Measures to Evaluate Quality of Care in Renal Cancer: Results of a Delphi study

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ABSTRACT

Purpose: To review current measures for renal cancer care and develop a comprehensive and updated list of measures for their practical use.

Methods: The study was developed by Fundación ECO, a Spanish foundation aiming to improve oncology quality of care. A systematic literature review was carried out to identify measures and knowledge gaps. A scientific committee composed of 9 experts reviewed the literature findings and added measures. A preliminary list of 42 measures was evaluated with the Delphi method to gather feedback from 47 medical oncology experts in Spain. Experts scored the appropriateness of the measures and ranked their priority in 2 consecutive online surveys. The scientific committee reviewed the Delphi results and developed the measures. A technical group from Universidad Francisco de Vitoria conducted and oversaw the Delphi method.

Results: The Delphi method led to consensus on all 42 measures. The scientific committee used a prioritisation matrix to select 25 of these measures for evaluating quality of care in renal cancer. These measures regarded structure, process, and outcome and covered general management, diagnosis, treatment, follow-up, and evaluation of health outcomes. Easy-to-use index cards were developed for all 25 measures, including their definition, formula, acceptable level of attainment, and rationale.

Conclusions: This manuscript aims to provide healthcare professionals with expert- and evidence-based measures that are useful for evaluating quality of care in renal cancer and cover all aspects and stages.

Keywords: renal cancer, indicators, measures, quality of care, Spain, Delphi

INTRODUCTION

Kidney cancer represents 2.2% of all malignancies and its incidence has continued to increase over time [1]. Currently, approximately 430,000 people worldwide are diagnosed with kidney cancer every year, with Europe and North America having the highest incidence [2]. Most kidney cancer patients have localised disease at diagnosis, which is associated with high 5-year survival of 92.6%. However, patients diagnosed with advanced disease have a poor prognosis, with a 5-year survival rate of 12% when distant metastasis is present [3].

Cancer outcomes are affected by various aspects of quality of care, such as early diagnosis, access to early treatment, treatment volume, and coordination between specialists [4]. Evaluation of quality of care through programs such as QOPI®, developed by the American Society of Clinical Oncology (ASCO), has led to the majority of participants developing quality improvement activities; however, results from these initiatives are often not published [5].

Regarding renal cancer in particular, development of a quality score for renal cancer surgery in a large-scale study of North American hospitals showed that up to a third of hospitals provided poor care for a given indicator. Notably, high quality scores were associated with improved patient outcomes, including lower mortality rates [6]. In another study, re-evaluation of renal cancer care made it possible to identify areas of improvement that directly impact patients, such as use of repeated imaging, biopsy, and surveillance to avoid surgery for masses that are non-malignant [7], or classifying certain procedures differently to accommodate for possible complications and additional days of hospitalisation [8].

There is paucity of data on the impact of evaluating quality of care in renal cancer in aspects other than surgery. On this note, studies or guidelines describing quality-of-care measures for renal cancer are scarce, with none used in Spain. Measures for this disease published elsewhere were either limited in their scope [9,10] or lacked details that would enable their use in clinical practice [11]. Additionally, QOPI® does not include specific measures for renal cancer [12]. To fill this knowledge gap, Fundación ECO (Excellence and Quality in Oncology)—a Spanish foundation of senior oncologists from the main Spanish hospitals involved in cancer treatment—developed this initiative. Here, we present the first expert- and evidence-based

comprehensive measures for evaluation of renal cancer quality of care, including instructions for their use.

METHODS

Study design

This study was developed and conducted by 3 groups of participants: a scientific committee, a technical group from Universidad Francisco de Vitoria (experts on Delphi method and quality of healthcare), and a panel of clinical experts on renal cancer, who responded to the Delphi surveys.

This study was divided into 4 stages. First, the scientific committee identified potential measures with a systematic literature review focused on quality of care in renal cancer. Second, the appropriateness of the measures was evaluated in a 2-step modified Delphi method by medical oncologists specialised in renal cancer. Third, the scientific committee prioritised and selected the final set of measures using a prioritisation matrix. Fourth, measures and standards were developed by the scientific committee, assisted by the technical group in a final meeting.

Scientific committee

The committee comprised 9 oncologists who are experts in renal cancer, who participated in every stage of this study. After committee recruitment was completed, the topic, methodology, and goals of the consensus process were discussed to the panel by teleconference.

Systematic literature review

A systematic literature review was carried out to identify measures regarding renal cancer care in clinical guidelines, research articles, consensus documents, consensus statements, and health technology assessment reports. Searches were carried out in May 2019 with no publication date restrictions and limited to articles published in English or Spanish. Search terms focused on renal cancer, guidelines, quality or performance measures, and outcome assessment (MeSH: [Kidney Neoplasm]; [Carcinoma, Renal Cell]; [Quality Indicators, Health Care]; [Outcome Assessment, Health Care]; [Patient Outcome Assessment]; [Standard of Care]; [Clinical Audit];

[Health Care Quality, Access, and Evaluation]; [Practice Guidelines]). Searches were conducted using PubMed, Cochrane Library, Trip databases, and several institutional websites (e.g. international scientific associations, national health services).

Delphi consensus method

Measures were extracted from the selected literature and evaluated by the scientific committee, who discussed their inclusion or exclusion in the Delphi process in an in-person meeting. An expert panel of 47 members—medical oncologists practicing in hospitals in Spain, specialised in renal cancer—participated in a 2-step modified Delphi method via online surveys. All experts participated in both surveys. Experts scored the measures based on their clinical appropriateness on a scale of 1 (extremely inappropriate) to 9 (extremely appropriate) and were also able to provide comments. After the first survey, respondents received a report with the results and comments provided by all members to allow them to revisit their responses, if appropriate. The scientific committee also received this information to evaluate possible modification of statements prior to the second survey. The Delphi method took place between December 2019 and February 2020.

Prioritisation matrix

The scientific committee reviewed the score obtained for each criterion with the Delphi method and determined whether it was appropriate, applicable (e.g. time, personnel), and worthwhile. To this end, a 5-point prioritisation matrix was used: 1 = extremely inappropriate (discard criterion); 2 = inappropriate overall (avoid criterion unless it is deemed important and there are no alternative options); 3 = undetermined (acceptable among other options); 4 = appropriate overall (recommended criterion); 5 = extremely appropriate (essential criterion). Measures were ranked based on the average score for each item, and the scientific committee selected those with the highest scores.

Development of measures and standards

The technical group developed index cards for each measure, following the model used by the Spanish Society of Quality in Healthcare (SECA) [13]. The scientific committee reviewed

the individual index cards, validated the measures, and decided the standard level for each of them.

Statistical analysis

Delphi consensus was defined as at least two-thirds of Delphi respondents selecting a score sub-category that encompassed the median score of the group. Following RAND/UCLA guidelines, these score sub-categories were: 1–3 (inappropriate), 4–6 (undetermined), or 7–9 (appropriate) [14]. Discordance was considered when more than one-third of the panel scored within one sub-category, and more than one-third scored another. Measures that achieved consensus were ranked according to the average score they were given by the scientific committee on the prioritisation matrix (scores 1–5). The 95% confidence intervals (95% CI) were calculated and measures were deemed appropriate if the lower 95% CI limit was ≥3.5 [15].

RESULTS

Literature review and selection of measures

The literature review yielded 635 documents which were reduced to 16 after assessing their relevance and removing duplicates. Out of the initial 59 measures identified from the literature and presented to the scientific committee, 42 were finally selected for further evaluation with the Delphi method and classified as related to structure (4), process (33), or outcome (5).

Delphi study and development of measures

The 2 rounds of Delphi method included the participation of 47 experts. Measures from the first survey that did not achieve consensus were recirculated in the second survey. With the Delphi method, the expert panel achieved consensus on the appropriateness of the 42 measures, from which the scientific committee selected 25 using a prioritisation scale (Figure 1).

The selected measures covered general management, diagnosis, treatment, follow-up, and evaluation of health outcomes (Table 1), and were classified as being related to structure (1),

process (20), or outcome (4). Index cards were developed for all 25 indicator and include their definition, formula, acceptable level of attainment, and rationale (Supplementary Material).

DISCUSSION

This study presents the first measures for renal cancer care in Spain, concerning all stages of the disease and spanning the complete process the patient undergoes from diagnosis to evaluation of health outcomes. Quality of care plays a key role in cancer outcomes [4]. Quality of care evaluation not only provides healthcare institutions with valuable data about their current functioning, but also helps assess the value and impact of initiatives. This is particularly important, as improvement of quality of care has been associated with improved patient outcomes [6].

Although several studies have evaluated the quality of care in renal cancer surgery [6–8], there are no published data on quality of care evaluation or improvement initiatives regarding other dimensions of renal cancer. This may be partially due to the overall low availability of quality-of-care measures for this disease. The few previous studies that developed a list of measures for renal cancer regarded only localised disease [9] or were very limited in their scope [10]. Wood et al. [11] proposed a list of measures in 2013 for quality of care in renal cancer, which covered several of the aspects included here. However, those measures provided little direction on how to implement them and concerned renal cell carcinoma only, whereas the measures we propose are applicable to all renal cancer patients. In Spain, a list of expert- and evidence-based measures for urology care was published in 2012 [16]; however, only 4 measures were specific to renal cancer and were mainly focused on surgery. This further highlights the need for the measures developed in our study, which consider all aspects of renal cancer care, from diagnosis to follow-up and evaluation of health outcomes, and regard localised and advanced disease. Additionally, we have arranged the information for each indicator in easy-to-use individual index cards that specify the formula for calculating their level of attainment, how often they should be evaluated, and important considerations (e.g. patients to exclude).

The National Comprehensive Cancer Network recently reviewed and endorsed a set of measures for quality measurement in cancer which were going to include renal cancer, among

others, but eventually focused only on the 4 most common cancers [17]. QOPI® by ASCO includes tracks for several specific tumour types, such as breast, lung, and colorectal; however, it currently does not include a track for renal cancer [12]. The measures presented here may serve as a basis for the development of QOPI® renal cancer-specific measures. On this note, one of the members of the scientific committee who coordinated this study is a member of the Genitourinary Measures Panel for ASCO. Additionally, 3 of the 9 members of the scientific committee practice in QOPI®-certified hospitals in Spain.

Evidence-based and expert-validated measures may be a valuable way for hospitals to perform internal audits that provide feedback for quality evaluation and improvement. However, barriers to quality of care must be considered, such as provider workload, lack of clarity on accountability, and lack of coordination of care [18]. Healthcare policy differences in Spain at an autonomous region level may result in changes in hospital workload and present barriers to the implementation of measures. When implementing outcome measures, risk adjustment should be taken into account to ensure that the differences found are due to differences in quality of care and not to other causes (e.g., higher patient load and complications in one hospital may result in higher mortality than in others) [19].

Given that most hospitals in Spain belong to the public healthcare system [20], and that the measures presented here were developed by oncologists practicing in Spain, one limitation of this study is that these measures may not be fully applicable in countries where additional stakeholders, and specific features of the healthcare system may need to be considered. However, the systematic literature review found a current worldwide lack of renal cancer measures that consider all stages and aspects of the disease. This highlights the need for the measures developed here, which we believe could be useful in other countries. One strength of this study was the systematic literature review that was carried out, which confirmed the need for measures in renal cancer care and identified useful ones. Another strength was the use of Delphi method, which is a systematic approach to finding consensus while maintaining anonymity of responders. Additionally, the Delphi method included 47 medical oncology experts for selecting quality measures, surpassing the median of 17 experts in similar studies [21].

Moreover, a scientific committee of 9 experts in renal cancer and quality of care evaluation reviewed the Delphi results and developed the measures.

The cancer treatment landscape is constantly evolving, and the measures presented here may need to be updated in line with developments in renal cancer care to reflect current needs. There is a need for studies that evaluate the quality of care in all stages of renal cancer and assess the impact of improvement-focused strategies. To this end, future work will involve using the measures developed here in a number of hospitals in Spain to evaluate the impact on quality of care perceived by both healthcare personnel and patients over time; it will also make it possible to identify challenges and unmet needs. We aim for these measures to be used in all hospitals that care for patients with renal cancer to improve quality of care and to ensure a high level of quality of care is met.

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TABLES

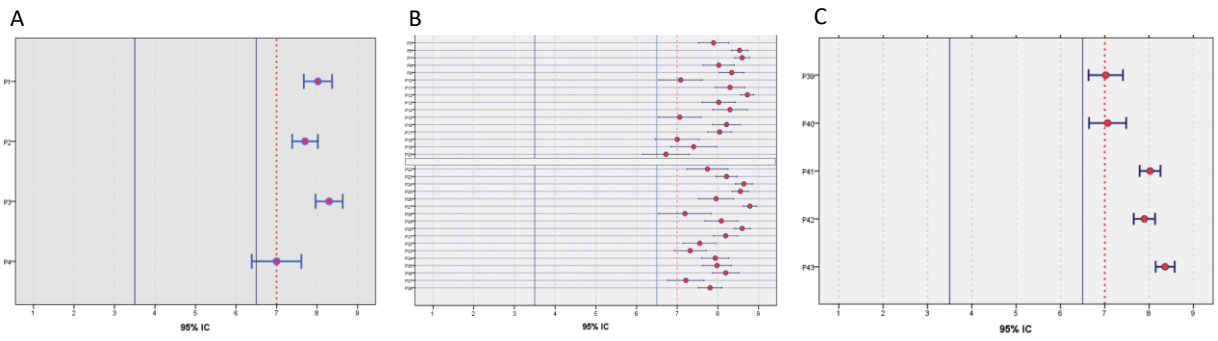
Table 1. List of measures for evaluating quality of care in renal cancer.

Topic	Type	Indicator
General management	Structure	Existence of a multidisciplinary Tumour Board
General management	Process	Time interval between diagnosis and treatment initiation
Diagnosis	Process	Availability of a complete clinical anamnesis of risk for renal cancer
Diagnosis	Process	Use of axial diagnostic tools (CT and MRI) for renal cancer diagnosis
Diagnosis	Process	Perform cranial imaging if neurologic involvement is suspected
Diagnosis	Process	Perform bone scintigraphy if bone metastasis is suspected

Diagnosis	Process	Complete staging using TNM system prior to initiating treatment
Diagnosis	Process	Core needle biopsy before initiating treatment in patients with localised renal cancer if surgery will not be conducted
Diagnosis	Process	Adequate histopathological classification
Diagnosis	Process	Availability of genetic counselling
Diagnosis	Process	Multidisciplinary assessment before initiating treatment
Diagnosis	Process	Adequate assessment of anaesthetic and surgical risk and possible patient comorbidities prior to initiating treatment
Treatment	Process	Partial nephrectomy of patients with renal cancer in T1a N0 M0 stage
Treatment	Process	Adrenalectomy in patients with suspected involvement
Treatment	Process	Prognostic assessment of patients with advanced/metastatic renal cancer
Treatment	Process	Adequate indication for nephrectomy
Treatment	Process	Correct anatomopathological study of patients who are going to receive systemic therapy
Treatment	Process	Propose participation in clinical trials
Treatment	Process	Palliative care for patients with end-stage renal cancer
Follow-up	Process	Follow-up of systemic therapy
Follow-up	Process	Temporary patient follow-up
Health outcomes	Outcome	Survival of patients with stage I renal cancer after surgery
Health outcomes	Outcome	Survival of patients with stage II renal cancer after surgery
Health outcomes	Outcome	Survival of patients with stage III renal cancer after surgery
Health outcomes	Outcome	Survival of patients with advanced/metastatic renal cancer

FIGURES

Figure 1. Delphi scores of measures.



Abbreviations: CT, computed tomography; IMDC, International Metastatic RCC Database Consortium; MRI, magnetic resonance imaging; OS, overall survival; PFS, progression-free survival; RECIST, Response evaluation criteria in solid tumours.

Measures to the right of the red line were considered highest priority. P1, Experience of institution in care of renal cancer patients; P2, Time interval from diagnosis until treatment is initiated; P3, A multidisciplinary team evaluates renal cancer patients; P4, Availability of genetic counselling; P5, Include in medical record full personal and family medical history; P6, Classify patients with diagnostic techniques that allow for transversal imaging; P7, Develop a selective study of if neurologic compromise is suspected; P8, Carry out bone scintigraphy if bone metastasis is suspected; P9, Stage patient with TNM system prior to treatment initiation, including type of lesion, size, location, presence of tumour thrombus, metastasis, and ruling out presence of intratumoural thrombus; P10, Patients diagnosed with renal cancer incidentally to exploration/testing not focused on ruling out renal cancer; P11, Carry out core needle biopsy before treatment if biopsy results can affect the therapeutic decision and the patient will not undergo surgery; P12, Appropriate histopathology classification following WHO-ISUP 2018 guidelines; P13, Availability of genetic counselling or possibility of referring patients with extrarenal manifestations, bilateral or multifocal cancer, diagnosed at an early age (<40 years) or with close relatives with renal cancer; P14, Patients evaluated by a multidisciplinary team prior to deciding treatment; P15, Actively monitor patients with histology diagnosis when nephrectomy is not initially indicated (tumour size <3 cm); P16, Adequately evaluate the health status and comorbidities of the patient prior to surgery; P17, Patients with renal cancer in stage T1a that undergo conservative surgery of nephrons or nephrectomy; P18, Carry out partial laparoscopic nephrectomy in patients with localised renal cancer (T2aN0Mx0, tumour size 7.1–10 cm); P19, Carry out partial nephrectomy in amenable patients with resectable tumours; P20, Actively monitor or carry out focalised therapy (radiofrequency or cryoablation) in patients with small renal masses (<4 cm) and who are older than 75 and/or with comorbidities; P22 (combination of P21 and P22), Biopsy the tumour that is going to undergo percutaneous thermal ablation before and during the intervention to ensure correct histopathology classification; P23, Patients with suspected involvement of adrenal glands where an initial adrenalectomy is indicated; P24, Conduct a prognostic evaluation of metastatic disease using validated scoring systems (e.g. IMDC); P25, Evaluate recurrence in patients with one metastasis who underwent local therapy (metastasectomy, cryoablation, stereotactic ablative radiotherapy, and radiofrequency); P26, Not indicate nephrectomy in patients who fulfil the IMDC bad prognostic criteria (except for local symptomatic disease); P27, Carry out anatomopathological study in patients with renal cancer who will receive systemic therapy if they do not undergo nephrectomy; P28, Patients with advanced/metastatic renal cancer should receive systemic therapy between diagnosis and death; P29, Consider all renal cancer patients for clinical trials if they meet the criteria and therapeutic needs; P30, Patients with end-stage renal cancer with appropriate care for their terminal disease; P31, Patients with metastatic renal cancer evaluated by a palliative care unit in the final stage of the disease; P32, Monitor stage I renal cancer patients with imaging tests 6 months after diagnosis, and then annually for 5 years, including anamnesis, physical exploration and lab tests; P33, Carry out CT or MRI 3–6 months after ablative therapy (unless contraindicated) and then annually until 5 years post-intervention, including anamnesis, physical exploration and lab tests; P34, Monitor stage II or III renal cancer patients with CT or MRI 3–6 months after diagnosis, then every 3–6 months for the first 3 years, then annually until 5 years, including anamnesis, physical exploration and lab tests; P35, Evaluate by CT the response/resistance to systemic therapy 2–3 months after it is initiated, following RECIST, with monthly anamnesis, physical exploration and lab tests during treatment; P36, Follow-up renal cancer patients at least during the first 5 years from diagnosis; P37, Follow-up renal function by evaluating glomerular filtration rate and proteinuria; P38, Refer patients to Nephrology or Internal Medicine if, after treatment, the patient presents chronic renal insufficiency or chronic kidney disease especially associated with proteinuria; P39, Patient mortality within 30 days post-surgery; P40, Patient mortality within 30 days post-systemic therapy; P41, Overall survival at 1, 3, and 5 years from diagnosis;

P42, OS, renal cancer-specific survival, and PFS after surgery for patients with stages I–III; P43, OS and PFS of patients with advanced/metastatic renal cancer.

DECLARATIONS

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Conflicts of interests

María José Méndez Vidal has received honoraria for honoraria for speaker and advisory role from Astellas, Astra Zeneca, Janssen, MSD, Bayer, Pfizer, Eisai, Ipsen, Sanofi, Roche, and BMS. Miguel Ángel Climent Durán has received honoraria for speaker engagements or advisory roles from BMS, Astellas, Janssen, MSD, Sanofi, Bayer, Roche, Pfizer, EUNSA, Pierre Fabre, Novartis and Ipsen; and travel funding from Janssen, Astellas, Roche, Ipsen, and MSD. Enrique Gallardo has received honoraria for speaker engagements, advisory roles or continuous medical education from Sanofi, Janssen, Astellas, Bayer, Ipsen, Pfizer, Roche, Novartis, Eisai, EUSA Pharma, BMS, AstraZeneca, Merck, Rovi, Daiichi Sankyo, Techdow, Rovi, Leo Pharma, Menarini, and Boehringer-Ingelheim; consulting fees from Merck and EUSA Pharma; and grant support from Astellas, Janssen, Sanofi, Bayer, Ipsen, Ferrer, Pfizer, Roche, GSK, BMS. Aránzazu González del Alba has received honoraria for speaker engagements, advisory roles or continuous medical education from Astellas, Sanofi, Astra Zeneca, Eusa Pharma, Janssen, Bayer, Pfizer, Novartis, Eisai, Ipsen, Roche, BMS, and Pierre Fabre; research funding from Astellas; and consulting fees from Astellas, Janssen. Martín Lázaro-Quintela reports honoraria for speaker engagements, advisory roles or continuous medical education from Roche, Eisai, Astellas, Janssen, Astra-Zeneca, MSD, Bayer, Pfizer, Eusa, Ipsen, Takeda, Sanofi, Roche, BMS, Merck, and Boehringer-Ingelheim; and research funding from Roche, Pfizer, and Janssen. Álvaro Pinto has received honoraria for advisory roles

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Ethical approval

This study did not involve humans and did not require approval from an Ethical Committee.

Informed consent

This study did not involve humans and informed consent was not necessary.

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DIMENSION: MULTIDISCIPLINARY CARE

Criterion 1: Multidisciplinary care for renal cancer patients STR-01

MEASURE: Existence of a multidisciplinary Tumour Board

DEFINITION: Every hospital who treats patients with renal cancer should have a specific committee that evaluates therapeutic decisions and includes all healthcare professionals involved in diagnosis and treatment.

FORMULA: Availability of a Multidisciplinary Tumour Board that integrates all healthcare professionals involved in diagnosis and treatment.

MEASURE of: Structure

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Renal cancer is a multidisciplinary disease that requires coordinated therapeutic interventions from different specialists. Prior to deciding treatment, the patient must be evaluated by a multidisciplinary team that reaches consensus on the therapeutic approach. Scientific evidence suggests better health outcomes are achieved and higher patient satisfaction when patients are managed by a multidisciplinary team.

Clarifications: Tumour Boards will be multidisciplinary teams that will ideally comprise: urologists, medical oncologists, radiation oncologists, nuclear medicine specialists, pathologists, radiologists, interventional radiologists and professionals in other areas, when appropriate (nephrology, physical therapy, nutrition, genetics).

SOURCE OF INFORMATION: Hospital / Clinical service

ACCEPTABLE LEVEL: To have a Tumour Board

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DIMENSION: RESPONSE CAPACITY

Criterion 2: Response capacity following therapeutic decision PRO-01

MEASURE: Time interval between diagnosis and treatment initiation

DEFINITION: Time interval (days) between diagnostic confirmation with therapeutic decision from the Tumour Board and effective treatment initiation.

FORMULA: (Number of patients with confirmed renal cancer diagnosis who initiated treatment in the last ≤14 days) x 100 / Total number of patients with confirmed renal cancer diagnosis and therapeutic decision

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: The time interval between assessment of a patient with renal cancer by the Tumour Board and treatment initiation indicates the agility of the process.

Exclusions: Death prior to initiating treatment, inclusion in a palliative care plan or patient decision to not receive treatment.

Clarifications:

- Confirmed renal cancer diagnosis is considered since therapeutic staging
- Therapeutic decision: after renal cancer diagnosis is confirmed, the treatment most appropriate for the patient is chosen (e.g. medical, surgical, radiotherapeutic)
- The recommended time interval between therapeutic decision and effective treatment initiation is 14 days.
- This indicator indirectly shows the oncology department's ability to manage the workload with the available resources.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥90% within 14 days

REFERENCES:

Hjelle KM, Johannesen TB, Beisland C. Postoperative 30-day Mortality Rates for Kidney Cancer Are Dependent on Hospital Surgical Volume: Results from a Norwegian Population-based Study. Eur Urol Focus. 2017 Apr;3(2-3):300-307. doi: 10.1016/j.euf.2016.10.001. Epub 2016 Oct 22.

Hjelle KM, Johannesen TB, Bostad L, Reisæter LA, Christian Beisland C. National Norwegian Practice Patterns for Surgical Treatment of Kidney Cancer Tumors 7 cm: Adherence to Changes in Guidelines May Improve Overall Survival. European Urology Oncology 1 (2018) 252 –261.

DIMENSION: EVALUATION OF RISK FOR RENAL CANCER

Criterion 3: Evaluation of risk for renal cancer PRO-02

MEASURE: Availability of a complete clinical anamnesis of risk for renal cancer

DEFINITION: Complete anamnesis must be carried out for early evaluation of risk for renal cancer, including complete personal history: smoking, overweight, dialysis, cystic disease, renal transplant, therapy received and cancer family history that includes date of diagnosis and death.

FORMULA: (Number of patients with complete anamnesis regarding the risk for renal cancer) x 100 / Total number of patients diagnosed with renal cancer

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Although there are no current guidelines on screening for renal cancer cells, annual follow-up is recommended for:

- Patients with hereditary factors associated to a higher incidence of renal cancer, such as polycystic kidney disease.
- Patients with severe terminal renal disease, especially those with severe comorbidities who have undergone dialysis at least for 3–5 years.
- Patients with a family history of renal cancer.
- Patients who have received radiotherapy.

Clarifications: The medical record must include the personal and family history and information from the physical examination. History concerns renal diseases, cancer, other risk factors*, hereditary factors, and cancer family history (including renal cancer).

Obtaining this information to track it over time is complicated and cannot be expected of all medical oncology departments, with the exception of hereditary cancer consultations.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥99%

REFERENCES:

Wood LA, Bjarnason GA, Black PC, Cagiannos I, Heng C, Kapoor A et al. Using the Delphi Technique to Improve Clinical Outcomes Through the Development of Quality Indicators in Renal Cell Carcinoma. DOI: 10.1200/JOP.2012.000870; 2013 published online ahead of print at jop.ascopubs.org.

DIMENSION: DIAGNOSIS AND STAGING OF THE DISEASE

Criterion 4: Adequate use of diagnostic imaging tools for renal cancer PRO-03

4.1 MEASURE: Use of axial diagnostic tools (CT and MRI) for renal cancer diagnosis

DEFINITION: Prior to initiating treatment, patients with renal cancer must be classified with diagnostic techniques that allow obtaining transversal images, such as CT and MRI.

FORMULA: (Number of patients diagnosed with renal cancer who have undergone transversal diagnostic imaging (MRI and/or CT) x 100 / Total number of patients diagnosed with renal cancer

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Anatomopathological assessment is needed to definitely diagnose renal cancer; however, transversal diagnostic imaging techniques are the preferred diagnostic tool.

Exclusions: Patients who cannot undergo these techniques due to their renal disease or allergy to contrast agents. Patients who are not valid candidates for initiating a specific treatment.

Clarifications: CT must be conducted with contrast to evaluate local and distant metastasis. MRI is an option for patients who are allergic to the radiocontrast agents used in CT and also for patients who require a more in-depth evaluation.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥95%

REFERENCES:

Scottish Cancer Taskforce National Cancer Quality Steering Group. Renal Cancer Clinical Quality Performance Indicators. Health Care Improvement Scotland 2017 v3.1.

Moideen N, Marzouk KH, Matheson KJ and Wood LA. Measuring quality care in localized renal cell cancer: use of appropriate preoperative investigations in a population-based cohort. Curr Oncol. 2017 Apr; 24(2):e152-e156.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Kidney Cancer V4.2019.

CT, computerised tomography; MRI, magnetic resonance imaging.

DIMENSION: DIAGNOSIS AND STAGING OF THE DISEASE

Criterion 4: Adequate use of diagnostic imaging tools for renal cancer PRO-04

4.2 MEASURE: Perform cranial imaging if neurologic involvement is suspected

DEFINITION: Cranial MRI or CT of patients with symptoms or signs of brain metastasis.

FORMULA: (Number of patients diagnosed with renal cancer and with suspected neurologic involvement who have undergone brain imaging) x 100 / Total number of patients diagnosed with renal cancer and with suspected neurologic involvement

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Most patients with brain metastasis present symptoms prior to diagnosis.

Exclusions: Patients who are not valid candidates for initiating a specific treatment.

Clarifications: Symptoms and signs to take into account will mainly consist of:

- Headache with or without nausea and vomiting
- Progressive focal deficit

- Changes in thinking abilities, comprehension or memory
- Weakness, dizziness or balance problems
- Changes in sensorial ability (sight, taste, smell, hearing, tact)
- Convulsions

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥99%

REFERENCES:

Scottish Cancer Taskforce National Cancer Quality Steering Group. Renal Cancer Clinical Quality Performance Indicators. Health Care Improvement Scotland 2017 v3.1.

Moideen N, Marzouk KH, Matheson KJ and Wood LA. Measuring quality care in localized renal cell cancer: use of appropriate preoperative investigations in a population-based cohort. Curr Oncol. 2017 Apr; 24(2):e152-e156.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Kidney Cancer V4.2019.

CT, computerised tomography; MRI, magnetic resonance imaging.

DIMENSION: DIAGNOSIS AND STAGING OF THE DISEASE

Criterion 4: Adequate use of diagnostic imaging tools for renal cancer PRO-05

4.3 MEASURE: Perform bone scintigraphy if bone metastasis is suspected

DEFINITION: Bone scintigraphy is recommended for patients who present symptoms or signs of bone metastasis.

FORMULA: (Number of patients diagnosed with renal cancer, with suspected bone metastasis and who have undergone bone scintigraphy) x 100 / Total number of patients diagnosed with renal cancer and with suspected bone metastasis

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Most patients with bone metastasis present symptoms prior to diagnosis.

Exclusions: Patients who are not valid candidates for initiating a specific treatment.

Clarifications:

- Symptoms and signs to take into account will mainly consist of:
  - Bone pain
  - Bone fracture (femur and humerus, most commonly)
  - Pain and swelling, when the bones involved are small (hands and feet)
  - Local and radiating pain, when the spine is affected
  - High levels of alkaline phosphatase in blood
  - High levels of calcium in blood and signs of its clinical consequences (nausea, vomiting, constipation confusion)
- Centres where bone scintigraphy is not available can substitute it for diffusion-weighted MRI to confirm bone metastasis.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥95%

REFERENCES:

Scottish Cancer Taskforce National Cancer Quality Steering Group. Renal Cancer Clinical Quality Performance Indicators. Health Care Improvement Scotland 2017 v3.1.

Moideen N, Marzouk KH, Matheson KJ and Wood LA. Measuring quality care in localized renal cell cancer: use of appropriate preoperative investigations in a population-based cohort. Curr Oncol. 2017 Apr; 24(2):e152-e156.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Kidney Cancer V4.2019.

Garbayo AJ, Villafranca E, De Blas A, Tejero A, Eslava E, Manterola A, Romero P, Martínez M. Metastastic bone disease. Diagnosis and treatment. An Sist Sanit Navar. 2004;27 Suppl 3:137-53

MRI, magnetic resonance imaging.

DIMENSION: DIAGNOSIS AND STAGING OF THE DISEASE

Criterion 4: Adequate use of diagnostic imaging tools for renal cancer PRO-06

4.4 MEASURE: Complete staging using TNM system prior to initiating treatment

DEFINITION: Complete staging using TNM system must be carried out prior to initiating treatment and must include type of lesion, size, localisation, presence of tumour thrombus, metastasis, and exclude intratumoural thrombus.

FORMULA: (Number of patients diagnosed with renal cancer and with adequate TNM classification by imaging tests prior to initiating treatment) x 100 / Total number of patients diagnosed with renal cancer

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: The TNM staging system helps determine prognosis, treatment, and follow-up for each patient.

Exclusions: Patients who are not valid candidates for initiating a specific treatment.

Clarifications: See American Join Committee on Cancer (AJCC) TNM Staging System for Kidney Cancer 8th edition.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥99%

REFERENCES:

Scottish Cancer Taskforce National Cancer Quality Steering Group. Renal Cancer Clinical Quality Performance Indicators. Health Care Improvement Scotland 2017 v3.1.

Moideen N, Marzouk KH, Matheson KJ and Wood LA. Measuring quality care in localized renal cell cancer: use of appropriate preoperative investigations in a population-based cohort. Curr Oncol. 2017 Apr; 24(2):e152-e156.

TNM, tumor, nodes, metastasis.

DIMENSION: DIAGNOSIS AND STAGING OF THE DISEASE

Criterion 5: Histopathological evaluation of renal cancer PRO-07

5.1 MEASURE: Core needle biopsy before initiating treatment in patients with localised renal cancer if surgery will not be conducted

DEFINITION: Histological diagnosis must be confirmed by core needle biopsy prior to initiating treatment of patients with localised renal cancer for whom radiofrequency ablation or cryotherapy are the first choice of treatment instead of surgery.

FORMULA: (Number of patients diagnosed with localised renal cancer for whom initial treatment is radiofrequency ablation or cryotherapy, and whose histological diagnosis is confirmed by core needle biopsy) x 100 / Total number of patients diagnosed with localised renal cancer for whom initial treatment is radiofrequency ablation or cryotherapy

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Minimally invasive techniques (radiofrequency ablation and cryotherapy) are indicated for patients with small renal masses with considerable comorbidities or limited life expectancy and in whom tumour ablation can be complete. Confirmation of histology by core needle biopsy allows for avoiding treating benign tumours.

Exclusions: Patients with lesions that are difficult to access and for whom biopsy will be clinically inappropriate (e.g. patients with cystic tumours). Also, patients who for various reasons must be treated urgently. Patients who are not valid candidates for initiating a specific treatment.

Clarifications: Core needle biopsy prior to initiating treatment may affect the therapeutic decision.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥90%

REFERENCES:

Gore JL. Quality Measures in Renal Cell Carcinoma. Sixteenth International Kidney Cancer Symposium November 2017. Available from: https://www.auanet.org/guidelines/renal-cancer-renal-mass-and-localized-renal-cancer-guideline.

Fineli A, Ismalia N, Bro B, Durack J, Eggener S, Evans A et al. Management of Small Renal Masses: Amer- ican Society of Clinical Oncology Clinical Practice Guideline. Journal of Clinical Oncology 2017, 35:6.

Scottish Cancer Taskforce National Cancer Quality Steering Group. Renal Cancer Clinical Quality Performance Indicators. Health Care Improvement Scotland 2017 v3.1.

DIMENSION: DIAGNOSIS AND STAGING OF THE DISEASE

Criterion 5: Histopathological evaluation of renal cancer PRO-08

5.2 MEASURE: Adequate histopathological classification

DEFINITION: Histopathological evaluation following WHO–ISUP criteria (2018) must be carried out prior to treatment initiation.

FORMULA: (Number of patients diagnosed with renal cancer who have a histopathological evaluation following WHO–ISUP criteria) x 100 / Total number of patients diagnosed with renal cancer

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Tumour are classified combining morphological, tumour, genetic, and immunohistochemical features, following quality standards defined by the International Society of Urological Pathology.

Anatomopathological parameters evaluated in biopsies and resected tumours are important for diagnosis, prognosis, management, and selection of adjuvant therapy, when needed.

Exclusion: Patients who are not valid candidates to initiate a specific treatment.

Clarifications: WHO–ISUP histological classification of renal cell tumours:

- Clear cell renal cell carcinoma
- Multilocular cystic renal cell carcinoma
- Chromophobe renal cell carcinoma
- Collecting duct (Bellini duct) carcinoma
- Renal medullary carcinoma
- MiT family translocation renal cell carcinoma
- Succinate dehydrogenase-deficient renal cell carcinoma
- Mucinous tubular and spindle cell renal cell carcinoma

- Tubulocystic renal cell carcinoma
- Acquired cystic disease-associated renal cell carcinoma
- Clear cell papillary renal cell carcinoma
- Hereditary leiomyomatosis and renal cell cancer
- Eosinophilic renal neoplasm
- Unclassified renal cell carcinoma
- Papillary adenoma
- Oncocytoma

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥97%

REFERENCES:

Escudier B, Porta M, Schmidinger M, Rioux-Leclercq N, Bex A, Khoo V et al. on behalf of the ESMO Guidelines Committee. Renal cell carcinoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology 0: 1–15, 2019. doi:10.1093/annonc/mdz056.

Ljungberg B, Bensalah K, Bex A, Canfield S, Dabestein S, Hofmann F et al. European Association of Urology (EAU) Renal Cell Cancer (RCC) Guidelines. Updated 2014. https://uroweb.org/guideline/renal-cell-carcinoma/

Moch H, Cubilla AL, Humphrey PA, Reuter VE, Ulbright TM. The 2016 WHO Classification of Tumours of the Urinary System and Male Genital Organs—Part A: Renal, Penile, and Testicular Tumours. European Urology. July 2016.Vol 70 (1), 93–105.

Warreb AY, Harrison D. WHO/ISUP classification, grading and pathological staging of renal cell carcinoma: standards and controversies. World Journal of Urology (2018) 36:1913–1926. https://doi. org/10.1007/s00345-018-2447-8.

ISUP, International Society of Urological Pathology; WHO, World Health Organization.

DIMENSION: DIAGNOSIS AND STAGING OF THE DISEASE

Criterion 6: Evaluation of family history and genetic counselling PRO-09

MEASURE: Availability of genetic counselling

DEFINITION: The availability or possibility to refer to genetic counselling or genetic testing patients with either:

- Renal cancer diagnosis at an early age (<46 years) and/or first-degree relatives or at least 2 second-degree relatives with renal cancer.
- Bilateral or multifocal renal cancer.
- Renal cancer with extrarenal involvement or
- Other metachronous tumours.

FORMULA: (Number of patients diagnosed with renal cancer who fulfil criteria for genetic testing and receive genetic counselling) x 100 / Total number of patients diagnosed with renal cancer who fulfil criteria for genetic testing

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Genetic testing is needed to plan adequate follow-up of relatives of patients diagnosed with renal cancer at an early age (<46 years) and/or first-degree relatives and at least 2 second-degree relatives with renal cancer, or bilateral or multifocal cancer with extrarenal involvement.

Exclusions: Patient decision to not undergo genetic counselling after giving informed consent or death prior to genetic testing.

Clarifications: Certification/accreditation of the reference laboratory must be provided. Clinical patient records must state the test results and that the patient has been informed.

SOURCE OF INFORMATION: Clinical documents from the hospital/clinical service

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥90%

REFERENCES:

Wood LA, Bjarnason GA, Black PC, Cagiannos I, Heng C, Kapoor A et al. Using the Delphi Technique to Improve Clinical Outcomes Through the Development of Quality Indicators in Renal Cell Carcinoma. DOI: 10.1200/JOP.2012.000870; 2013 published online ahead of print at jop.ascopubs.org.

DIMENSION: ACTIONS PRIOR TO INITIATING DEFINITIVE TREATMENT

Criterion 7: Multidisciplinary care for renal cancer patients PRO-10

MEASURE: Multidisciplinary assessment before initiating treatment

DEFINITION: Patients with renal cancer should be evaluated by a multidisciplinary team before initiating treatment.

FORMULA: (Number of patients diagnosed with renal cancer evaluated by a multidisciplinary team before initiating treatment) x 100 / Number of patients diagnosed with renal cancer

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Hospitals where renal cancer is treated must have specific multidisciplinary committees—including all healthcare professionals who participate in diagnosis and therapeutic decisions—for assessing patients prior to making therapeutic decisions.

Exclusions: Patients whose characteristics allow them to be treated following specific hospital-defined protocols where evaluation by a Tumour Board is not anticipated.

Clarifications: Tumour Boards will be multidisciplinary teams comprised of specialists in urology, anatomical pathology, radiology, medical oncology, radiation oncology, nuclear medicine, nephrology, and others, as appropriate (physical therapy, nutrition, genetics).

SOURCE OF INFORMATION: Hospital / Medical Oncology Department

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥95%

REFERENCES:

Wood LA, Bjarnason GA, Black PC, Cagiannos I, Heng C, Kapoor A et al. Using the Delphi Technique to Improve Clinical Outcomes Through the Development of Quality Indicators in Renal Cell Carcinoma. DOI: 10.1200/JOP.2012.000870; 2013 published online ahead of print at jop.ascopubs.org.

Scottish Cancer Taskforce National Cancer Quality Steering Group. Renal Cancer Clinical Quality Performance Indicators. Health Care Improvement Scotland 2017 v3.1.

Graham JR, Heng C, Brugarolas J and Vaishampayan U. Personalized Management of Advanced Kidney Cancer. 2018 ASCO Educational Book.

NHS Quality Improvement Scotland (2008). Management of Core Cancer Services Standards [online]. Available from: http://www.healthcareimprovementscotland.org/our_work/cancer_care_improvement/cancer_resources/standards_for_cancer_services.aspx

DIMENSION: ACTIONS PRIOR TO INITIATING DEFINITIVE TREATMENT

Criterion 8: Preoperative evaluation of the patient PRO-11

MEASURE: Adequate assessment of anaesthetic and surgical risk and possible patient comorbidities prior to initiating treatment

DEFINITION: Assessment of anaesthetic and surgical risk of the patient by evaluating their health status, including comorbidities.

FORMULA: (Number of patients diagnosed with renal cancer and assessed as having adequate anaesthetic and surgical risk prior to initiating surgical treatment) x 100 / Total number of patients diagnosed with renal cancer who undergo surgical treatment

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: A correct evaluation of health status and possible comorbidities of all patients is needed to determine the anaesthetic and surgical risk, life expectancy, and post-surgical renal function.

Clarifications: Active vigilance should be an initial option for patients with high anaesthetic and surgical risk, low life expectancy at 5 years, and considerable risk of terminal post-surgical renal disease.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: 100%

REFERENCES:

Wood LA, Bjarnason GA, Black PC, Cagiannos I, Heng C, Kapoor A et al. Using the Delphi Technique to Improve Clinical Outcomes Through the Development of Quality Indicators in Renal Cell Carcinoma. DOI: 10.1200/JOP.2012.000870; 2013 published online ahead of print at jop.ascopubs.org.

Fineli A, Ismalia N, Bro B, Durack J, Eggener S, Evans A et al. Management of Small Renal Masses: American Society of Clinical Oncology Clinical Practice Guideline. Journal of Clinical Oncology 2017, 35:6.

DIMENSION: PATIENTS WITH RENAL CANCER IN EARLY STAGES

Criterion 9: Adapting surgical treatment PRO-12

MEASURE: Partial nephrectomy of patients with renal cancer in T1a N0 M0 stage

DEFINITION: The treatment of choice for patients with T1a N0 M0 stage is partial nephrectomy.

FORMULA: (Number of patients diagnosed with renal cancer of T1a N0 M0 stage who have undergone partial nephrectomy) x 100 / Total number of patients diagnosed with renal cancer of T1a N0 M0 stage

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Compared to radical or total nephrectomy, partial nephrectomy preserves renal function, reduces mortality, reduces the incidence of cardiovascular events, and increases the quality of life of patients.

Clinical trials have shown that long-term survival following partial nephrectomy in patients with renal cancer of T1a N0 M0 stage is similar to that of patients who undergo radical or total nephrectomy.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥95%

REFERENCES:

Wood LA, Bjarnason GA, Black PC, Cagiannos I, Heng C, Kapoor A et al. Using the Delphi Technique to Improve Clinical Outcomes Through the Development of Quality Indicators in Renal Cell Carcinoma. DOI: 10.1200/JOP.2012.000870; 2013 published online ahead of print at jop.ascopubs.org.

Scottish Cancer Taskforce National Cancer Quality Steering Group. Renal Cancer Clinical Quality Performance Indicators. Health Care Improvement Scotland 2017 v3.1.

Fineli A, Ismalia N, Bro B, Durack J, Eggener S, Evans A et al. Management of Small Renal Masses: Ame- rican Society of Clinical Oncology Clinical Practice Guideline. Journal of Clinical Oncology 2017, 35:6.

Lawson KA, Saarela O, Liu Z, Lavallée LT, Breau RH, Wood L et al. Benchmarking quality for renal cancer surgery: Canadian Kidney Cancer information system (CKCis) perspective. Can Urol Assoc J 2017;11(8):232-7. http://dx.doi.org/10.5489/cuaj.4397.

DIMENSION: PATIENTS WITH RENAL CANCER IN EARLY STAGES

Criterion 10: Adapting surgical treatment PRO-13

MEASURE: Adrenalectomy in patients with suspected involvement

DEFINITION: Adapting surgical treatment for patients with early-stage renal cancer by conducting ipsilateral adrenalectomy if involvement of the adrenal gland is suspected.

FORMULA: (Number of patients with early-stage renal cancer with suspected involvement of the adrenal gland who undergo ipsilateral adrenalectomy) x 100 / Total number of patients with early-stage renal cancer with suspected involvement of the adrenal gland

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Scientific evidence shows ipsilateral nephrectomy in patients with early-stage renal cancer should not be routinely conducted. This procedure is conducted only in cases where involvement of the adrenal gland is suspected.

Exclusions: Patients who are not valid candidates for initiating a specific treatment.

Clarifications: Patients for whom adrenalectomy is indicated and feasible.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥90%

REFERENCES:

MacLennan S, Imamura M, Lapitan MC et al. Systematic review of oncological outcomes following surgical management of localised renal cancer. Eur Urol 2012; 61(5): 972–993.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Kidney Cancer V4.2019.

DIMENSION: TREATMENT OF PATIENTS WITH ADVANCED/METASTATIC RENAL CANCER

Criterion 11: Adequate prognostic assessment of patients with advanced/metastatic renal cancer PRO-14

MEASURE: Prognostic assessment of patients with advanced/metastatic renal cancer

DEFINITION: Adequate prognostic assessment of patients with advanced/metastatic renal cancer with the validated IMDC risk score prior to initiating treatment.

FORMULA: (Number of patients diagnosed with advanced/metastatic renal cancer who undergo prognostic assessment with the validated IMDC risk score prior to initiating treatment) x 100 / Total number of patients diagnosed with advanced/metastatic renal cancer who have initiated treatment

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Prognostic assessment of patients with advanced/metastatic renal cancer with the validated IMDC risk score is instrumental in deciding the most appropriate treatment for each patient—especially before using targeted therapy.

Exclusions: Patients who are not valid candidates for initiating a specific treatment.

Clarifications:

- IMDC prognostic criteria:
  - 1 year from time of diagnosis to systemic therapy initiation
  - Karnofsky Performance Status <80%
  - Haemoglobin < lower limit of normal (normal: 12 g/dL)
  - Corrected calcium > upper limit of normal (normal: 8.5–10.2 mg/dL)
  - Neutrophils > upper limit of normal (normal: 2.0–7.0×10^9cells/L)

- Platelets > upper limit of normal (normal: 150,000–400,000 cells/µL)

- IMDC classification:

- Favourable risk: no prognostic factors

- Intermediate risk: 1–2 prognostic factors

- Poor (high) risk: 3–6 prognostic factors

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥95%

REFERENCES:

Wood LA, Bjarnason GA, Black PC, Cagiannos I, Heng C, Kapoor A et al. Using the Delphi Technique to Improve Clinical Outcomes Through the Development of Quality Indicators in Renal Cell Carcinoma. DOI: 10.1200/JOP.2012.000870; 2013 published online ahead of print at jop.ascopubs.org.

Scottish Cancer Taskforce National Cancer Quality Steering Group. Renal Cancer Clinical Quality Performance Indicators. Health Care Improvement Scotland 2017 v3.1.

Graham JR, Heng C, Brugarolas J and Vaishampayan U. Personalized Management of Advanced Kidney Cancer. 2018 ASCO Educational Book.

Heng DY, Xie W, Regan MM, Warren MA, Golshayan AR, Sahi C et al. Prognostic factors for overall survival in patients with metastatic renal cell carcinoma treated with vascular endothelial growth factor-targeted agents: results from a large, multicenter study. J Clin Oncol. 2009 Dec 1;27(34):5794-9. doi: 10.1200/JCO.2008.21.4809. Epub 2009 Oct 13.

Pérez-Valderrama B, Arranz Arija JA, Rodríguez Sánchez A, Pinto Marín A, Borrega P. et al. Validation of the International Metastatic Renal-Cell Carcinoma Database Consortium (IMDC) prognostic model for first-line pazopanib in metastatic renal carcinoma: the Spanish Oncologic Genitourinary Group (SOGUG) SPAZO study. Annals of Oncology 27: 706–711, 2016 oi:10.1093/annonc/mdv601.

DIMENSION: TREATMENT OF PATIENTS WITH ADVANCED/METASTATIC RENAL CANCER

Criterion 12: Adapting the therapeutic recommendation PRO-15

MEASURE: Adequate indication for nephrectomy

DEFINITION: Adequate indication for nephrectomy (radical or partial) in patients with advanced/metastatic renal cancer, following the IMDC risk score.

FORMULA: (Number of patients diagnosed with advanced/metastatic renal cancer with a poor IMDC risk score who undergo nephrectomy) x 100 / Total number of patients diagnosed with advanced/metastatic renal cancer with a poor IMDC risk score

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Given that not all patients with advanced/metastatic renal cancer benefit from nephrectomy, when planning and adapting treatment for each patient, the prognostic evaluation with the IMDC risk score and the absolute and relative contraindications should be taken into account.

Exclusions: Patients with symptomatic localised renal cancer.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≤20%

REFERENCES:

Lázaro M, Valderrama PB, Suárez C, deVelasco G, Beato C, Chirivella I, González del Alba A, Laínez N, Méndez Vidal MJ, Arranz JA. SEOM clinical guideline for treatment of kidney cancer (2019). Clinical and Translational Oncology (2020) 22:256–269. doi.org/10.1007/s12094-019-02285-7.

Brian M, Shinder BM, Rhee K, Farrell D, Nicholas J, Farber N, Mark N, Stein MN, Jang TL and Singer EA. Surgical Management of Advanced and Metastatic Renal Cell Carcinoma: A Multidisciplinary Approach. Frontiers in Oncology 2017;7 (107). doi: 10.3389/fonc.2017.00107.

Moch H, Artibani W, Delahunt B, Ficarra V, Knuechel R, Montorsi F et al. Reassessing the current UICC/ AJCC TNM staging for renal cell carcinoma. Eur Urol. 2009 Oct;56(4):636-43. doi: 10.1016/j.euru- ro.2009.06.036. Epub 2009 Jul 7.

Heng DY, Xie W, Regan MM, Warren MA, Golshayan AR, Sahi C et al. Prognostic factors for overall survival in patients with metastatic renal cell carcinoma treated with vascular endothelial growth factor-targeted agents: results from a large, multicenter study. J Clin Oncol. 2009 Dec 1;27(34):5794-9. doi: 10.1200/JCO.2008.21.4809. Epub 2009 Oct 13.

Pérez-Valderrama B, Arranz Arija JA, Rodríguez Sánchez A, Pinto Marín A, Borrega P. et al. Validation of the International Metastatic Renal-Cell Carcinoma Database Consortium (IMDC) prognostic model for first-line pazopanib in metastatic renal carcinoma: the Spanish Oncologic Genitourinary Group (SOGUG) SPAZO study. Annals of Oncology 27: 706–711, 2016 oi:10.1093/annonc/mdv601.

IMDC, International Metastatic renal cell carcinoma Database Consortium.

DIMENSION: TREATMENT OF PATIENTS WITH ADVANCED AND/OR METASTATIC RENAL CANCER

Criterion 13: Adapting the previous evaluation to the therapeutic recommendation PRO-16

MEASURE: Correct anatomopathological study of patients who are going to receive systemic therapy

DEFINITION: Anatomopathological study should be carried out in renal cancer patients who are going to receive systemic therapy if they are not going to undergo nephrectomy.

FORMULA: (Number of patients diagnosed with renal cancer who are going to receive systemic therapy and who undergo a prior anatomopathological study) x 100 / Total number of patients diagnosed with renal cancer who are going to receive systemic therapy.

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Anatomopathological features found in a complete histological study are key for selecting the appropriate systemic therapy for each patient.

Clarifications: Tumour classification will combine morphological, tumour, genetic, and immunohistochemical features, following the quality standards defined by the International Society of Urological Pathology.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥99%

REFERENCES

Gore JL. Quality Measures in Renal Cell Carcinoma. Sixteenth International Kidney Cancer Symposium November 2017. Available from: https://www.auanet.org/guidelines/renal-cancer-renal-mass-and-localized-renal-cancer-guideline.

DIMENSION: INCLUSION OF PATIENTS IN CLINICAL TRIALS

Criterion 14: Adapting the therapeutic recommendation PRO-17

MEASURE: Propose participation in clinical trials

DEFINITION: Consider participation of all renal cancer patients in available clinical trials that fit their clinical characteristics and therapeutic needs.

FORMULA: (Number of patients diagnosed with renal cancer to whom participation in clinical trials is proposed) x 100 / Total number of patients diagnosed with renal cancer.

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: All patients with metastatic renal cancer should be considered for participation in available clinical trials that fit their clinical characteristics and therapeutic needs.

Clarifications: Participation in clinical trials must be made available to patients, regardless of the hospital at which the trial is being conducted. If the clinical trial is conducted in another hospital, it is important to mediate between centres/departments.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥30%

REFERENCES:

Scottish Cancer Taskforce National Cancer Quality Steering Group. Renal Cancer Clinical Quality Performance Indicators. Health Care Improvement Scotland 2017 v3.1.

Fineli A, Ismalia N, Bro B, Durack J, Eggener S, Evans A et al. Management of Small Renal Masses: American Society of Clinical Oncology Clinical Practice Guideline. Journal of Clinical Oncology 2017, 35:6.

DIMENSION: PALLIATIVE CARE

Criterion 15: Integral care of the patient PRO-18

MEASURE: Palliative care for patients with end-stage renal cancer

DEFINITION: Patients with end-stage renal cancer should have services that allow receiving integral healthcare, appropriate to their terminal condition.

FORMULA: (Number of patients diagnosed with end-stage renal cancer who receive palliative care) x 100 / Total number of patients diagnosed with end-stage renal cancer.

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Physical symptoms (e.g. pain, oedema in arms and legs, gastrointestinal alterations, pruritus) and psychological aspects of patients with end-stage renal cancer should be addressed by palliative care and mental health services.

Clarifications: Patients with terminal disease should receive specific care, adequate to their condition, with access to a palliative care unit coordinated by the medical oncology department.

End-stage disease is defined as a patient having, at most, 6 months of life due to the progression of the disease and a lack of curative treatment.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥95%

REFERENCES:

QOPI® 2019 MEASURE SUMMARY. American Society of Clinical Oncology. Available from: https://prac- tice.asco.org/sites/default/files/drupalfiles/QOPI-2019-Round-1-Reporting-Tracks-Public-Posting.pdf

Declaración sobre la atención médica al final de la vida (report). Organización Médica Colegial y Sociedad Española de Cuidados Paliativos. January 2002.

WHO Expert Committee. Cancer pain relief and palliative care: Report of a WHO expert committee. Technical report series 804. Geneva: World Health Organization, 1990.

DIMENSION: ADEQUATE FOLLOW-UP

Criterion 16: Adequate patient follow-up PRO-19

MEASURE: Follow-up of systemic therapy

DEFINITION: In addition to anamnesis, physical examination and monthly laboratory analysis during treatment, the response or resistance to therapy must be evaluated by MRI 2–3 months after treatment initiation, using Response Evaluation Criteria in Solid Tumors (RECIST).

FORMULA: (Number of patients diagnosed with renal cancer who receive systemic therapy and undergo an MRI 2–3 months after treatment initiation to evaluate response or resistance to therapy following RECIST) x 100 / Total number of patients diagnosed with renal cancer who receive systemic therapy

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Evaluation of response to systemic treatment with an MRI 2–3 months after its initiation is needed to determine whether to continue or modify the treatment.

Clarifications: Response Evaluation Criteria in Solid Tumors

- CR: complete response, disappearance of all lesions and adenopathy.
- PR: partial response, ≥30% decrease in the sum of the longest diameters from baseline.
- SD: stable disease, not meeting criteria for PD/PR.
- PD: progressive disease, ≥20% increase in the sum of the longest diameters or appearance of new lesions compared to the previous MRI.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥90%

REFERENCES:

Escudier B, Porta M, Schmidinger M, Rioux-Leclercq N, Bex A, Khoo V et al. on behalf of the ESMO Guidelines Committee. Renal cell carcinoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology 0: 1–15, 2019. doi:10.1093/annonc/mdz056.

DIMENSION: ADEQUATE FOLLOW-UP

Criterion 17: Adequate patient follow-up PRO-20

MEASURE: Temporary patient follow-up

DEFINITION: Renal cancer patients must be followed-up for at least the first 5 years after diagnosis.

FORMULA: (Number of patients diagnosed with renal cancer ≤5 years ago and being followed-up) x 100 / Total number of patients diagnosed with renal cancer ≤5 years ago

MEASURE of: Process

RATIONALE / EXCLUSIONS / CLARIFICATIONS

Rationale: Close follow-up of renal cancer patients based on stage is needed during the first 5 years after diagnosis to avoid a late diagnosis of recurrent disease.

Exclusions: Patients who survived less than 5 years.

Clarifications: Follow-up of stage I renal cancer patients must be carried out with diagnostic imaging at 6 months of survival and then annually until 5 years after diagnosis.

CT or MRI should be carried out 3–6 months after ablative technique (except if contraindicated) and then annually until 5 years after the intervention.

To follow-up patients with stage II/III disease, baseline CT or MRI should be carried out in the first 3–6 months, then every 3–6 months during the first 3 years, and then annually until 5 years after diagnosis.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥90%

REFERENCES:

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Kidney Cancer V4.2019.

Escudier B, Porta M, Schmidinger M, Rioux-Leclercq N, Bex A, Khoo V et al. on behalf of the ESMO Guidelines Committee. Renal cell carcinoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology 0: 1–15, 2019. doi:10.1093/annonc/mdz056

CT, computed tomography; MRI, magnetic resonance imaging.

HEALTH OUTCOMES

Criterion 18: Survival after surgery OUT-01

MEASURE: Survival of patients with stage I renal cancer after surgery

DEFINITION: Evaluate overall survival of patients with stage II disease (T2N0M0) after surgery.

FORMULA: (Number of patients diagnosed with stage II renal cancer who underwent surgery and survived 5 years after the intervention) x 100 / Total number of patients diagnosed with stage II renal cancer who underwent surgery 5 years ago.

MEASURE of: Outcome

RATIONALE / EXCLUSIONS / CLARIFICATIONS:

Rationale: Health outcomes resulted from decisions or modifications in care protocols must be taken into account to evaluate change in departmental procedures and treatment-related decisions or integration of new treatments for patients with renal cancer.

Exclusions: Patients lost to follow-up due to them receiving care at another healthcare facility.

Clarifications: The value in the denominator must be the total number of patients who underwent surgery 5 years prior to the calculation. For example, if in 2020 we want to calculate the number of patients with stage II renal cancer who survive 5 years after surgery, the denominator would be the total number of patients with stage II disease who underwent surgery in 2015.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥75%

REFERENCES:

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Kidney Cancer V4.2019.

Survival kidney cancer. Cancer Research UK. Available from: https://www.cancerresearchuk.org/about-cancer/kidney-cancer/survival (visited July 20, 2020)

Kidney and Renal Pelvis Cancer SEER Survival Rates by Time Since Diagnosis, 2000-2016. Available from: https://seer.cancer.gov/explorer/application.html?site=72&data_type=4&graph_type=6&compa-reBy=sex&chk_sex_1=1&chk_sex_3=3&chk_sex_2=2&race=1&age_range=1&stage=106&advopt_pre-cision=1&advopt_display=2 (visited July 20, 2020)

HEALTH OUTCOMES

Criterion 19: Survival after surgery OUT-02

MEASURE: Survival of patients with stage II renal cancer after surgery

DEFINITION: Evaluate overall survival of patients with stage I disease (T1N0M0) after surgery.

FORMULA: (Number of patients diagnosed with stage I renal cancer who underwent surgery and survived 5 years after the intervention) x 100 / Total number of patients diagnosed with stage I renal cancer who underwent surgery 5 years ago.

MEASURE of: Outcome

RATIONALE / EXCLUSIONS / CLARIFICATIONS:

Rationale: Health outcomes resulted from decisions or modifications in care protocols must be taken into account to evaluate change in departmental procedures and treatment-related decisions or integration of new treatments for patients with renal cancer.

Exclusions: Patients lost to follow-up due to them receiving care at another healthcare facility.

Clarifications: The value in the denominator must be the total number of patients who

underwent surgery 5 years prior to the calculation. For example, if in 2020 we want to calculate the number of patients with stage I renal cancer who survive 5 years after surgery, the denominator would be the total number of patients with stage I disease who underwent surgery in 2015.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥75%

REFERENCES:

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Kidney Cancer V4.2019.

Survival kidney cancer. Cancer Research UK. Available from: https://www.cancerresearchuk.org/about-cancer/kidney-cancer/survival (visited July 20, 2020)

HEALTH OUTCOMES

Criterion 20: Survival after surgery OUT-03

MEASURE: Survival of patients with stage III renal cancer after surgery

DEFINITION: Evaluate overall survival of patients with stage III disease (T1N1M0, T2N1M0 and T3NxM0) after surgery.

FORMULA: (Number of patients diagnosed with stage III renal cancer who underwent surgery and survived 5 years after the intervention) x 100 / Total number of patients diagnosed with stage III renal cancer who underwent surgery 5 years ago.

MEASURE of: Outcome

RATIONALE / EXCLUSIONS / CLARIFICATIONS:

Rationale: Health outcomes resulted from decisions or modifications in care protocols must be taken into account to evaluate change in departmental procedures and treatment-related decisions or integration of new treatments for patients with renal cancer.

Exclusions: Patients lost to follow-up due to them receiving care at another healthcare facility.

Clarifications: The value in the denominator must be the total number of patients who underwent surgery 5 years prior to the calculation. For example, if in 2020 we want to calculate the number of patients with stage III renal cancer who survive 5 years after surgery, the denominator would be the total number of patients with stage III disease who

underwent surgery in 2015.

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL: ≥75%

REFERENCES:

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Kidney Cancer V4.2019.

Survival kidney cancer. Cancer Research UK. Available from: https://www.cancerresearchuk.org/about-cancer/kidney-cancer/survival (visited July 20, 2020)

Kidney and Renal Pelvis Cancer SEER Survival Rates by Time Since Diagnosis, 2000-2016. Available from: https://seer.cancer.gov/explorer/application.html?site=72&data_type=4&graph_type=6&compa-reBy=sex&chk_sex_1=1&chk_sex_3=3&chk_sex_2=2&race=1&age_range=1&stage=106&advopt_pre-cision=1&advopt_display=2 (visited July 20, 2020)

HEALTH OUTCOMES

Criterion 21: Survival OUT-04

MEASURE: Survival of patients with advanced/metastatic renal cancer

DEFINITION: Overall survival from diagnosis of advanced/metastatic renal cancer.

FORMULA:

At 1 year: (Number of patients with advanced/metastatic renal cancer who survive one year after being diagnosed) x 100 / Total patients with advanced/metastatic renal cancer diagnosed one year ago.

At 3 years: (Number of patients with advanced/metastatic renal cancer who survive three years after being diagnosed) x 100 / Total patients with advanced/metastatic renal cancer diagnosed three years ago.

At 5 years: (Number of patients with advanced/metastatic renal cancer who survive five years after being diagnosed) x 100 / Total patients with advanced/metastatic renal cancer diagnosed five years ago.

MEASURE of: Outcome

RATIONALE / EXCLUSIONS / CLARIFICATIONS:

Rationale: Health outcomes resulted from decisions or modifications in care protocols must be taken into account to evaluate change in departmental procedures and treatment-related decisions or integration of new treatments for patients with renal cancer.

Exclusions: Patients lost to follow-up due to them receiving care at another healthcare facility.

Clarifications: The value in the denominator should be:

- 1-year survival: total number of patients diagnosed with renal cancer the previous year (current year minus 1)
- 3-year survival: total number of patients diagnosed with renal cancer 3 years prior to the current year (current year minus 3)
- 5-year survival: total number of patients diagnosed with renal cancer 5 years prior to the current year (current year minus 5)

SOURCE OF INFORMATION: Clinical documents

CALCULATION PERIOD: Annual

ACCEPTABLE LEVEL:

- Overall 1-year survival: ≥37%. IMDC Favourable Risk: 95%; Intermediate Risk: 74%; Poor Risk: 30%
- Overall 3-year survival: ≥17%. IMDC Favourable Risk: 74%; Intermediate Risk: 33%; Poor Risk: 15%
- Overall 5-year survival: ≥10%

REFERENCES:

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Kidney Cancer V4.2019.

Survival kidney cancer. Cancer Research UK. Available from: https://www.cancerresearchuk.org/about-cancer/kidney-cancer/survival (visited July 20, 2020)

Kidney and Renal Pelvis Cancer SEER Survival Rates by Time Since Diagnosis, 2000-2016. Available from: https://seer.cancer.gov/explorer/application.html?site=72&data_type=4&graph_type=6

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reBy=sex&chk_sex_1=1&chk_sex_3=3&chk_sex_2=2&race=1&age_range=1&stage=106
&advopt_pre-cision=1&advopt_display=2 (visited July 20, 2020)

Pérez-Valderrama B, Arranz Arija JA, Rodríguez Sánchez A, Pinto Marín A, Borrega P. et al. Validation of the International Metastatic Renal-Cell Carcinoma Database Consortium (IMDC) prognostic model for first-line pazopanib in metastatic renal carcinoma: the Spanish Oncologic Genitourinary Group (SOGUG) SPAZO study. Annals of Oncology 27: 706–711, 2016 oi:10.1093/annonc/mdv601.

IMDC, International Metastatic renal cell carcinoma Database Consortium.