **Joint agreements** | | **Score** | **Degree of fulfilment*** | |
|---|---|---|---|---|
| | | | In 4 CN | |
| 1.1.001 | Quality assurance – internal quality report (Cooperation agreement) | 1 | 25% | 1/4 |
| 1.1.002 | Quality workshop – external quality report (Cooperation agreement) | 1 | 25% | 1/4 |
| 1.2.001 | Accessions of health insurance companies (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| 1.2.002 | Accessions of SHI-accredited physicians (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| 1.2.003 | Participating health insurance companies (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| 1.2.004 | Participating SHI-accredited physicians (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| 1.2.005 | Withdrawals of health insurance companies (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| 1.2.006 | Withdrawals of SHI-accredited physicians (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| 1.2.007 | Participating isPO-onco-guides (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| 1.2.008 | Declaration of participation to health insurance company (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| 1.2.009 | Withdrawal of patients (§ 630 BGB IV Contract for Special Care) | 1 | 25% | 1/4 |
| 1.2.010 | Brief report to the SHI-accredited physician (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| 1.2.011 | Invoice to the SHI-accredited physician (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| 1.2.012 | Patient letters (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| 1.2.013 | Reporting to the health insurance companies (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| 1.2.014 | Health insurance company-specific attachments (§ 630 BGB IV Contract for Special Care) | 5 | 100% | 4/4 |
| Ø Assessment: Joint agreements | | **4.3** | **86%** | - |
| **Care concept** | | **Score** | **Degree of fulfilment** | |
| | | | in nFC-ispo | |
| 2.1.001 | Care manual | 5 | 100% | 1/1 |
| 2.1.002 | Care concept | 5 | 100% | 1/1 |
| 2.1.003 | Network concept | 5 | 100% | 1/1 |

| | | | | |
|---|---|---|---|---|
| 2.1.004 | Quality management concept | 5 | 100% | 1/1 |
| 2.1.005 | Process management manual | 5 | 100% | 1/1 |
| 2.1.006 | Quality management manual | 5 | 100% | 1/1 |
| 2.1.007 | Care management manual | 5 | 100% | 1/1 |
| 2.1.008 | Knowledge management and competences (training concept) | 5 | 100% | 1/1 |
| Ø Assessment: Care concept | | **5** | **100%** | - |
| **Care management** | | **Score** | **Degree of fulfilment** | |
| 3.1.001 | Manuals | 5 | 100% | 1/1 |
| 3.1.002 | Clinical pathways | 5 | 100% | 1/1 |
| 3.1.003 | Selection and execution recommendations | 5 | 100% | 1/1 |
| 3.1.004 | Formal administrative documents | 5 | 100% | 1/1 |
| 3.1.005 | Clinical documents | 5 | 100% | 1/1 |
| 3.1.006 | Standard operating procedures | 5 | 100% | 1/1 |
| Ø Assessment: Care management | | **5** | **100%** | - |
| **Quality assurance** | | **Score** | **Degree of fulfilment** | |
| 4.1.001 | Scope | 5 | 100% | 1/1 |
| 4.1.002 | Management processes | 5 | 100% | 1/1 |
| 4.1.003 | Support processes | 5 | 100% | 1/1 |
| 4.1.004 | Core processes | 5 | 100% | 1/1 |
| 4.2.001 | Vision | 5 | 100% | 1/1 |
| 4.2.002 | Mission | 5 | 100% | 1/1 |
| 4.2.003 | Corporate identity | 5 | 100% | 1/1 |
| 4.3.001 | Clinical pathway for care level 0 | 5 | 100% | 1/1 |
| 4.3.002 | Clinical pathway for care level 1 | 5 | 100% | 1/1 |
| 4.3.003 | Clinical pathway for care level 2 | 5 | 100% | 1/1 |
| 4.3.004 | Clinical pathway for care level 3a | 5 | 100% | 1/1 |
| 4.3.005 | Clinical pathway for care level 3b | 5 | 100% | 1/1 |
| 4.4.001 | Quality circles – Meetings | 5 | 87.5% | 28/32 |
| 4.4.002 | Quality workshops – Meetings | 5 | 87.5% | 7/8 |
| 4.4.003 | Quality workshops – Participation | 3 | 50% | 4/8 |
| 4.5.001 | Training module 1: The isPO project and the new form of care | 5 | 100% | 1/1 |
| 4.5.002 | Training module 2: The psycho-oncological care networks | 5 | 100% | 1/1 |

| | | | | |
|---|---|---|---|---|
| 4.5.003 | Training module 3: The stepped care concept | 5 | 100% | 1/1 |
| 4.5.004 | Training module 4: The quality management | 5 | 100% | 1/1 |
| 4.5.005 | Training module 5: Care level 0 – basic training | 5 | 100% | 1/1 |
| 4.5.006 | Training module 6: Care level 1 – basic training | 5 | 100% | 1/1 |
| 4.5.007 | Training module 7: Care level 2 – basic training | 5 | 100% | 1/1 |
| 4.5.008 | Training module 8: Care level 3a – basic training | 5 | 100% | 1/1 |
| 4.5.009 | Training module 9: Care level 3b – basic training | 5 | 100% | 1/1 |
| 4.5.010 | Institutional organisation chart | 5 | 100% | 1/1 |
| 4.5.011 | Cross-institutional organisation chart | 5 | 100% | 1/1 |
| 4.5.012 | Responsibility and powers | 5 | 100% | 1/1 |
| Ø Assessment: Quality assurance | | **4.9** | **97%** | - |
| **Quality development** | | **Score** | **Degree of fulfilment** | |
| 5.1.001 | Quality circles – evaluation | 5 | 81.3% | 26/32 |
| 5.1.002 | Quality workshops - evaluation | 1 | 37.5% | 3/8 |
| 5.2.001 | Action plan | 5 | 100% | 8/8 |
| 5.2.002 | Controlling report | 3 | 62.5% | 5/8 |
| Ø Assessment: Quality development | | **3.5** | **64.1%** | - |
| **IT-supported documentation and assistance system** | | **Score** | **Degree of fulfilment** | |
| 6.1.001 | Treatment documentation along the care levels | 5 | 100% | 1/1 |
| 6.1.002 | Billing management | 5 | 100% | 1/1 |
| 6.1.003 | Quality management | 5 | 100% | 1/1 |
| 6.1.004 | Reporting | 5 | 100% | 1/1 |
| Ø Assessment: IT-supported documentation and assistance system | | **5** | **100%** | - |
| **Human resources** | | **Score** | **Degree of fulfilment** | |
| 7.1.001 | Human resources: Network coordinator | 5 | 100% | 4/4 |
| 7.1.002 | Human resources: Case Manager | 5 | 100% | 4/4 |
| 7.1.003 | Human resources: Psychotherapist (PT) | 5 | 100% | 4/4 |
| 7.1.004 | Human resources: Psychosocial specialist (PS) | 5 | 87.5% | 3,5/4 |
| 7.1.005 | Human resources: isPO-onco-guide | 3 | 75% | 3/4 |
| 7.1.006 | Human resources: Case Manager isPO-onco-guide | 1 | 37.5% | 1,5/4 |
| 7.1.007 | Human resources: Physicians | 5 | 100% | 4/4 |

| | | | |
|---|---|---|---|
| Ø Assessment: Human resources | **4.1** | **86%** | - |
| | | | |
| Ø Assessment: Joint agreements | 4.3 | 86% | |
| Ø Assessment: Care concept | 5 | 100% | |
| Ø Assessment: Care management | 5 | 100% | |
| Ø Assessment: Quality assurance | 4,9 | 97% | |
| Ø Assessment: Quality development | 3.5 | 64.1% | |
| Ø Assessment: IT-supported documentation and assistance system | 5 | 100% | |
| Ø Assessment: Human resources | 4.1 | 86% | |
| **Ø Overall assessment: Qualiy characteristics** | **4.5** | | |

**Appendix 3.** Results of the utility analysis for the quality indicators in the nFC-isPO.

**PART II: Quality indicators**

| **Evaluation scheme:** What are the results of performance measurement by quality indicator? | **Results show a positive trend in the last 2 years** | **Results are stable and/or largely meet targets** | **Results are stable, but have optimisation potential** | **Results are unstable and vary strongly** | **No (sufficient) data available** |
|---|---|---|---|---|---|
| | 5 points | 4 points | 3 points | 2 points | 1 point |

| **Quality indicators** | | **Score** | | | | |
|---|---|---|---|---|---|---|
| | | **Ø** | CN1 | CN2 | CN 3 | CN 4 |
| 8.1.001 | New enrolment: Enrolment in contract according to 140a SCB V | **4** | 3 | 5 | 4 | 4 |
| 8.1.002 | New enrolment: enrolment in contract according to 630a BGB | **4** | 3 | 4 | 4 | 5 |
| 8.1.003 | Initial actions carried out: Enrolment interview (care level 0-3) | **4** | 3 | 5 | 4 | 4 |
| 8.1.004 | Initial actions carried out: isPO-onco-guide consultation (care level 0-3) | **3.5** | 2 | 4 | 4 | 4 |
| 8.1.005 | Initial actions carried out: PS initial consultation with help level I (care level 2) | **3.5** | 3 | 4 | 4 | 3 |
| 8.1.006 | Initial actions carried out: PS initial consultation with help level II/III (care level 2) | **3.5** | 3 | 4 | 4 | 3 |
| 8.1.007 | Initial actions carried out: Initial PT consultation (care level 3a) | **3.5** | 3 | 3 | 4 | 4 |
| 8.1.008 | Initial actions carried out: Initial PT consultation (care level 3b) | **4.3** | 5 | 4 | 4 | 4 |
| 8.1.009 | Initial actions carried out: 3b-Decision by PT | **3.8** | 3 | 4 | 4 | 4 |
| 8.1.010 | Initial actions carried out: PS initial consultation with help level I (care level 3b) | **4** | 4 | 4 | 4 | 4 |
| 8.1.011 | Initial actions carried out: PS initial consultation with help level II/III (care level 3b) | **4** | 4 | 4 | 4 | 4 |
| 8.1.012 | Critical incident in care level 1 plus supplementary care by PS or PT | **4.5** | 4 | 5 | 4 | 5 |
| 8.1.013 | Critical incident in care level 2 plus supplementary care by PT | **4.3** | 3 | 5 | 4 | 5 |
| 8.1.014 | Critical incident in care level 3a plus supplementary care by PS | **5** | 5 | 5 | 5 | 5 |
| 8.1.015 | Consultations conducted: Consultations of all care levels | **4.8** | 5 | 5 | 5 | 4 |
| 8.1.016 | Consultations conducted: Enrolment interviews (all care levels) | **4.3** | 3 | 5 | 5 | 4 |
| 8.1.017 | Consultations conducted: isPO-onco-guide consultations (all care levels) | **3.8** | 2 | 5 | 4 | 4 |
| 8.1.018 | Consultations conducted: PS consultations (care level 2) | **4.3** | 3 | 5 | 5 | 4 |
| 8.1.019 | Consultations conducted: PT consultation (care level 3a) | **4.8** | 5 | 5 | 5 | 4 |
| 8.1.020 | Consultations conducted: PT consultation (care level 3b) | **4.5** | 5 | 5 | 4 | 4 |
| 8.1.021 | Consultations conducted: PS consultation (care level 3b) | **4.5** | 5 | 5 | 4 | 4 |
| 8.1.022 | Consultations conducted: PT consultation (for patients with critical incident) | **4.3** | 5 | 4 | 4 | 4 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 8.1.023 | Consultations conducted: PS consultation (for patients with critical incident) | **4.3** | 5 | 4 | 4 | 4 |
| 8.1.024 | Assessments performed: T1-HADS-Assessment applied | **4** | 3 | 5 | 4 | 4 |
| 8.1.025 | Assessments performed: T1-KEA-Assessment applied | **4** | 3 | 5 | 4 | 4 |
| 8.1.026 | Assessments performed: T1-PSR-Assessment applied | **4** | 3 | 5 | 4 | 4 |
| 8.1.027 | Assessments performed: T2-HADS-Assessment applied | **4.3** | 4 | 5 | 4 | 4 |
| 8.1.028 | Assessments performed: T2-KEA-Assessment applied | **4** | 3 | 5 | 4 | 4 |
| 8.1.029 | Assessments performed: T2-PSR-Assessment applied | **4** | 3 | 5 | 4 | 4 |
| 8.1.030 | Assessments performed: T2-isPO-onco-guide consultation evaluation applied | **4** | 3 | 5 | 4 | 4 |
| 8.1.031 | Assessments performed: T3-HADS-Assessment applied | **4.5** | 5 | 5 | 4 | 4 |
| 8.1.032 | Assessments performed: T3-KEA-Assessment applied | **4.5** | 5 | 5 | 4 | 4 |
| 8.1.033 | Assessments performed: T3-PSR-Assessment applied | **4.5** | 5 | 5 | 4 | 4 |
| 8.1.034 | Average time taken to organise access per patient: Initial diagnosis – physician’s consultation | **2.3** | 2 | 2 | 2 | 3 |
| 8.1.035 | Average time taken to organise access per patient: Physician’s consultation – receipt of the recommendation letter | **2.8** | 5 | 2 | 2 | 2 |
| 8.1.036 | Average time taken to organise access per patient: Physician’s consultation – enrolment interview | **2.8** | 4 | 2 | 3 | 2 |
| 8.1.037 | Average time taken to organise access per patient: Receipt of the recommendation letter – enrolment interview | **2.5** | 4 | 2 | 2 | 2 |
| 8.1.038 | Average time taken to organise access per patient: Enrolment interview – PIC | **3.5** | 3 | 4 | 3 | 4 |
| 8.1.039 | Average time taken to organise access per patient: PIC – submittal T1 examination | **3.8** | 3 | 4 | 4 | 4 |
| 8.1.040 | Average time taken to organise access per patient: Submittal T1 examination – T1-approval | **4.3** | 4 | 3 | 5 | 5 |
| 8.1.041 | Average time taken to receive care services per patient: PIC – T1-HADS-Assessment | **4.3** | 4 | 4 | 5 | 4 |
| 8.1.042 | Average time taken to receive care services per patient: PIC – isPO-onco-guide consultation | **2.8** | 2 | 3 | 2 | 4 |
| 8.1.043 | Average time taken to receive care services per patient: PIC – psychosocial specialist initial consultation (care level 2) | **3.5** | 3 | 5 | 4 | 2 |
| 8.1.044 | Average time taken to receive care services per patient: PIC – PT initial consultation (care level 3a) | **3.5** | 3 | 3 | 4 | 4 |
| 8.1.045 | Average time taken to receive care services per patient: PIC – PT initial consultation (care level 3b) | **3.8** | 3 | 4 | 4 | 4 |
| 8.1.046 | Average time taken to receive care services per patient: PIC – PT 3b Decision (care level 3b) | **4** | 3 | 5 | 4 | 4 |
| 8.1.047 | Average time taken to receive care services per patient: PIC – PS initial consultation (care level 3b) | **3.3** | 3 | 4 | 2 | 4 |
| 8.1.048 | Average time taken to receive care services per patient: PIC – T2-HADS-Assessment | **3.8** | 4 | 4 | 4 | 3 |
| 8.1.049 | Average time taken to receive care services per patient: PIC – PS T2 follow-up consultation (care level 2) | **3.5** | 3 | 5 | 3 | 3 |
| 8.1.050 | Average time taken to receive care services per patient: PIC – PT T2 follow-up consultation (care level 3a) | **3.5** | 3 | 5 | 3 | 3 |
| 8.1.051 | Average time taken to receive care services per patient: PIC – PT T2 follow-up consultation ( care level 3b) | **3.5** | 3 | 5 | 3 | 3 |
| 8.1.052 | Average time taken to receive care services per patient: PIC – T3-HADS-Assessment | **4.3** | 4 | 4 | 5 | 4 |
| 8.1.053 | Average time taken to receive care services per patient: PIC – PS T3 final consultation (care level 2) | **2.3** | 2 | 3 | 1 | 3 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 8.1.054 | Average time taken to receive care services per patient: PIC – PT T3 final consultation (care level 3a) | **4** | 3 | 5 | 4 | 4 |
| 8.1.055 | Average time taken to receive care services per patient: PIC – PT T3 final consultation (care level 3b) | **4** | 3 | 5 | 4 | 4 |
| 8.1.056 | Average time taken to receive care services per patient: PIC – PS T3 final consultation (care level 3b) | **3.8** | 3 | 4 | 4 | 4 |
| 8.1.057 | Average time taken between psychosocial specialist initial consultation and follow-up consultation | **2.8** | 3 | 4 | 2 | 2 |
| 8.1.058 | Average time taken between PS initial and T2-Follow-up consultation | **3.3** | 3 | 5 | 2 | 3 |
| 8.1.059 | Average time taken between PS initial and T3-Final consultation | **3.5** | 2 | 5 | 4 | 3 |
| 8.1.060 | Average time taken between PT initial consultation and follow-up consultation | **3.3** | 3 | 3 | 3 | 4 |
| 8.1.061 | Average time taken between PT initial consultation and T2-Follow-up consultation | **3.3** | 3 | 4 | 3 | 3 |
| 8.1.062 | Average time taken between PT initial consultation and T3-Final consultation | **3.8** | 3 | 5 | 3 | 4 |
| 8.1.063 | Average time taken between all PS consultations in care level 2 | **3.5** | 3 | 4 | 3 | 4 |
| 8.1.064 | Average time taken between all PT consultations in care level 3a | **3.5** | 3 | 4 | 3 | 4 |
| 8.1.065 | Average time taken between all PT consultations in care level 3b | **3.8** | 3 | 4 | 4 | 4 |
| 8.1.066 | Average time taken between all PS consultations in care level 3b | **2.3** | 3 | 1 | 2 | 3 |
| 8.1.067 | Average time taken when organising the assessments: T1-HADS assessment patient letter | **2.5** | 3 | 3 | 3 | 1 |
| 8.1.068 | Average time taken to organise the assessments: T1-HADS-Assessment – brief report to physician | **2.5** | 3 | 3 | 3 | 1 |
| 8.1.069 | Average time taken to organise the assessments: T2-HADS-Assessment – patient letter | **2** | 2 | 2 | 3 | 1 |
| 8.1.070 | Average time taken to organise the assessments: T2-HADS-Assessment – brief report to physician | **2** | 2 | 2 | 3 | 1 |
| 8.1.071 | Average time taken to organise the assessments: T3-HADS-Assessment – patient letter | **2.5** | 3 | 3 | 3 | 1 |
| 8.1.072 | Average time taken to organise the assessments: T3-HADS-Assessment – brief report to physician | **2.3** | 3 | 2 | 3 | 1 |
| 8.1.073 | Average time taken to organise the assessments: Patient informed consent – T2-cover letter | **4** | 4 | 4 | 4 | 4 |
| 8.1.074 | Average time taken to organise the assessments: T2-cover letter – T2-reminder letter | **3.5** | 4 | 5 | 1 | 4 |
| 8.1.075 | Average time taken to organise the assessments: Patient informed consent – T3-cover letter | **3.8** | 4 | 4 | 4 | 3 |
| 8.1.076 | Average time taken to organise the assessments: T3-cover letter – T3-reminder letter | **3.8** | 5 | 5 | 3 | 2 |
| 8.1.077 | Average time taken between care service provision and documentation: Physician's consultation | **3.8** | 4 | 5 | 3 | 3 |
| 8.1.078 | Average time taken between care service provision and documentation: Enrolment interview | **3.8** | 4 | 4 | 3 | 4 |
| 8.1.079 | Average time taken between care service provision and documentation: T1-HADS-Assessment | **4** | 4 | 4 | 4 | 4 |
| 8.1.080 | Average time taken between care service provision and documentation: isPO-onco-guide consultation | **2.8** | 3 | 3 | 2 | 3 |
| 8.1.081 | Average time taken between care service provision and documentation: PS initial consultation (care level 2) | **2.3** | 2 | 2 | 2 | 3 |
| 8.1.082 | Average time taken between care service provision and documentation: PT initial consultation (care level 3a) | **2.3** | 2 | 2 | 2 | 3 |
| 8.1.083 | Average time taken between care service provision and documentation: PT consultation (care level 3b) | **2.8** | 3 | 3 | 2 | 3 |
| 8.1.084 | Average time taken between care service provision and documentation: PS initial consultation (care level 3b) | **2.3** | 2 | 3 | 2 | 2 |

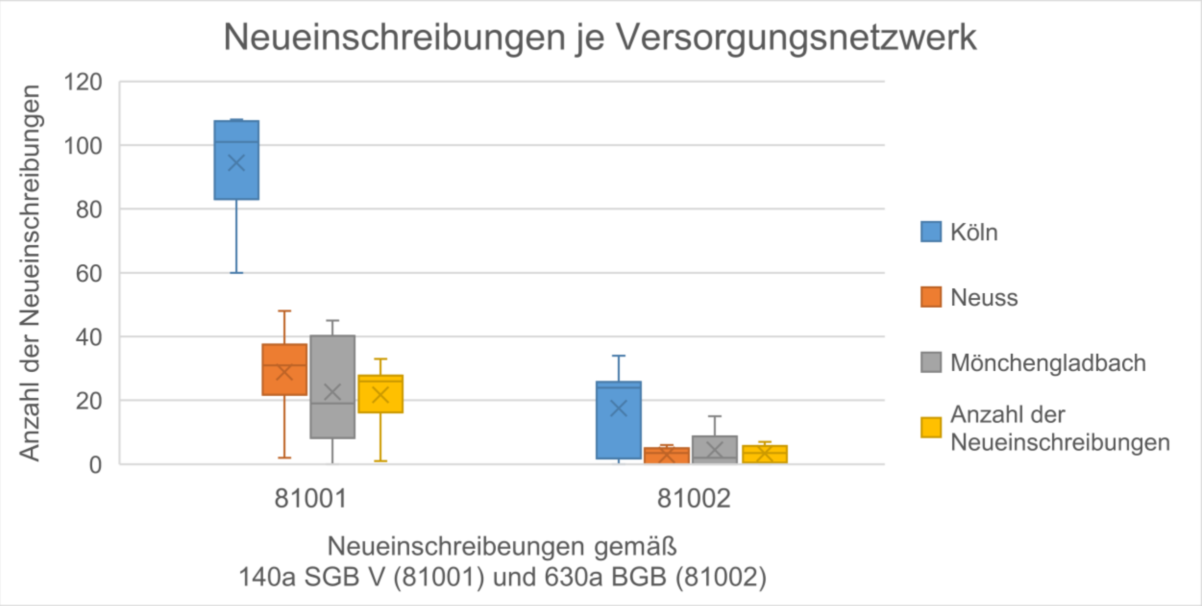
| | | | | | | |
|---|---|---|---|---|---|---|
| 8.1.085 | Average time taken between care service provision and documentation: All HADS-Assessments | **3.3** | 3 | 4 | 3 | 3 |
| 8.1.086 | Average time taken between care service provision and documentation: All PS consultations (care level 2 and 3b) | **3.3** | 3 | 4 | 3 | 3 |
| 8.1.087 | Average time taken between care service provision and documentation: All PT consultations (care level 3a and 3b) | **3.3** | 3 | 3 | 3 | 4 |
| 8.1.088 | Changes in anxiety and depression scores: Mean difference HADS total score T1-T2 | **3.3** | 3 | 4 | 3 | 3 |
| 8.1.089 | Changes in anxiety and depression scores: Mean difference HADS total score T2-T3 | **3.5** | 3 | 5 | 3 | 3 |
| 8.1.090 | Changes in anxiety and depression scores: Mean difference HADS total score T1-T3 | **3.8** | 4 | 4 | 3 | 4 |
| 8.1.091 | Total number of isPO-onco-guide consultations requested by patients | **3.8** | 3 | 4 | 4 | 4 |
| 8.1.092 | isPO-onco-guide consultations by patients unwanted | **3.5** | 2 | 4 | 4 | 4 |
| 8.1.093 | Patients in care level 2 | **5** | 5 | 5 | 5 | 5 |
| 8.1.094 | Total number of PS consultations for patients in care level 2 | **4.8** | 4 | 5 | 5 | 5 |
| 8.1.095 | PS initial consultations with patients in care level 2 | **4.3** | 4 | 4 | 5 | 4 |
| 8.1.096 | PS follow-up consultations with patients in care level 2 | **4** | 4 | 4 | 3 | 5 |
| 8.1.097 | PS T2-Follow-up consultations with patients care level 2 | **4.3** | 4 | 5 | 4 | 4 |
| 8.1.098 | PS T3-Final consultations with patients in care level 2 | **4.3** | 4 | 4 | 4 | 5 |
| 8.1.099 | Average duration of PS consultations (in minutes) with patients in care level 2 | **4** | 4 | 4 | 4 | 4 |
| 8.1.100 | Patients in care level 3a | **4.8** | 5 | 5 | 5 | 4 |
| 8.1.101 | Total number of PT consultations with patients in care level 3a | **4.8** | 5 | 5 | 5 | 4 |
| 8.1.102 | PT initial consultations with patients in care level 3a | **3.5** | 3 | 4 | 3 | 4 |
| 8.1.103 | PT follow-up consultations with patients in care level 3a | **4.5** | 5 | 4 | 5 | 4 |
| 8.1.104 | PT T2-Follow-up consultations with patients in care level 3a | **4** | 4 | 4 | 4 | 4 |
| 8.1.105 | PT T3-Final consultation with patients in care level 3a | **4.3** | 5 | 4 | 4 | 4 |
| 8.1.106 | Average duration of PT consultations (in minutes) with patients in care level 3a | **4.3** | 5 | 4 | 4 | 4 |
| 8.1.107 | Patients in care level 3b | **5** | 5 | 5 | 5 | 5 |
| 8.1.108 | Total number of PT consultations with patients in care level 3b | **4.5** | 5 | 5 | 3 | 5 |
| 8.1.109 | PT initial consultations with patients in care level 3b | **4.3** | 4 | 4 | 5 | 4 |
| 8.1.110 | PT follow-up consultations with patients in care level 3b | **4** | 5 | 4 | 3 | 4 |
| 8.1.111 | PT T2-Follow-up consultations with patients in care level 3b | **4** | 4 | 4 | 4 | 4 |
| 8.1.112 | PT T3-Final consultation with patients in care level 3b | **4.5** | 5 | 4 | 4 | 5 |
| 8.1.113 | Average duration of PT consultations (in minutes) with patients in care level 3b | **4** | 4 | 4 | 4 | 4 |
| 8.1.114 | Patients in level 3b (PS consultations) | **5** | 5 | 5 | 5 | 5 |
| 8.1.115 | Total number of PS consultations for patients in care level 3b | **4.5** | 5 | 5 | 3 | 5 |
| 8.1.116 | PS initial consultations with patients in care level 3b | **4.5** | 5 | 5 | 4 | 4 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 8.1.117 | PS follow-up consultations with patients in care level 3b | **4.3** | 4 | 4 | 4 | 5 |
| 8.1.118 | PS T3-Final consultations with patients in care level 3b | **4.3** | 4 | 4 | 4 | 5 |
| 8.1.119 | Average duration of PS consultations (in minutes) with patients in care level 3b | **3.5** | 4 | 3 | 3 | 4 |
| 8.1.120 | Average number of consultations per patient: Conversations of all care levels | **4** | 4 | 4 | 4 | 4 |
| 8.1.121 | Average number of consultations per patient: Enrolment interview | **4** | 4 | 4 | 4 | 4 |
| 8.1.122 | Average number of consultations per patient: isPO-onco-guide consultation | **4** | 4 | 4 | 4 | 4 |
| 8.1.123 | Average number of consultations per patient: PS consultations (care level 2) | **4** | 4 | 4 | 4 | 4 |
| 8.1.124 | Average number of consultations per patient: PT consultation (care level 3a) | **4** | 4 | 4 | 4 | 4 |
| 8.1.125 | Average number of consultations per patient: PT consultation (care level 3b) | **4** | 4 | 4 | 4 | 4 |
| 8.1.126 | Average number of consultations per patient: PS consultations (care level 3b) | **4** | 4 | 4 | 4 | 4 |
| 8.1.127 | Average number of consultations per patient: PT consultation for patients with critical incident | **3.8** | 4 | 4 | 3 | 4 |
| 8.1.128 | Average number of consultations per patient: PS consultations for patients with critical incident | **2.5** | 4 | 1 | 4 | 1 |
| **Ø Assessment quality indicators:** | | **3.8** | **3.6** | **4.1** | **3.6** | **3.7** |
| | | | | | | |
| Ø Assessment qualiy characteristics: | | 4.5 | | | | |
| Ø Assessment quality indicators: | | 3.8 | | | | |
| **Overall assessment:** | | **4.2** | | | | |

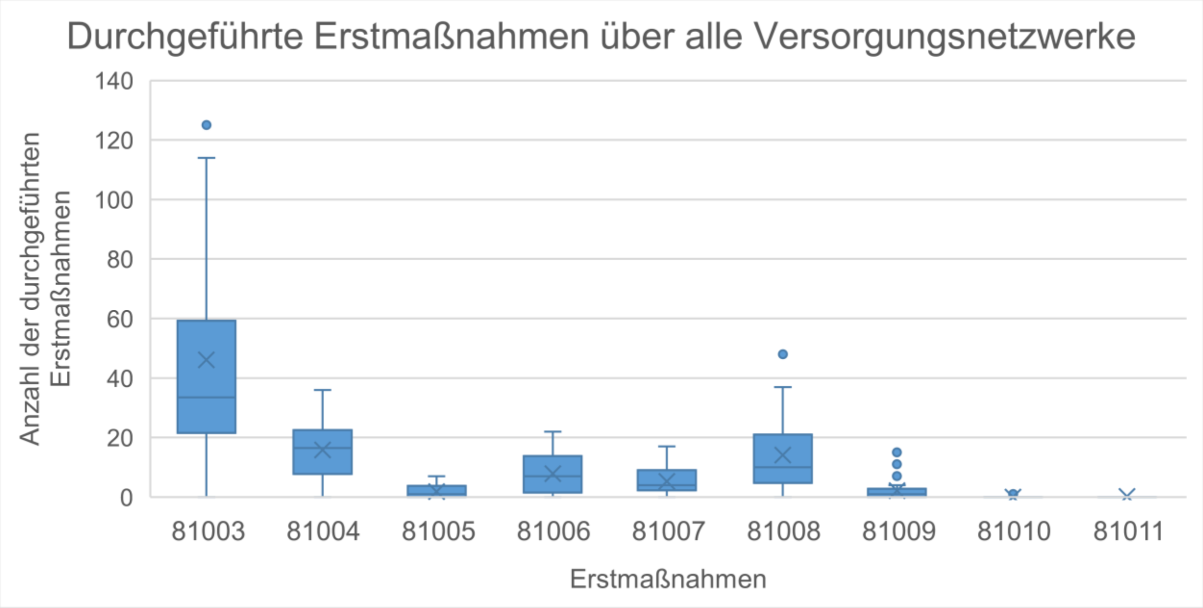
*X/4 = of four care networks; the quality aspect must be implemented in each care network; X/1 = the quality aspect must be implemented for the entire nFC-isPO programme (including the 4 networks).

**CN= Care Networks

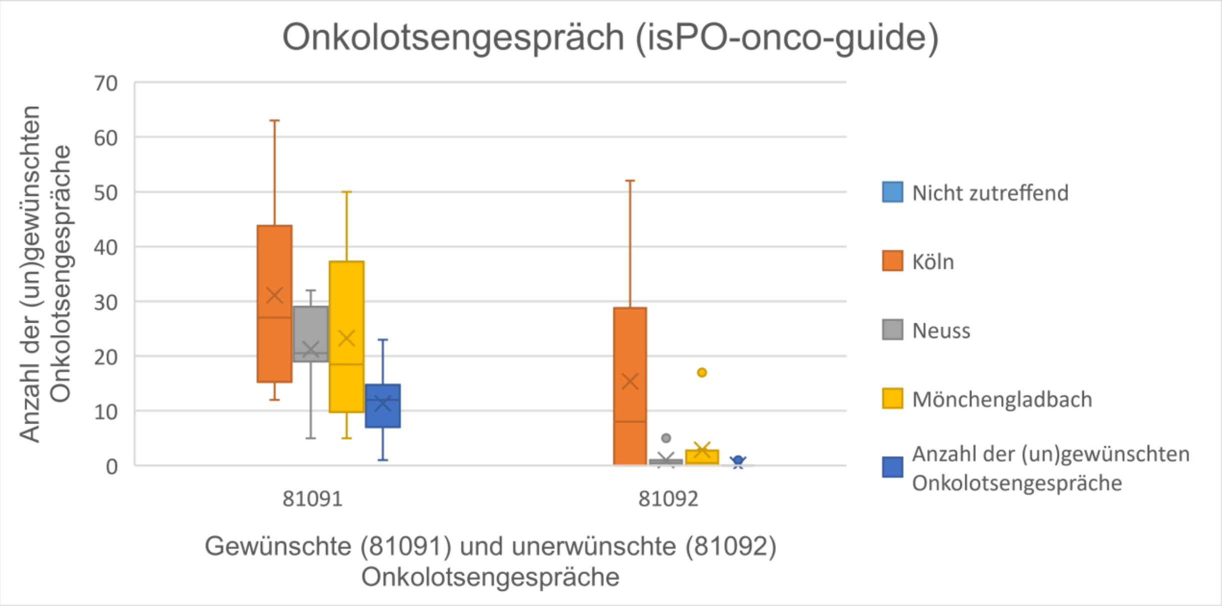
**Appendix 4.** New enrolments in contracts according to 140a SCB V (ID: 8.1.001) and 630a BGB (ID: 8.1.002).



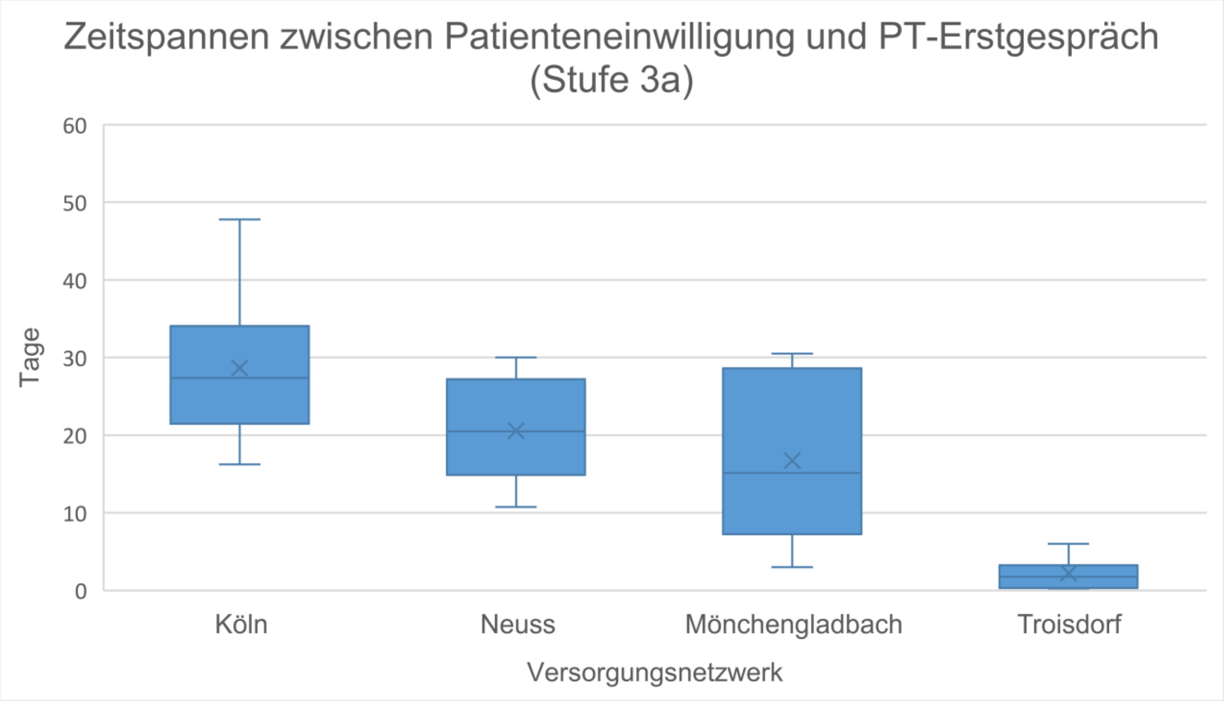
**Appendix 5.** Initial actions carried out for **‘**Enrolment interview (care level 0-3) (ID: 8.1.003)’, ‘isPO-onco-guide consultation (care level 0-3) (ID: 8.1.004)’, ‘PS initial consultation with help level I (care level 2) (ID: 8.1.005)’, ‘PS initial consultation with help level II/III (care level 2) (ID: 8.1.006)’, ‘Initial PT consultation (care level 3a) (ID: 8.1.007)’, Initial PT consultation (care level 3b) (ID: 8.1.008)’, 3b-Decision by PT (ID: 8.1.009)’, PS initial consultation with help level I (care level 3b) (ID: 8.1.010)’ and ‘PS initial consultation with help level II/III (care level 3b) (ID: 8.1.011)’.



**Appendix 6.** IsPO-onco-guide consultations wanted (ID: 8.1.091) and unwanted (ID: 8.1.092).



**Appendix 7.** Time in days between patient consent and first psychotherapy consultation per care network.

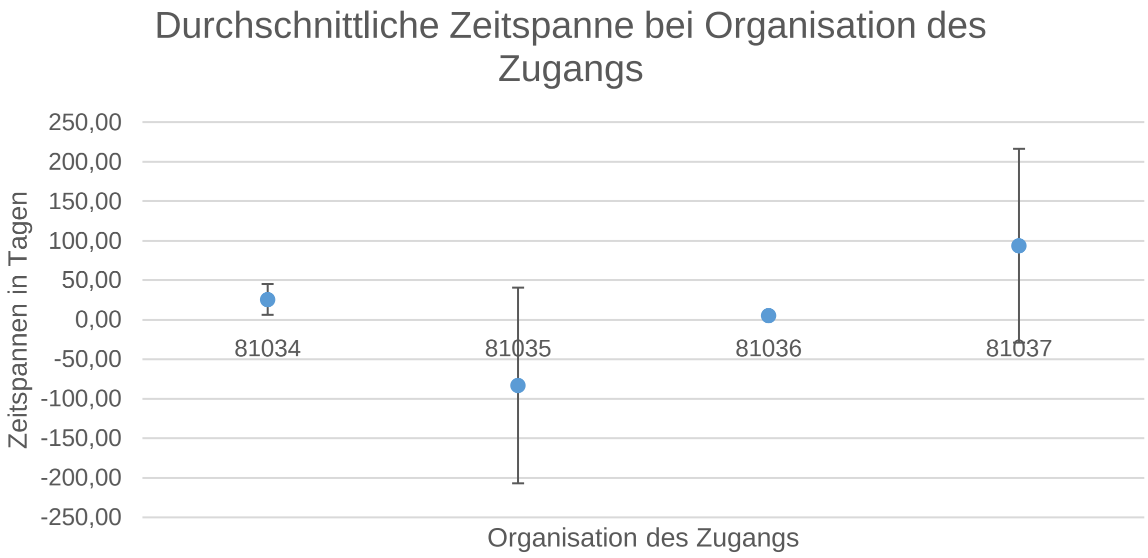


**Appendix 8.** Overview of all statistically outlying quality indicator results.

| ID | Quality indicators | Ø | K | MG | NE | TR |
|---|---|---|---|---|---|---|
| 8.1.034 | Average time taken to organise access per patient: Initial diagnosis – physician's consultation | **2.3** | 2 | 2 | 2 | 3 |
| 8.1.035 | Average time taken to organise access per patient: Physician's consultation – receipt of the recommendation letter | **2.8** | 5 | 2 | 2 | 2 |
| 8.1.036 | Average time taken to organise access per patient: Physician's consultation – enrolment interview | **2.8** | 4 | 2 | 3 | 2 |
| 8.1.037 | Average time taken to organise access per patient: Receipt of the recommendation letter – enrolment interview | **2.5** | 4 | 2 | 2 | 2 |
| 8.1.053 | Average time taken to receive care services per patient: PIC – PS T3 final consultation (care level 2) | **2.3** | 2 | 3 | 1 | 3 |
| 8.1.057 | Average time taken between psychosocial specialist initial consultation and follow-up consultation | **2.8** | 3 | 4 | 2 | 2 |
| 8.1.066 | Average time taken between all PS consultations in care level 3b | **2.3** | 3 | 1 | 2 | 3 |
| 8.1.067 | Average time taken when organising the assessments: T1-HADS assessment patient letter | **2.5** | 3 | 3 | 3 | 1 |
| 8.1.068 | Average time taken to organise the assessments: T1-HADS-Assessment – brief report to physician | **2.5** | 3 | 3 | 3 | 1 |
| 8.1.069 | Average time taken to organise the assessments: T2-HADS-Assessment – patient letter | **2** | 2 | 2 | 3 | 1 |
| 8.1.070 | Average time taken to organise the assessments: T2-HADS-Assessment – brief report to physician | **2** | 2 | 2 | 3 | 1 |
| 8.1.071 | Average time taken to organise the assessments: T3-HADS-Assessment – patient letter | **2.5** | 3 | 3 | 3 | 1 |
| 8.1.072 | Average time taken to organise the assessments: T3-HADS-Assessment – brief report to physician | **2.3** | 3 | 2 | 3 | 1 |
| 8.1.080 | Average time taken between care service provision and documentation: isPO-onco-guide consultation | **2.8** | 3 | 3 | 2 | 3 |
| 8.1.081 | Average time taken between care service provision and documentation: PS initial consultation (care level 2) | **2.3** | 2 | 2 | 2 | 3 |
| 8.1.082 | Average time taken between care service provision and documentation: PT initial consultation (care level 3a) | **2.3** | 2 | 2 | 2 | 3 |
| 8.1.083 | Average time taken between care service provision and documentation: PT consultation (care level 3b) | **2.8** | 3 | 3 | 2 | 3 |
| 8.1.084 | Average time taken between care service provision and documentation: PS initial consultation (care level 3b) | **2.3** | 2 | 3 | 2 | 2 |

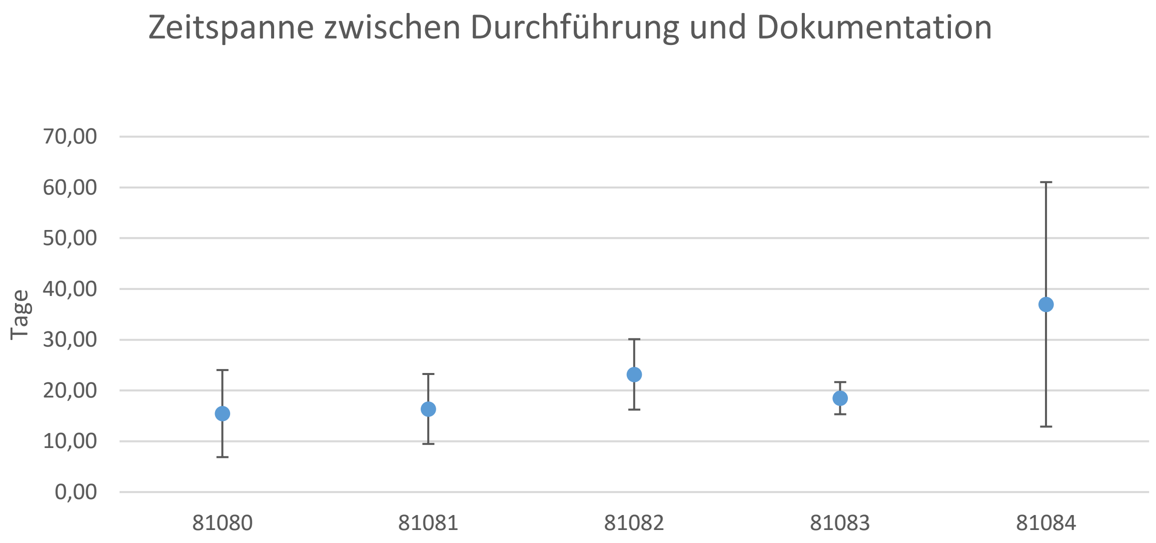
**Appendix 9.** Exemplary results for outlier quality indicators (Part 1).

Average time to organise access per patient for ‘Initial diagnosis – physician’s consultation (ID: 8.1.034)‘, ‘Physician’s consultation – receipt of the recommendation letter (ID: 8.1.035)‘, ‘Physician’s consultation – enrolment interview (ID: 8.1.036)‘ and ‘Receipt of the recommendation letter – enrolment interview (ID: 8.1.037)’.

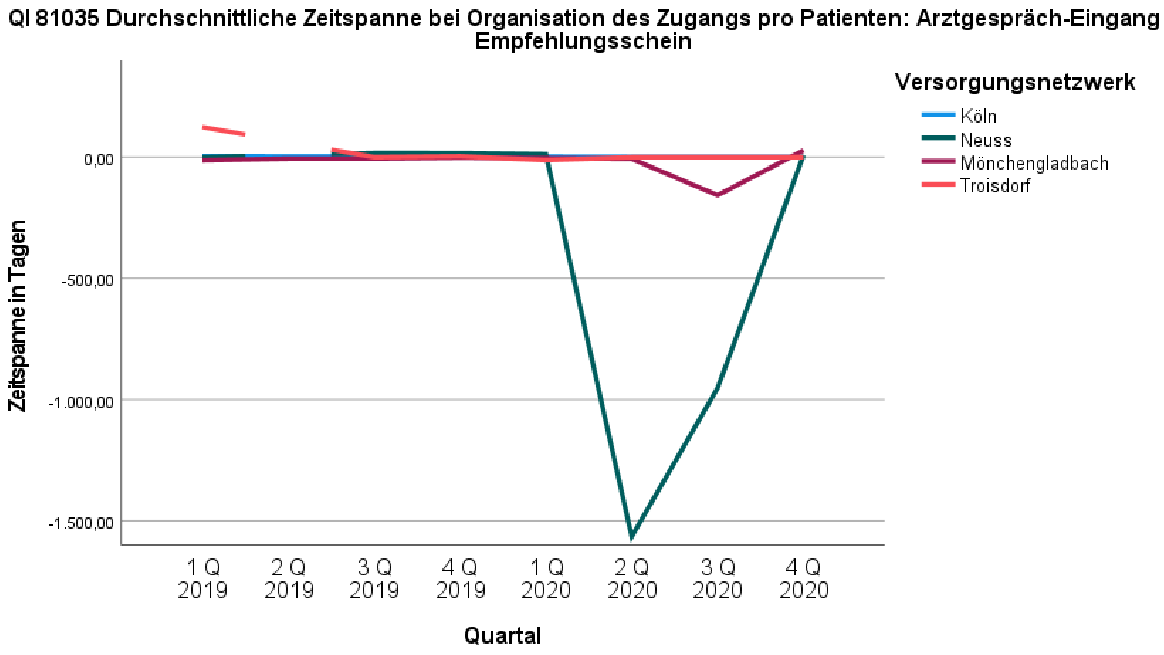


**Appendix 10.** Exemplary results for outlier quality indicators (Part 2).

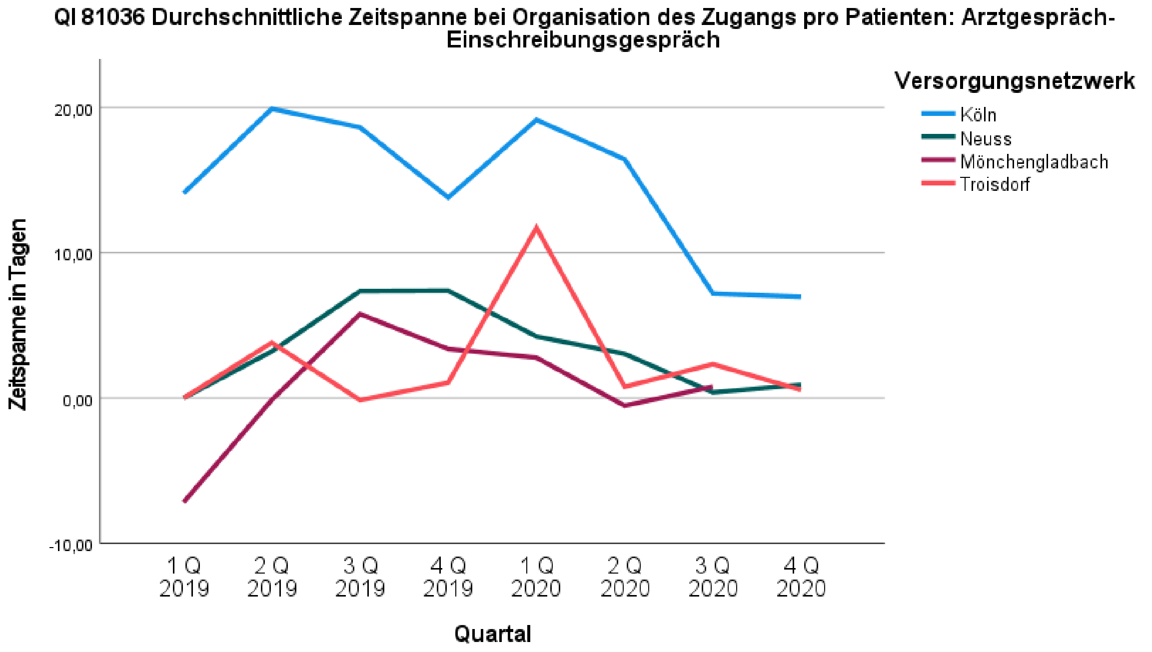
Average time between delivery of a service and documentation for ‘isPO-onco-guide consultation (ID: 8.1.080)‘, ‘PS initial consultation (care level 2) (ID: 8.1.081)‘, ‘PT initial consultation (care level 3a) (ID: 8.1.081)‘, ‘PT consultation (care level 3b) (ID: 8.1.083)‘ and ‘PS initial consultation (care level 3b) (ID:8.1.084)‘.



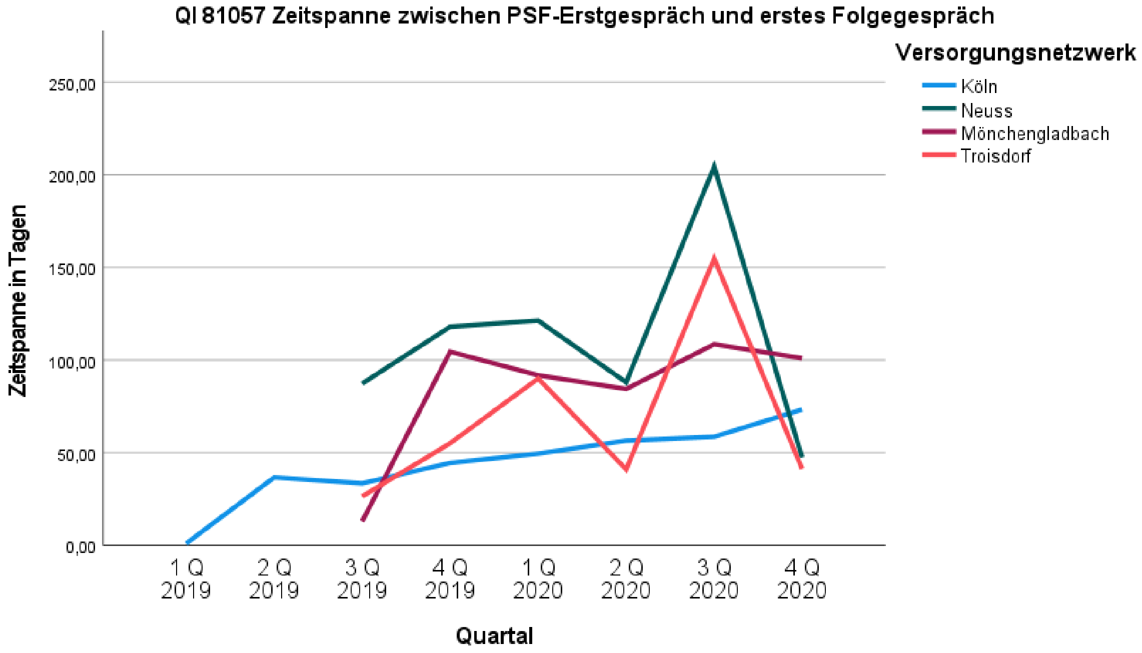
**Appendix 11.** Exemplary result for data entry errors.



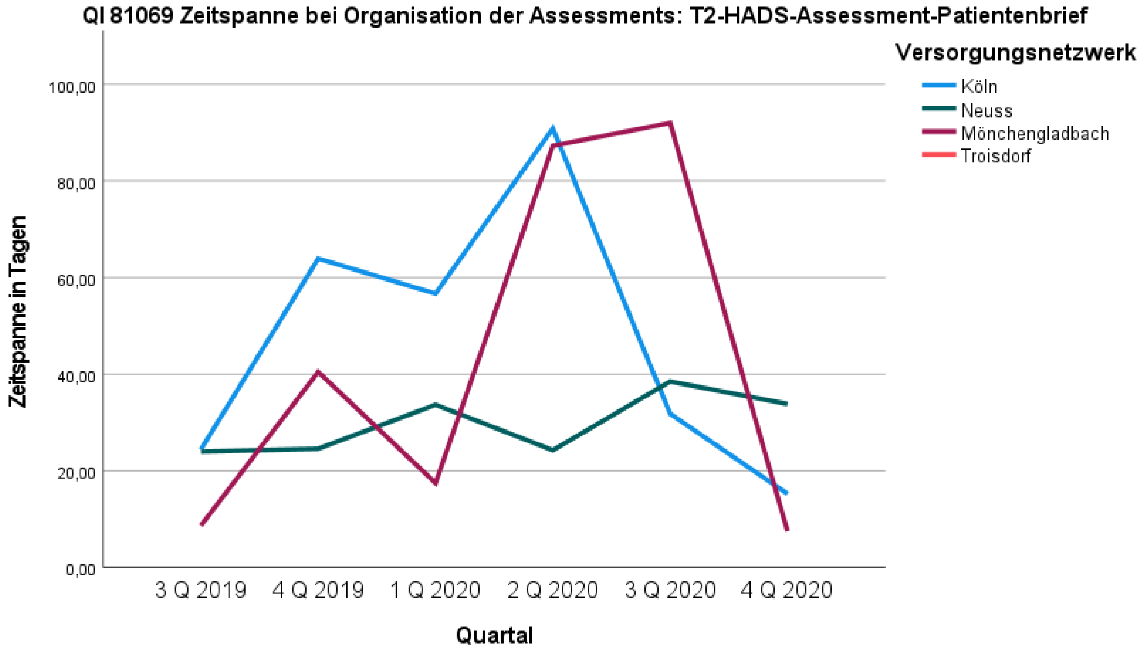
**Appendix 12.** Exemplary result for procedural problems in managing interfaces.



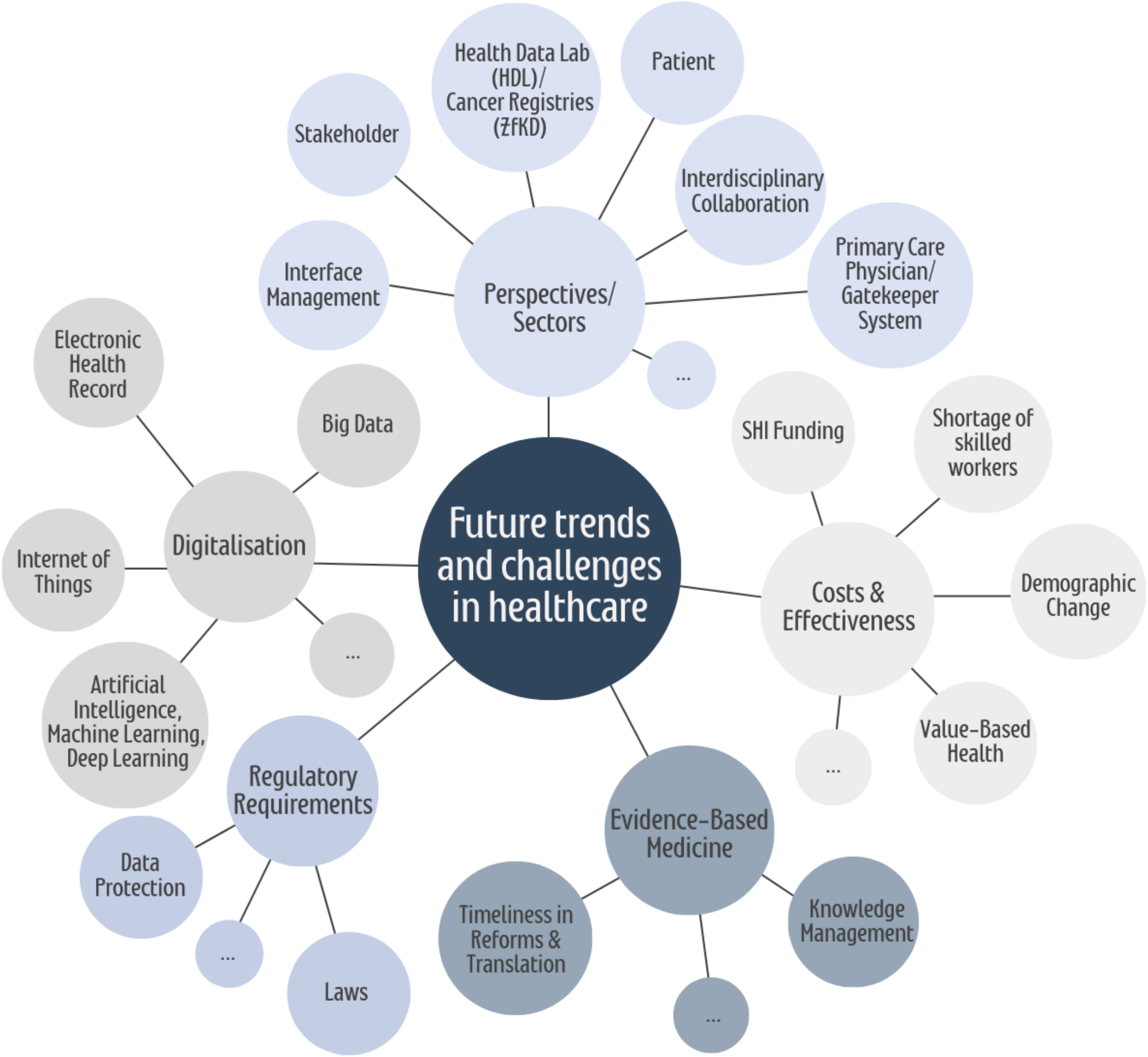
**Appendix 13.** Exemplary result for the impact of SARS-CoV-2 (Part 1).



**Appendix 14.** Exemplary result for the impact of SARS-CoV-2 (Part 2).



**Appendix 15.** Future trends and challenges in healthcare.



**Appendix 16.** Healthcare 4.0 implications for future quality management systems.

| Quality management principles | Exemplary qualitative and quantitative measures | Quality management system of NFC-ISPO | Potential contributions from Healthcare 4.0 |
|---|---|---|---|
| **Customer focus** | • Patient satisfaction<br>• Improved reputation<br>• Patient safety | Electronic health record in CAPSYS, cross-sectoral application, quality indicator for patient satisfaction | • Patient engagement platforms for scheduling appointments, accessing medical records and communicating securely with healthcare providers<br>• IoT devices and wearables to monitor patients in real-time<br>• AI-based predictive analytics such as symptom checking applications and disease prediction<br>• Telemedicine platforms for virtual consultations and follow-ups |
| **Leadership** | • Unity of purpose<br>• Alignment of strategies, policies processes and resources<br>• Effective communication between all administrative levels | Quality policy, mission and vision statements, participatory design, digital helpdesk, quality circles and workshops, manuals, organisational charts, qualification matrix | • AI-based smart recourses allocation<br>• Implementation support module (sustainability and scalability)<br>• Collaborative digital platforms and project management tools that facilitate real-time communication and task tracking<br>• Personalised qualification plans including VR and AR for healthcare professionals<br>• DSS for strategic planning and policy making |
| **Commitment of people** | • Increased employee motivation<br>• Job satisfaction<br>• Culture of self-evaluation and self-improvement | Participatory design, quality circle and workshops, trainings and qualification matrix | • Wellness and health tracking apps/wearables that promote physical and mental well-being<br>• Digital tools for setting and tracking individual and team goals<br>• Virtual mentoring programmes and coaching platforms<br>• Personalised performance dashboards for self-assessment<br>• Gamification and rewards platforms |
| **Process approach** | • Identification of key processes and areas for improvement<br>• Optimise performance and effective process management<br>• Manage processes, and relationships and dependencies | Process map, (digital) clinical pathways, electronic document management system, SOPs, automated and standardised reporting system | • IoT devices for real-time monitoring and alerts for process management (interoperability)<br>• Blockchain technology to ensure transparency and traceability in processes such as financial transactions, supply chain management, and regulatory compliance<br>• Cloud-based platforms that enable secure and collaborative document sharing, ensuring that policies and strategies are easily accessible and up to date<br>• AI-based predictive modelling to forecast patient volumes, resource requirements, and other critical variables<br>• DSS for process planning and optimisation |

| Quality management principles | Exemplary qualitative and quantitative measures | Quality management system of NFC-ISPO | Potential contributions from Healthcare 4.0 |
|---|---|---|---|
| **Improvement** | • Systems that respond to user needs<br>• Improved ability to respond to evolving processes, products and market needs<br>• Support for innovation drivers | Quality indicators, participatory quality development process, automated and standardised quality reports | • IoT devices to monitor and collect data from multiple points in the healthcare process<br>• AI-based predictive analytics to anticipate future user needs based on historical data and trends<br>• Digital dashboards that visually represent key performance metrics and strategic goals<br>• CC platforms to create flexible and scalable healthcare systems based on demand, ensuring responsiveness to changing user loads<br>• Open APIs and collaboration platforms |
| **Evidence-based decision making** | • Clear and agreed decision making process<br>• Data availability and clarity<br>• Effective past decisions<br>• Analysis and evaluation of data using appropriate methods and tools | Quality indicators, best available evidence (e.g. S3 psycho-oncology guideline, National Cancer Plan), participatory design, consesus techniques, automated and standardised quality reports | • DSS to provide relevant (clinical) information, options, and potential outcomes<br>• Data warehousing solutions to centralise and organise data ensuring interoperability to make data easily accessible and understandable to decision makers<br>• Decision tracking and analytics to record, document and evaluate past decisions and adjust future strategies accordingly<br>• NLP tools to extract insights from unstructured data sources, such as clinical notes, conferences or case reviews |
| **Relationship management** | • Stakeholders are identified and appropriate communication tools are identified for each<br>• Stakeholders are satisfied and their feedback is taken into account<br>• Suppliers respond to material requests on time and with the required quality<br>• Supply chain is stable and there is no downtime due to lack of supply | Participatory design, cross-sectoral appraoch, digital helpdesk | • Open APIs<br>• Collaboration platforms and project management tools that facilitate real-time communication and task tracking |

AI = Artificial Intelligence; API =Application Programming Interfaces; AR = Augmented Reality; CC = Cloud Computing; DSS = Decision Support Systems; IoT = Internet of Things; NLP = Natural Language Processing; SOP = Standard Operating Procedure; VR = Virtual Reality

# Doctoral Student's Declaration of Contribution

## Publication 1

### Developing quality indicators for cross-sectoral psycho-oncology in Germany: combining the RAND/UCLA appropriateness method with a Delphi technique

Lisa Derendorf, Stephanie Stock, Dusan Simic, Clarissa Lemmen

*BMC Health Services Research, 2023, 23(1):599*

*DOI: 10.1186/s12913-023-09604-3; IF: 2,8 (2022)*

**Authors' contributions:**

Lisa Derendorf and Clarissa Lemmen developed the idea of the study and developed and reviewed the specific (analytical) methods of the study. Lisa Derendorf was responsible for managing and coordinating the planning and implementation of the research activities. Lisa Derendorf planned, coordinated, carried out and analysed the study. Lisa Derendorf used statistical and computational methods to analyse and synthesise the study data. Clarissa Lemmen and Stephanie Stock provided scientific and technical support. Dusan Simic and Stephanie Stock provided financial support for the project leading to this publication. Lisa Derendorf wrote and edited the first draft of this publication. Clarissa Lemmen contributed to the preparation of this publication by providing critical review, comments or revisions. All authors critically read, revised and approved the published version of the manuscript.

## Publication 2

### Participatory health research in cross-sectoral psycho-oncology: implementation and results of participatory methods in quality development

Lisa Derendorf, Stephanie Stock, Michael Kusch, Hildegard Labouvie, Clarissa Lemmen

*Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen (ZEFQ), 2024*

*Under revision*

**Authors' contributions:**

Lisa Derendorf, Michael Kusch, Hildegard Labouvie and Clarissa Lemmen developed the idea for this study. Lisa Derendorf planned, coordinated, conducted, and analysed the study. Lisa Derendorf and Clarissa Lemmen developed and tested the specific (analytical) methods of the study. Lisa Derendorf, Hildegard Labouvie and Clarissa Lemmen managed the research process, in particular the implementation of the participatory survey. Lisa Derendorf applied statistical and computational methods to analyse and synthesise the study data and programmed, implemented and supervised the web survey. Lisa Derendorf and Clarissa Lemmen checked the reproducibility of the results. Lisa Derendorf, Michael Kusch and Clarissa Lemmen recruited participants for the survey. Lisa Derendorf was responsible for managing and coordinating the planning and implementation of the research activities. Clarissa Lemmen and Stephanie Stock provided scientific and technical support. Michael Kusch, Hildegard Labouvie and Stephanie Stock provided financial support for the project leading to this publication. Lisa Derendorf created, edited, and visualised the first draft of the publication. Clarissa Lemmen, Michael Kusch and Stephanie Stock supported the production of the publication through critical reading, comments and revisions. All authors critically read, revised and approved the published version of the manuscript.

## Publication 3

### Assessing the implementation of a comprehensive quality management system for cross-sectoral psycho-oncology in Germany

Lisa Derendorf, Michael Kusch, Stephanie Stock, Clarissa Lemmen

*Journal of Healthcare Quality Research, 2023, 39(1):32-40*

*DOI: 10.1016/j.jhqr.2023.10.007; IF: 1,2 (2022)*

**Authors' contribution:**

Lisa Derendorf and Clarissa Lemmen developed the idea for this study. Lisa Derendorf planned, coordinated, carried out and analysed the study. Lisa Derendorf and Clarissa Lemmen developed and tested the specific (analytical) methods of the study. Lisa Derendorf used statistical and computational methods to analyse and synthesise the study data. Lisa Derendorf, Michael Kusch and Clarissa Lemmen verified the reproducibility of the results. Lisa Derendorf was responsible for managing and coordinating the planning and execution of the research activities. Clarissa Lemmen and Stephanie Stock provided scientific and technical support. Michael Kusch and Stephanie Stock provided financial support for the project leading to this publication. Lisa Derendorf created, edited, and visualised the first draft of the publication. Clarissa Lemmen and Stephanie Stock supported the production of the publication through critical reading, comments, and revisions. All authors critically read, revised, and approved the published version of the manuscript.

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## Curriculum Vitae

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## Professional Experience

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| 10/2017 – 06/2024 | **Research Associate**<br>Institute of Health Economics and Clinical Epidemiology,<br>Faculty of Medicine and University Hospital of Cologne,<br>University of Cologne, Cologne, Germany |
| 04/2013 – 04/2014 | **Student Assistant**<br>Kassenärztliche Vereinigung Nordrhein, Cologne, Germany |

## Education

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| 07/2018 – 05/2024 | **Interdisciplinary Programme Health Sciences,** PhD Studies,<br>University of Cologne, Cologne, Germany |
| 10/2014 – 04/2017 | **Master of Science Health Economics,**<br>University of Cologne, Cologne, Germany |
| 10/2011 – 09/2014 | **Bachelor of Science Health Economics,**<br>University of Cologne, Cologne, Germany |
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## Scientific Publications

### Articles

- Kusch M, Labouvie H, Schiewer V, et al. (2022): Integrated, cross-sectoral psycho-oncology (isPO): a new form of care for newly diagnosed cancer patients in Germany. In: BMC Health Services Research 22 (1), S. 543. DOI: 10.1186/s12913-022-07782-0.
- Zelenak C, Nagel J, Bersch K, et al. (2023): Integrated care for older multimorbid heart failure patients: protocol for the ESCAPE randomized trial and cohort study. In: ESC heart failure. DOI: 10.1002/ehf2.14294.
- Derendorf L, Stock S, Simic D, et al. (2023): Developing quality indicators for cross-sectoral psycho-oncology in Germany: combining the RAND/UCLA appropriateness method with a Delphi technique. In: BMC Health Serv Res 23(1): 599. DOI: 10.1186/s12913-023-09604-3.
- Derendorf L, Kusch M, Stock S, et al. (2023): Assessing the implementation of a comprehensive quality management system for cross-sectoral psycho-oncology in Germany. In: Journal of Healthcare Quality Research 39(1):32-40. DOI: 10.1016/j.jhqr.2023.10.007.
- Derendorf L, Stock S, Kusch M, et al. (2024): Stakeholder Participation in Quality Management: Implementation and Results of Participatory Methods in Quality Development. In: Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen – under revision.
- Derendorf, L., Stock, S., Simic, D. et al. Health economic evaluation of blended collaborative care for older multimorbid heart failure patients: study protocol. Cost Eff Resour Alloc 22, 29 (2024). https://doi.org/10.1186/s12962-024-00535-2

**Poster, Conference Papers and Presentations**

- Derendorf L, Lemmen C, Kusch M, Simic D, Stock S: Studienprotokoll: Entwicklung und Umsetzung eines sektorenübergreifenden Qualitätsmanagementsystems in der Psychoonkologie. Posterpräsentation. Hg. v. 4. Interdisziplinärer Kongress ‘Quality of Cancer Care’ (QoCC 2019). Berlin 2019. Online verfügbar unter https://www.qocc.de/files/content/poster/Q-07_L_Derendorf.pdf, zuletzt geprüft am 04.03.2020.
- Derendorf L, Lemmen C, Kusch M, Simic D, Stock, S: 4. Interdisziplinärer Kongress ‘Quality of Cancer Care’ (QoCC 2019). Abstracts zur Posterpräsentation. Studienprotokoll: Entwicklung und Umsetzung eines sektoren-übergreifenden Qualitätsmanagementsystems in der Psychoonkologie. In: Forum 34 (1) 2019, S. 99–100. DOI: 10.1007/s12312-018-0552-7.
- Lemmen C, Derendorf L, Simic D, Stock S: Entwicklung von Qualitätsstandards für eine integrierte, sektorenübergreifende Psychoonkologie. Vortragsreihe: Psychoonkologie auf dem Weg in die Regelversorgung/Regelfinanzierung. 34. Deutscher Krebskongress 2020. Berlin 2020.
- Derendorf L, Lemmen C, Simic D, Stock S: Entwicklung von Qualitätsindikatoren für die integrierte, sektorenübergreifende Psychoonkologie (isPO): Zwischenergebnisse eines modifizierten Delphi-Verfahrens. German Medical Science GMS Publishing House 2020.
- Lemmen C, Derendorf L, Simic D, Hagemeier A, Labouvie H, Haas P, Kusch M, Stock S: Maßnahmen zur Sicherstellung der Versorgungsqualität in der neuen Versorgungsform isPO/Integrierte, sektorenübergreifende Psychoonkologie. German Medical Science GMS Publishing House 2021.

# Affidavit

Eidesstattliche Erklärung

Hiermit versichere ich an Eides statt, dass ich die vorliegende Dissertationsschrift selbstständig und ohne die Benutzung anderer als der angegebenen Hilfsmittel angefertigt habe. Alle Stellen – einschließlich Tabellen, Karten und Abbildungen –, die wörtlich oder sinngemäß aus veröffentlichten und nicht veröffentlichten anderen Werken im Wortlaut oder dem Sinn nach entnommen sind, sind in jedem Einzelfall als Entlehnung kenntlich gemacht. Ich versichere an Eides statt, dass diese Dissertationsschrift noch keiner anderen Fakultät oder Universität zur Prüfung vorgelegen hat; dass sie – abgesehen von unten angegebenen Teilpublikationen – noch nicht veröffentlicht worden ist sowie, dass ich eine solche Veröffentlichung vor Abschluss der Promotion nicht ohne Genehmigung der / des Vorsitzenden des IPHS-Promotionsausschusses vornehmen werde. Die Bestimmungen dieser Ordnung sind mir bekannt. Die von mir vorgelegte Dissertation ist von Prof. Dr. med. Stephanie Stock betreut worden.

Darüber hinaus erkläre ich hiermit, dass ich die Ordnung zur Sicherung guter wissenschaftlicher Praxis und zum Umgang mit wissenschaftlichem Fehlverhalten der Universität zu Köln gelesen und sie bei der Durchführung der Dissertation beachtet habe und verpflichte mich hiermit, die dort genannten Vorgaben bei allen wissenschaftlichen Tätigkeiten zu beachten und umzusetzen.

Übersicht der Publikationen:

[1] Derendorf L, Stock S, Simic D, et al.: Developing quality indicators for cross-sectoral psycho-oncology in Germany: combining the RAND/UCLA appropriateness method with a Delphi technique. In: BMC Health Services Research 2023;23(1):599. https://doi.org/10.1186/s12913-023-09604-3.

[2] Derendorf L, Stock S, Kusch M, et al.: Stakeholder Participation in Quality Management: Implementation and Results of Participatory Methods in Quality Development. In: Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen – under revision.

[3] Derendorf L, Kusch M, Stock S, et al.: Assessing the implementation of a comprehensive quality management system for cross-sectoral psycho-oncology in Germany. In: Journal of Healthcare Quality Research 2023:39(1):32-40. https://doi.org/10.1016/j.jhqr.2023.10.007.

Ich versichere, dass ich alle Angaben wahrheitsgemäß nach bestem Wissen und Gewissen gemacht habe und verpflichte mich, jedmögliche, die obigen Angaben betreffenden Veränderungen, dem IPHS-Promotionsausschuss unverzüglich mitzuteilen.

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| Datum | Unterschrift |