RENAL BIOPSY FOR TUMOUR STRUCTURED REPORTING PROTOCOL

(1st Edition 2018)

Incorporating the

International Collaboration on Cancer Reporting (ICCR)

Dataset for the reporting of Renal Biopsy for Tumour www.ICCR-Cancer.org

Core Document versions:

- 1. ICCR Dataset for the Reporting of Renal Biopsy for Tumour 1st edition
- 2. AJCC Cancer Staging Manual 8th edition
- 3. World Health Organization (WHO). Classification of tumours. Pathology and genetics of the urinary system and male genital organs. $4^{\rm th}$ edition.

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Scope

This protocol contains standards and guidelines for the preparation of structured reports for core biopsy specimens for tumour of the kidney. Excision specimens are not included – a separate dataset is available and should be used for these cases.

Structured reporting aims to improve the completeness and usability of pathology reports for clinicians, and improve decision support for cancer treatment. The protocol provides the framework for the reporting of renal biopsies, whether as a minimum data set or fully comprehensive report.

Abbreviations

AJCC American Joint Committee on Cancer

ALK anaplastic lymphoma kinase ccRCC clear cell renal cell carcinoma CG Commentary for a guideline CS Commentary for a standard FISH Fluorescent in-situ hybridization

HLRCC hereditary leiomyomatosis and renal cell carcinoma associated

renal cell carcinoma

ICCR International Collaboration on Cancer Reporting ISUP International Society of Urological Pathology

LIS laboratory information system

LVI lymphovascular invasion

PBS Pharmaceutical Benefits Scheme

RCC Renal cell carcinoma

RCPA Royal College of Pathologists of Australasia

TNM tumour-node-metastasis

UICC International Union Against Cancer

WHO World Health Organization

Definitions

The table below provides definitions for general or technical terms used in this protocol. Readers should take particular note of the definitions for 'standard', 'quideline' and 'commentary', because these form the basis of the protocol.

Ancillary study

An ancillary study is any pathology investigation that may form part of a cancer pathology report but is not part of routine histological assessment.

Clinical information

Patient information required to inform pathological assessment, usually provided with the specimen request form, also referred to as "pre-test information".

Commentary

Commentary is text, diagrams or photographs that clarify the standards (see below) and guidelines (see below), provide examples and help with interpretation, where necessary (not every standard or guideline has commentary).

Commentary is used to:

- define the way an item should be reported, to foster reproducibility
- explain why an item is included (e.g. how does the item assist with clinical management or prognosis of the specific cancer).
- cite published evidence in support of the standard or guideline
- state any exceptions to a standard or guideline.

In this document, commentary is prefixed with 'CS' (for commentary on a standard) or 'CG' (for commentary on a guideline), numbered to be consistent with the relevant standard or guideline, and with sequential alphabetic lettering within each set of commentaries (eg CS1.01a, CG2.05b).

General commentary

General commentary is text that is not associated with a specific standard or guideline. It is used:

- to provide a brief introduction to a chapter, if necessary
- for items that are not standards or guidelines but are included in the protocol as items of potential importance, for which there is currently insufficient evidence to recommend their inclusion. (Note: in future reviews of protocols, such items may be reclassified as either standards or guidelines, in line with diagnostic and prognostic advances, following evidentiary review).

Guideline

Guidelines are recommendations; they are not mandatory, as indicated by the use of the word 'should'. Guidelines cover items that are unanimously agreed should be included in the dataset but are not supported by NHMRC level III-2 evidence. These elements may be clinically important and recommended as good practice but are not yet validated or regularly used in patient management.

Guidelines include key information other than that which is essential for clinical management, staging or prognosis of the cancer such as macroscopic observations and interpretation, which are fundamental to the histological diagnosis and conclusion eg macroscopic tumour details, block identification key, may be included as either required or recommended elements by consensus of the expert committee. Such findings are essential from a clinical governance perspective, because they provide a clear, evidentiary decision-making trail.

Guidelines are not used for research items.

In this document, guidelines are prefixed with 'G' and numbered consecutively within each chapter (eg G1.10).

Macroscopic findings

Measurements, or assessment of a biopsy specimen, made by the unaided eye.

Microscopic findings

In this document, the term 'microscopic findings' refers to histomorphological assessment.

Predictive factor

A predictive factor is a measurement that is associated with response or lack of response to a particular therapy.

Prognostic factor

A prognostic factor is a measurement that is associated with clinical outcome in the absence of therapy or with the application of a standard therapy. It can be thought of as a measure of the natural history of the disease.

Standard

Standards are mandatory, as indicated by the use of the term 'must'. Standards are essential for the clinical management, staging or prognosis of the cancer. These elements will either have evidentiary support at Level III-2 or above (based on prognostic factors in the NHMRC levels of evidence¹ document). In rare circumstances, where level III-2 evidence is not available an element may be made a Standard where there is unanimous agreement in the expert committee. An appropriate staging system eg Pathological TNM staging would normally be included as a required element. These elements must be recorded and at the discretion of the pathologist included in the pathology report according to the needs of the recipient of the report.

The summation of all standards represents the minimum dataset for the cancer.

In this document, standards are prefixed with 'S' and numbered consecutively within each chapter (eq S1.02).

Structured report

A report format which utilises standard headings, definitions and nomenclature with required information.

Synoptic report

A structured report in condensed form (as a synopsis or precis).

Synthesis

Synthesis is the process in which two or more pre-existing elements are combined, resulting in the formation of something new.

The Oxford dictionary defines synthesis as "the combination of components or elements to form a connected whole".

In the context of structured pathology reporting, synthesis represents the integration and interpretation of information from two or more modalities to derive new information.

Introduction

Renal Parenchymal Malignancy (Renal Cell Carcinoma)

Renal cell carcinoma was not described in antiquity, with the first confirmed case of RCC being reported in France in 1810.² The first classification of renal neoplasia was produced in 1824 and since then a variety of classifications have been proposed.³ Despite these early attempts to classify RCC, it is only in the last two decades that there has been any real appreciation as to the wide variety of morphotypes of RCC that exist.

In the first edition of the WHO classification, published in 1981, epithelial malignancies of the renal parenchyma were classified as Renal Cell Carcinoma and Other.4 The publication of the Mainz Classification in 1986 and the work of the Heidelberg (1996) and Rochester (1997) Consensus Groups provided the basis for classifying RCC into a variety of sub-types, each with differing clinical, histological and genetic features.^{5,6} These conclusions were reinforced by the third WHO classification working group who met in 2002, with the final classification being released in 2004.7 In this classification ten distinctive sub-types of renal parenchymal neoplasia were recognized, with a further category - that of Renal Cell Carcinoma - Unclassified being reserved for those tumours whose features differ from those of the recognized in the 2004 classification. It is from the group of tumours classified as Renal Cell Carcinoma - Unclassified that several novel variants of renal epithelial malignancy have been identified and since the publication of the 2004 WHO Classification, a further six tumour sub-types have been recognized.8 The classification of RCC was expanded in the ISUP Vancouver9 classification published in 2014, and in the 2016 4th edition of the WHO classification. 10

The failure to appreciate from the outset that RCC is a group of tumours rather than a single tumour entity, has had a major impact upon outcome prediction for these forms of malignancy. In particular, the failure to identify tumour sub-type in data sets has served to introduced an uncontrolled variable into statistical analyses and this has served to undermine the credibility of numerous prognostic studies.¹¹

More recently major studies have validated the sub-classification of RCC on the basis of tumour-related outcome data. ¹²⁻¹⁴ These studies have also attempted to identify prognostic parameters for each sub-type of RCC and specifically, there has been considerable emphasis on the evaluation of the predictive importance of tumour stage and grade. ¹⁵ This is of particular importance as RCCs as a group have a considerable morbidity and mortality accounting for 2% of cancer deaths worldwide. In the United States, the annual incidence of renal cell carcinoma has increased by 46.9% over the past 17 years rising from 27,200 cases in 1990 to an estimated 63,990 cases in 2017. ^{16,17} In Australia, in 2017 the estimated age adjusted incidence of RCC is 12 cases per 100,000 ¹⁸ while in New Zealand the incidence was 8.1 cases per 100,000 in 2013. ¹⁹

Importance of histopathological reporting

Information derived from the careful assessment and dissection of the gross specimen, the judicious selection of tissues for histological examination and the

provision of a pathology report that contains information of both clinical and prognostic utility is central to contemporary medical practice.

The information contained within pathology reports on specimens removed for the management of RCC provide guidance for further treatment options and permit assessment of outcome.

It is recognized that some morphotypes of RCC have a less aggressive clinical course than others and as a consequence consideration may be given to undertaking further surgical interventions if a patient subsequently develops metastatic disease. Further, for those patients who have disease that is found to be incurable following surgery, a variety of chemotherapeutic options are available, and current protocols relate to specific tumour sub-types. For both of these scenarios it is clear that subsequent management is informed by the pathology report that details the morphology of the primary tumour.

It is well recognized that the most important single prognostic parameter for RCC is tumour stage. Information regarding the completeness of surgical excision and involvement of anatomic boundaries by tumour is essential for staging purposes. Evaluation of other features contained with a standard report for RCC, such as tumour grade relating to specific morphotypes of RCC, the presence of sarcomatoid or rhabdoid differentiation, and the presence and degree of tumour necrosis provide information that is essential for determining prognosis in individual cases.

Benefits of structured reporting

The pathology report lays the foundation for a patient's cancer journey and conveys information which:

- Provides the definitive diagnosis
- Includes critical information for Tumour-Node-Metastasis (TNM) staging
- Evaluates the adequacy of the surgical excision
- Provides morphological and biological prognostic markers which determine personalised cancer therapy

However, the rapid growth in ancillary testing such as immunohistochemistry, flow cytometry, cytogenetics, and molecular studies, have made the task of keeping abreast of advances on specific cancer investigations extremely difficult for pathologists. The use of structured reporting checklists by pathologists ensures that all key elements are included in the report specifically those which have clinical management, staging or prognostic implications. Consequently minimum or comprehensive datasets for the reporting of cancer have been developed^{20,21} around the world. Both the United Kingdom,²² and United States²³ have produced standardised cancer reporting protocols or "datasets" for national use for many years.

The use of cancer reporting checklists improves completeness and quality of cancer reporting and thereby ensures an improved outcome for cancer patients. This has long term cost implications for public health by ensuring the most effective and timely treatment based on accurate and complete information.

The use of a structured reporting format also facilitates easy extraction of the necessary information by secondary users of the information ie cancer registries.

International Collaboration on Cancer Reporting

The International Collaboration on Cancer Reporting (ICCR), founded in 2011 by the Australasian (RCPA), US (CAP) and UK (RCPath) Colleges of Pathology and the Canadian Association of Pathology (CAP-ACP) in association with the Canadian Partnership Against Cancer (CPAC), was established to explore the possibilities of a collaborative approach to the development of common, internationally standardised and evidence-based cancer reporting protocols for surgical pathology specimens.

The ICCR, recognising that standardised cancer datasets have been shown to provide significant benefits for patients and efficiencies for organisations through the ease and completeness of data capture²⁴⁻²⁷ undertook to use the best international approaches and the knowledge and experience of expert pathologists, and produce cancer datasets which would ensure that cancer reports across the world will be of the same high quality – ensuring completeness, consistency, clarity, conciseness and above all, clinical utility.

Representatives from the four countries participating in the initial collaboration undertook a pilot project in 2011 to develop four cancer datasets - Lung, Melanoma, Prostate (Radical Prostatectomy), and Endometrium. Following on from the success of this pilot project, the ICCR was joined by the European Society of Pathology (ESP) in 2013 and in 2014 incorporated a not-for-profit organisation focussed on the development of internationally agreed evidence-based datasets developed by world leading experts. The ICCR Datasets are made freely available from its website www.ICCR-Cancer.org

Design of this protocol

This structured reporting protocol has been developed incorporating the ICCR dataset on renal biopsies for tumour as the foundation.

This protocol includes all of the ICCR cancer dataset elements as well as additional information, elements and commentary as agreed by the RCPA expert committee. It provides a comprehensive framework for the assessment and documentation of pathological features of renal biopsies for tumour.

ICCR dataset elements for renal biopsies for tumour are included verbatim. ICCR Required elements are mandatory and therefore represented as standards in this document. ICCR Recommended elements, that is, those which are not mandatory but are recommended, may be included as guidelines or upgraded to a standard based on the consensus opinion of the local expert committee.

The ICCR elements are identified in each chapter with the ICCR logo placed before the Standard or Guideline number or bullet and the ICCR element description and commentary is boarded by a grey box as shown below:

1C(1-CR) G3.02

The intraglandular extent should be recorded as a percentage.

Additional commentary by the RCPA expert committee may be added to an ICCR element but is not included in the grey bordered area nor indicated with an ICCR logo eg



If present, the laterality of the lymph nodes submitted may be recorded as left, right or bilateral.

If present, record site and number. All lymph node CS2.03a tissue should be submitted for histological examination.

Further information on the ICCR is available at www.iccr-cancer.org

Checklist

Consistency and speed of reporting is improved by the use of discrete data elements recorded from the checklist. Items suited to tick boxes are distinguished from more complex elements requiring free text or narrative. A structured or discrete approach to responses is favoured, however the pathologist is encouraged to include free text or narrative where necessary to document any other relevant issues, to give reasons for coming to a particular opinion and to explain any points of uncertainty.

Report format

The structure provided by the following chapters, headings and subheadings describes the elements of information and their groupings, but does not necessarily represent the format of either a pathology report (Chapter 7) or checklist (Chapter 6). These, and the structured pathology request form (Appendix 1) are templates that represent information from this protocol, organised and formatted differently to suit different purposes.

Key documentation

- Guidelines for Authors of Structured Cancer Pathology Reporting Protocols, Royal College of Pathologists of Australasia, 2009²⁸
- World Health Organization (WHO). Classification of tumours. Pathology and genetics of the urinary system and male genital organs. Humphrey PA, Moch H, Reuter VE, Ulbright TM editors. 4th edition. Lyon, France: IARC Press;2016.10
- AJCC Cancer Staging Manual, 8th edition, American Joint Committee on Cancer, 2016²⁹

Updates since last edition

Not applicable.

Authority and development

This section provides information about the process undertaken to develop this protocol.

This 1st edition of the protocol is an amalgam of two separate processes:

- 1. This protocol is based on the ICCR Dataset for the Reporting of Renal Biopsies for Tumour 1st edition. All ICCR elements from this dataset, both required (mandatory) and recommended (optional), are included in this protocol, verbatim. (It should be noted that RCPA feedback from all Anatomical Pathology fellows and specifically the local expert committee was sought during the development process of the ICCR dataset.) Details of the ICCR development process and the international expert authoring committee responsible for the ICCR dataset are available on the ICCR website: iccr-cancer.org.
- 2. Additional elements, values and commentary have been included as deemed necessary by the local expert committee. In addition, the standard inclusions of RCPA protocols eg example reports, request information etc, have also been added.

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Stakeholders

ACT Health

ACT Cancer Registry

Australian Cancer Network

Australian Commission on Safety and Quality in Health Care

Australian Digital Health Agency

Australian Institute of Health and Welfare

Cancer Australia

Cancer Council ACT

Cancer Council Queensland

Cancer Council Victoria

Cancer Council Western Australia

Cancer Institute NSW

Cancer Services Advisory Committee (CanSAC)

Cancer Voices NSW

Clinical Oncology Society of Australia (COSA)

Department of Health, Australia

Department of Health, New Zealand

Faculty of Radiation Oncology Genito-Urinary Group (FROGG)

Health Informatics Society of Australia (HISA)

Independent Review Group of Pathologists

Medical Software Industry Association (MSIA)

National Pathology Accreditation Advisory Council (NPAAC)

New Zealand Cancer Registry

Northern Territory Cancer Registry

Pathology Australia

Public Pathology Australia

Queensland Cooperative Oncology Group (QCOG)

RCPA Anatomical Pathology Advisory Committee (APAC)

Representatives from laboratories specialising in anatomical pathology across Australia

Royal Australasian College of Physicians (RACP)

South Australia Cancer Registry

Standards Australia

Tasmanian Cancer Registry

The Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)

The Medical Oncology Group of Australia

The Prostate Cancer Foundation of Australia (PCFA)

The Prostate Cancer Foundation of New Zealand (PCFNZ)

The Royal Australasian College of Surgeons (RACS)

The Royal Australian and New Zealand College of Radiologists (RANZCR)

The Royal Australian College of General Practitioners (RACGP)

The Royal College of Pathologists of Australasia (RCPA)

The Urological Society Of Australia And New Zealand (USANZ)

Western Australia Clinical Oncology Group (WACOG)

Development process

This protocol has been developed following the ten-step process set out in *Guidelines for Authors of Structured Cancer Pathology Reporting Protocols.*²⁸

Where no reference is provided, the authority is the consensus of the local expert group for local inclusions and the ICCR Dataset Authoring Committee for ICCR components denoted with the ICCR logo.

1 Pre-analytical

This chapter relates to information that should be recorded on receipt of the specimen in the laboratory.

The pathologist is reliant on the quality of information received from the clinicians or requestor. Some of this information may be received in generic pathology request forms, however, the additional information required by the pathologist specifically for the reporting of renal biopsies is outlined in Appendix 1 also includes a standardised request information sheet that may be useful in obtaining all relevant information from the requestor.

Surgical handling procedures affect the quality of the specimen and recommendations for appropriate surgical handling are included in Appendix 1.

S1.01 All demographic information provided on the request form and with the specimen must be recorded.

- CS1.01a The Royal College of Pathologists of Australasia (RCPA) The Pathology Request-Test-Report Cycle Guidelines for Requesters and Pathology Providers must be adhered to.³⁰ This document specifies the minimum information to be provided by the requesting clinician for any pathology test.
- CS1.01b Whether or not the patient identifies as Aboriginal and/ or Torres Strait Islander. This is in support of a government initiative to monitor the health of indigenous Australians particularly in relation to cancer.
- CS1.01c The patient's health identifiers may include the patient's Medical Record Number as well as a national health number such as a patient's Individual Healthcare Identifier (IHI) (Australia) or the National Healthcare Identifier (New Zealand).

S1.02 All clinical information as documented on the request form must be recorded verbatim.

- CS1.02a The request information may be recorded as a single text (narrative) field or it may be recorded in a structured format.
- CS1.02b The copy doctors requested on the request form must be recorded.

S1.03 The pathology accession number of the specimen must be recorded.

S1.04 The principal clinician involved in the patient's care and responsible for investigating the patient must be recorded.

CS1.04a The principal clinician should provide key information regarding the clinical presentation of the patient. Follow up may be required with the principle clinician for a number of

reasons:

- The clinical assessment and staging may be incomplete at the time of biopsy.
- The pathology request is often authored by the clinician performing the surgical excision/biopsy rather than the clinician who is investigating and managing the patient.
- The identity of this clinician is often not indicated on the pathology request form

In practice therefore, it is important in such cases that the reporting pathologist should be able to communicate with the managing clinician for clarification.

- CS1.04b The Australian Healthcare identifiers i.e. Healthcare Provider Identifier Individual (HPI-I) and Healthcare Provider Identifier Organisation (HPI-O) should be included, where possible, to identify the principal clinician involved in the patient's care.
- G1.01 Any clinical information received in other communications from the requestor or other clinician should be recorded together with the source of that information.

2 Specimen handling and macroscopic findings

This chapter relates to the procedures required after the information has been handed over from the requesting clinician, and the specimen has been received in the laboratory.

Specimen handling

Detailed fixation and specimen handling instructions are available from the RCPA online Cut-up Manual:

www.rcpa.edu.au/Library/Practising-Pathology/Macroscopic-Cut-Up

Macroscopic findings

S2.01 The labelling of the specimen(s) must be clearly recorded.

G2.01 The nature of the specimen at the time of reception should be given.

CG2.01a Choose from fresh or fixed (identify fixative).

S2.02	The laterality and type of sampling ie unifocal or multifocal, must be recorded.			
IC (+CR	CS2.02a	Specimen laterality information is needed for identification and patient safety purposes.		
		Core biopsy from two different tumours is uncommon. This may occur in presumed von Hippel Lindau syndrome patients. If, for example, more than 1 tumour is being monitored for growth rate, both may be sampled as part of the same procedure.		
G2.02	The operative procedure should be recorded as core/needle biopsy or other. The number of specimens submitted and the length/ maximum dimension of each specimen should be recorded.			
G2.03	The site(s) of tumour in the kidney should be described.			
C & CD	CG2.03a	The position of the tumour in relation to the renal cortex or medulla may also have diagnostic importance. This is especially important for small tumours where a site of origin within the medulla would support a diagnosis of collecting duct carcinoma or medullary carcinoma. ¹⁰		

G2.04 The colour of the specimen should be recorded.

S2.03 A block identification key listing the nature and origin of all tissue blocks must be recorded.

- G2.05 A descriptive or narrative field should be provided to record any macroscopic information that is not recorded in the above standards and guidelines, and that would normally form part of the macroscopic description.
 - CG2.05a The traditional macroscopic narrative recorded at the time of specimen dissection is often reported separately from the cancer dataset. Although this remains an option, it is recommended that macroscopic information be recorded within the overall structure of this protocol.
 - CG2.05b Much of the information recorded in a traditional macroscopic narrative is covered in the standards and guidelines above and in many cases, no further description is required.
 - CG2.05c A traditional macroscopic description may be required when the Laboratory Information System (LIS) does not allow a structured approach.
 - CG2.05d Where the LIS offers an electronic interface for structured data entry the need for narrative can be significantly reduced to describe only information not otherwise captured.

3 Microscopic findings

Microscopic findings relates to purely histological (morphological) assessment. Information derived from multiple investigational modalities, or from two or more chapters, is described in Chapter 5.

104cR S3.01	The histological tumour type must be recorded (Refer to Appendix 4).		
TC (L CR	CS3.01a	Many of the various sub-types of renal epithelial neoplasia exhibit differing clinical behaviour and prognosis. 8,10,29,31-35 This has been confirmed in large single and multicentre studies for the main tumour sub-types. Several series have also clearly demonstrated that many of the newly described entities of renal malignancy have a prognosis that differs from that of clear cell renal cell carcinoma. In addition to this protocols for the various types of adjuvant anti-angiogenic therapy relate to specific tumour sub-types. 36	
		The 2013 International Society of Urological Pathology (ISUP) Vancouver Classification of adult renal tumours identified an emerging/provisional category of renal cell carcinoma (RCC). While appearing distinctive, these rare tumours had not been fully characterized by morphology, immunohistochemistry and molecular studies. This category was also included in the fourth edition of the World Health Organization (WHO) classification of renal neoplasia. In the WHO classification oncocytoid RCC postneuroblastoma, thyroid-like follicular RCC, anaplastic lymphoma kinase (ALK) rearrangement-associated RCC, RCC with (angio) leiomyomatous stroma, eosinophilic solid and cystic clear cell renal cell carcinoma, and biphasic squamoid and alveolar renal cell carcinoma are included in this category. These entities should be classified under 'other' with the name specified.	
		Papillary RCC has traditionally been subdivided into Type 1 and Type 2. ³⁷ Recent studies have shown these tumours to be clinically and biologically distinct. Type 1 tumours are associated with alterations in the MET pathway while type 2 tumours are associated with activation of the NRF2-ARE pathway. On the basis of molecular features type 2 tumours may be sub-divided into at least 3 subtypes. ³⁸ Type 1 and type 2 tumours show differing immunohistochemical staining with type 1 tumours more frequently expressing cytokeratin 7 in comparison to type 2. ^{9,10,37,38}	
		Oncocytic papillary renal cell carcinoma is a category included in the fourth edition of the WHO renal tumour classification. While not fully characterized, this tumour is best included in the broader papillary category.	

Papillary RCC is associated with a more favourable outcome than clear cell renal cell carcinoma (ccRCC), collecting duct carcinoma and hereditary leiomyomatosis and renal cell carcinoma – associated renal cell carcinoma (HLRCC)^{10,35} Papillary subtyping is also of prognostic significance with type 1 tumours having a better prognosis then those with type 2 morphology.^{35,37,38}

On occasion it may be difficult to accurately classify tumours with deeply eosinophilic cytoplasm on renal biopsy. Here the differential diagnosis includes oncocytoma, chromophobe renal cell carcinoma, oncocytic papillary renal cell carcinoma and post-neuroblastoma renal cell carcinoma. Immunohistochemical assessment may be helpful but due to the limited tissue available in a needle biopsy this may be inconclusive. In such instances the term oncocytic neoplasm may be used with a note emphasising that this is not a diagnostic category but a descriptor that includes both benign and malignant entities. ^{39,40}

The benign entities of renal neoplasia commonly encountered in renal biopsies such as oncocytoma, angiomyolipoma, papillary adenoma, metanephric adenoma and other forms of adenoma should be classified under 'other' with the diagnosis specified.



S3.02

The histological WHO/ISUP tumour grade must be recorded.



CS3.02a

Grade should be assigned based on the single high power field showing the greatest degree of nucleolar size and/or nuclear pleomorphism.

This grading system is the World Health Organization/ International Society of Urological Pathology (WHO/ISUP) grading system for renal cell carcinoma which is recommended in the 2016 WHO. 10,35 This system has been validated as a prognostic parameter for clear cell and papillary renal cell carcinoma. 35,41,42 It has not been validated for other types of renal cell carcinoma but may be used for descriptive purposes. 43 The current recommendation is that chromophobe renal cell carcinoma is not graded. 10,44

There is debate regarding the validity of grading renal cell neoplasms in needle biopsies because of the likelihood that the tissue sampled may not be representative. This is of particular concern in large renal neoplasms where there can be considerable morphologic variability. In some series it is recommended that tumours in renal core biopsies not be graded. If a grade is given it should be qualified with a note stating that the provided grade may underestimate the true grade of the tumour. ^{39,40}



S3.03

Evidence of sarcomatoid morphology must be recorded.

TC (LCR)	S3.04	CS3.03a	The presence of sarcomatoid morphology is seen in approximately 5% of renal cell carcinomas and is associated with a poor prognosis. 35,45-48 Numerous studies have confirmed that sarcomatoid morphology may occur within any of the main subtypes of renal cell carcinoma and represents high grade disease. 9,10 The five year survival for patients with sarcomatoid morphology is of the order of 15 to 22%. 9,10,45-48 The outcome associated with sarcomatoid morphology is stage dependent. 49 The presence of sarcomatoid morphology is incorporated into the WHO/ISUP grading system (Grade 4). 35		
	33.04	LVIGETICE	or manuola morphology must be recorded.		
TC (L-CR		CS3.04a	Similar to the sarcomatoid morphology, rhabdoid morphology is a feature of high grade disease. 35,50 Tumours showing this phenotype resemble rhabdoid cells having bulky eosinophilic cytoplasm and an eccentric nucleus, often with a prominent nucleolus. 9,10 Rhabdoid change is associated with a poor prognosis. It has been shown that 71% of patients with rhabdoid morphology developed metastases with a mean follow-up of 4.5 months. Within 2 years it was also noted that 43% of patients in this series had died, with a median survival rate of 8-31months. 35,50-52 In approximately 25% of tumours with rhabdoid morphology, there is co-existing sarcomatoid carcinoma. The presence of rhabdoid morphology is incorporated into the WHO/ISUP grading system (Grade 4). 35		
IC (1 CR	S3.05	Evidence	lence of tumour necrosis must be recorded.		
IC4-CR		CS3.05a	The presence of tumour necrosis has been shown to be a prognostic indicator for clear cell renal cell carcinoma and chromophobe renal cell carcinoma independent of tumour stage. ^{35,53} Papillary renal cell carcinoma typically contains foci of necrosis, however the prognostic significance of this is, at best debated. At present, it is recommended that the presence of both macroscopic and microscopic (coagulative) necrosis be recorded. ³⁵		
IC (+CR	S3.06	The prese	presence or absence of lymphovascular invasion must be orded.		
IC (4CR		CS3.06a	Microvascular invasion has been shown to correlate with the development of metastases and with survival, independent of tumour size, primary tumour category, and grade. ⁵⁴		
			In both clear cell and papillary RCC, tumour spread is predominantly haematogenous via the sinus veins, renal vein and vena cava to the lung. Infiltration of the perirenal fat can result in retroperitoneal spread. Lymphatic spread to the nodes of the renal hilum may also occur and is more		

		common in papillary RCC than with ccRCC. ²⁹		
TC (LCR	S3.07	The nature of any co-existing renal pathology in non-neoplastic kidney must be reported.		
IC (CR		CS3.07a	It is important to recognize that medical kidney diseases may be present in nonneoplastic renal tissue in nephrectomy and nephroureterectomy specimens. 55,56 Arterionephrosclerosis (or hypertensive nephropathy) and diabetic nephropathy are most frequently seen, and in two separate series medical renal disease was seen in 17% to 60% of cases. The findings of greater than 20% global glomerulosclerosis or advanced diffuse diabetic glomerulosclerosis are predictive of significant decline in renal function 6 months after radical nephrectomy. 56 Evaluation for medical renal disease should be performed in each case; PAS and/or Jones methenamine silver stains should applied if necessary. Consultation with a nephropathologist should be pursued as needed. For the assessment of co-existing pathology in renal tissue adjacent to tumour the local effects of an expansile and/or infiltrative neoplasm should be considered. This may be associated with an appreciable degree of inflammation and scarring, and it is not uncommon to see localized secondary interstitial nephritis, glomerulosclerosis and tubular atrophy.	

G3.01 Any additional relevant comments should be recorded.

4 Ancillary studies findings

Ancillary studies may be used to determine lineage, clonality or disease classification or subclassification; as prognostic biomarkers; or to indicate the likelihood of patient response to specific biologic therapies.

Some studies, such as Her-2 testing, are required under the Pharmaceutical Benefits Scheme, to enable certain specific therapies to be prescribed.

G4.01	Whether or not ancillary tests are performed should be recorded and the results incorporated into the pathology report.		
TC (L-CR)	CG4.01a Ancillary studies are being increasingly utilized for subtyping of renal cell neoplasms. It is now recognized to Immunohistochemical assessment of tumours can be diagnostically helpful. 57		
TC (+CR	CG4.01b	Fluorescent in-situ hybridization (FISH) can be used to confirm a diagnosis of translocation carcinoma (MiT family tumour) and has been shown to be of utility in distinguishing oncocytoma from chromophobe renal cell carcinoma. ¹⁰ Cytogenetics may be undertaken in some instances; however, this is not usually performed as part of the routine assessment of a renal tumour.	
€¢c₽	CG4.01c	There are currently no ancillary tests that are accepted as having prognostic significance for renal cell neoplasms. 57,58,59,60	

5 Synthesis and overview

Information that is synthesised from multiple modalities and therefore cannot reside solely in any one of the preceding chapters is described here.

For example, tumour stage is synthesised from multiple classes of information – clinical, macroscopic and microscopic.

By definition, synthetic elements are inferential rather than observational, often representing high-level information that is likely to form part of the report 'Summary' or 'Diagnosis' section in the final formatted report.

Overarching case comment is synthesis in narrative format. Although it may not necessarily be required in any given report, the provision of the facility for overarching commentary in a cancer report is essential.

- G5.01 The "Diagnostic summary" section of the final formatted report should include:
 - a. Specimen laterality (S2.03)
 - b. Operative procedure (S2.02)
 - c. Tumour site(s) (G2.03)
 - d. Tumour type (S3.01)
 - e. Tumour grade (S3.02)
- S5.01 The reporting system must provide a field for free text or narrative in which the reporting pathologist can give overarching case comment, if required.
 - CS5.01a This field may be used, for example, to:
 - document any noteworthy adverse gross and/or histological features
 - explain the decision-making pathway, or any elements of clinicopathological ambiguity, or factors affecting diagnostic certainty, thereby allowing communication of diagnostic subtlety or nuance that is beyond synoptic capture
 - document further consultation or results still pending.
 - CS5.01b Use of this field is at the discretion of the reporting pathologist.
- G5.02 The edition/version number of the RCPA protocol on which the report is based should be included on the final report.
 - CS5.02a For example, the pathology report may include the following wording at the end of the report: "the data fields within this formatted report are aligned with the criteria as set out in the RCPA document " XXXXXXXXXXXX XXXX Edition dated XXXXXXXX.".

6 Structured checklist

The following checklist includes the standards and guidelines for this protocol which must be considered when reporting, in the simplest possible form. The summation of all "Standards" is equivalent to the "Minimum Data Set" for renal parenchymal malignancy. For emphasis, standards (mandatory elements) are formatted in bold font.

- S6.01 The structured checklist provided may be modified as required but with the following restrictions:
 - a. All standards and their respective naming conventions, definitions and value lists must be adhered to.
 - b. Guidelines are not mandatory but are recommendations and where used, must follow the naming conventions, definitions and value lists given in the protocol.
- G6.01 The order of information and design of the checklist may be varied according to the laboratory information system (LIS) capabilities and as described in *Functional Requirements for Structured Pathology Reporting of Cancer* Protocols.⁶¹
 - CG6.01a Where the LIS allows dissociation between data entry and report format, the structured checklist is usually best formatted to follow pathologist workflow. In this situation, the elements of synthesis or conclusions are necessarily at the end. The report format is then optimised independently by the LIS.
 - CG6.01b Where the LIS does not allow dissociation between data entry and report format, (for example where only a single text field is provided for the report), pathologists may elect to create a checklist in the format of the final report. In this situation, communication with the clinician takes precedence and the checklist design is according to principles given in Chapter 7.
- G6.02 Where the checklist is used as a report template (see G6.01), the principles in Chapter 7 and Appendix 2 apply.
 - CG6.02a All extraneous information, tick boxes and unused values should be deleted.
- G6.03 Additional comment may be added to an individual response where necessary to describe any uncertainty or nuance in the selection of a prescribed response in the checklist. Additional comment is not required where the prescribed response is adequate.

Item descriptions in italics are conditional on previous responses.

Values in all caps are headings with sub values.

S/G	Item description	Response type	Conditional
Pre-analytic	al		
S1.01	Demographic information provided		
S1.02	Information provided on	Not provided	
	request form	OR	
		Text	
		OR	
		Structured entry as below:	
	Relevant past medical history	Text	
	Predisposing factors (including genetic status)	Text	
	Pre-operative treatment	Text	
	Relevant family history	Text	
	Extent of disease	Text	

Previous biopsy/surgical specimens	Text
Clinical or differential diagnosis	Text
Laterality	Single selection value list:
	 Left Unifocal Multifocal Right Unifocal Multifocal Bilateral Unifocal in both kidneys Multifocal in one kidney Multifocal in both kidneys Other eg horseshoe kidney, specify
	UnifocalMultifocal
Nature of operation	Single selection value list:
	Core/needle biopsy
	Other, specify
Operative findings	Text
New primary lesion or	Single selection value list:
recurrence	New primary
	Recurrence – regional, describe
	Recurrence – distant, describe

S1.03	Pathology accession number	Alpha-numeric	
S1.04	Principal clinician	Text	
G1.01	Comments	Text	
Macroscopic	findings		
S2.01	Specimen labelled as	Text	
G2.01	Nature of specimen	Single selection value list:	
		 Fixed, specify fixative 	
		• Fresh	

IC (1-CR S2.02	Specimen laterality	Not specified	
		OR	
		Single selection value list:	
		 Left Unifocal Multifocal Right Unifocal Multifocal Bilateral Unifocal in both kidneys Multifocal in one kidney Multifocal in both kidneys Other eg horseshoe kidney, specify Unifocal Multifocal 	
1C (LCR) G2.02	Operative procedure	Not specified	For each specimen type complete the applicable
		OR	questions
		Single selection value list:	
		Core/needle biopsy	
		Other, <i>specify</i>	

IC (LCR	Number of cores	Numeric:	
		OR	
		Number cannot be determined	
IC (LCR	Length	Text: Core id (if >1 core submitted)	
		AND	
		Numeric:mm	
		<u>Notes</u>	
		For each core identified, record a length in mm.	
IC (+CR	OTHER	Text	
IC (LCR G2.03	Tumour site(s)	Single selection value list:	
		 Not provided 	
		 Cannot be assessed 	
		OR	
		Multi selection value list (select all that apply):	
		Upper pole	
		Mid zone	
		Lower pole	
		• Cortex	
		 Medulla 	
		• Other, <i>specify</i>	
G2.04	Colour	Single selection value list:	

		Yellow	
		• Brown	
		• White	
		• Green	
S2.03	Block identification key	Text	
G2.05	Additional macroscopic comments	Text	
Microscopic	findings		
10 4 CR S3.01	Histological tumour type	Non diagnostic, <i>Specify why</i> OR	
		Multi selection value list (select all that apply):	
		Clear cell renal cell carcinoma	
		 Multilocular clear cell renal cell neoplasm of low malignant potential 	
		Papillary renal cell carcinoma	
		o Type 1	
		o Type 2	
		o Oncocytic	
		o NOS	
		Chromophobe renal cell carcinoma	
		 Hybrid oncocytic chromophobe tumour 	

- Collecting duct carcinoma
- Renal medullary carcinoma
- MiT family translocation renal cell carcinoma
 - Xp11 translocation renal cell carcinoma
 - o t(6;11) renal cell carcinoma
 - o Other, specify
- Mucinous tubular and spindle cell carcinoma
- Tubulocystic renal cell carcinoma
- Acquired cystic disease associated renal cell carcinoma
- Clear cell papillary/tubulopapillary renal cell carcinoma
- Hereditary leiomyomatosis and renal cell carcinoma-associated renal cell carcinoma
- Succinate dehydrogenase (SDH) deficient renal carcinoma
- Renal cell carcinoma, unclassified
- Other, specify

Notes:

Occasionally more than one histologic type of carcinoma occurs within the same kidney specimen. Each tumour type should be separately recorded.

1c & cr S3.02	Histological tumour grade - WHO/ISUP	 Single selection value list: Not applicable Grade X - Cannot be assessed Grade 1 - Nucleoli absent or inconspicuous and basophilic at 400x magnification Grade 2 - Nucleoli conspicuous and eosinophilic at 400x magnification, visible but not prominent at 100x magnification Grade 3 - Nucleoli conspicuous and eosinophilic at 100x magnification Grade 4 - Extreme nuclear pleomorphism and/or multi nuclear giant cells and/or rhabdoid and/or sarcomatoid differentiation 	
1c4cR S3.03	Sarcomatoid morphology Rhabdoid morphology	Single selection value list: Not identified Present Single selection value list: Not identified	
1c4-cR S3.05	Necrosis	 Present Single selection value list: Not identified Present 	

IC(4-CR S3.06	Lymphovascular invasion	Single selection value list:	
		Not identified	
		Present	
1C(1-CR) S3.07	Co-existing pathology in non- neoplastic kidney	Single selection value list:	
		None identified	
		 Insufficient tissue for evaluation (<5 mm tissue adjacent to the tumour) 	
		OR	
		Multi selection value list (select all that apply):	
		 Glomerular disease, specify type 	
		Tubulointerstitial disease, specify type	
		 Vascular disease, specify type 	
		 Cyst(s), specify type 	
		 Tubular (papillary) adenoma(s) 	
		Other, specify	
G3.01	Additional microscopic comment	Text	
Ancillary find	dings		
ICA-CR G4.01	Ancillary studies	Single selection value list:	
		Not performed	
		Performed, specify tests and results	
Synthesis an	d overview		

G5.01	Diagnostic summary	Text	
	Include:		
	a. Specimen laterality (S2.03)		
	b. Operative procedure (S2.02)		
	c. Tumour site(s) (G2.03)		
	d. Tumour type (S3.01)		
	e. Tumour grade (S3.02)		
S5.01	Overarching comment	Text	
G5.02	Edition/version number of the RCPA protocol on which the report is based	Text	

7 Formatting of pathology reports

Good formatting of the pathology report is essential for optimising communication with the clinician, and will be an important contributor to the success of cancer reporting protocols. The report should be formatted to provide information clearly and unambiguously to the treating doctors, and should be organised with their use of the report in mind. In this sense, the report differs from the structured checklist, which is organised with the pathologists' workflow as a priority.

Uniformity in the format as well as in the data items of cancer reports between laboratories makes it easier for treating doctors to understand the reports; it is therefore seen as an important element of the systematic reporting of cancer. For guidance on formatting pathology reports, please refer to Appendix 2.

Appendix 1 Pathology request information and surgical handling procedures

This appendix describes the information that should be collected before the pathology test. Some of this information can be provided on generic pathology request forms; any additional information required specifically for the reporting of renal cancer may be provided by the clinician on a separate request information sheet. An example request information sheet is included below. Elements which are in bold text are those which pathologists consider to be required information. Those in non-bold text are recommended.

Also included in this appendix are the procedures that are recommended before handover of specimens to the laboratory.

Patient information

- Adequate demographic and request information should be provided with the specimen.
 - Items relevant to cancer reporting protocols include:
 - · patient name
 - date of birth
 - sex
 - identification and contact details of requesting doctor
 - date of request
 - Whether or not the patient identifies as Aboriginal and/ or Torres Strait Islander. This is in support of a government initiative to monitor the health of indigenous Australians particularly in relation to cancer.
- The patient's health identifiers should be provided.
 - The patient's health identifiers may include the patient's Medical Record Number as well as a national health number such as a patient's Individual Healthcare Identifier (IHI) (Australia) or the National Healthcare Identifier (New Zealand).
- The Australian Healthcare identifiers i.e. Healthcare Provider Identifier Individual (HPI-I) and Healthcare Provider Identifier Organisation (HPI-O) should be use, where possible, to identify the requesting doctor.

Clinical Information

- Any relevant past medical history should be provided.
- Any relevant predisposing factors, including genetic status where appropriate, should be provided.
- If the patient has received any pre-operative treatment this should be recorded.
 - Previous radiation therapy or chemotherapy may impact on the morphology of the tumour and this must be taken into account by the reporting pathologist.
- Any relevant family history should be provided.
 - Familial syndromes that predispose individuals to renal neoplasia are well recognized and several of these are associated with specific sub-types of RCC.
- > Details of the extent of disease as determined from both clinical assessment and imaging studies should be provided.
 - Relevant information as to the extent of disease obtained from examination of the patient and from imaging studies is necessary for the accurate staging of the tumour.
- > The details of any previous biopsy or surgical specimens removed from the patient should be provided.
 - The details of any tissue removed from the patient will provide information as to the extent of the tumour. Diagnostic information regarding the nature of the tumour as determined by biopsy, may inform handling of the specimen, especially if genetic studies are being considered. Comparison of the finding from previous biopsies/surgical specimens may alert the pathologist to a second, possibly occult, malignancy.
- > The laterality of the lesion must be recorded.
 - Laterality information is needed for identification purposes.
- The clinical diagnosis or differential diagnosis should be recorded.
 - Providing the provisional clinical diagnosis or differential diagnosis improves clinicopathological correlation and improves diagnostic accuracy.
- > The nature of the operation must be recorded.

> The operative findings should be recorded.

Record if this is a new primary cancer or a recurrence of a previous cancer, if known.

 The term recurrence defines the return, reappearance or metastasis of cancer (of the same histology) after a disease free period.

Recurrence should be classified as distant metastases or regional (local) recurrence.

Regional (local) recurrence refers to the recurrence of cancer cells at the same site as the original (primary) tumour or the regional lymph nodes.

Distant metastasis refers to the spread of cancer of the same histologic type as the original (primary) tumour to distant organs or distant lymph nodes.

 This information will provide an opportunity for previous reports to be reviewed during the reporting process, which may provide valuable information to the pathologist. This information also has implications for recording cancer incidence and evidence based research.

Example request information sheet

amily name	
iven name(s)	Indigenous Status Aboriginal but not Torres Strait Islander origin Torres Strait Islander but not Aboriginal origin Both Aboriginal and Torres Strait Islander origin Neither Aboriginal nor Torres Strait Islander origin
ate of birth Date of request	Not stated/inadequately described
DD - MM - YYYY	YYYY
atient identifiers .g. MRN, IHI or NHI (please indicate which) Copy to doctor	g doctor - name and contact details
name and contact details	
ELEVANT PAST MEDICAL HISTORY	LATERALITY
REDISPOSING FACTORS (INCL. GENETIC STATUS)	Left Right Unifocal Unifocal Multifocal Multifocal Bilateral Unifocal in both kidneys Multifocal in both kidneys
EE-OPERATIVE TREATMENT	Other eg horseshoe kidney Unifocal Multifocal
ELEVANT FAMILY HISTORY	NATURE OF OPERATION Ore/needle biopsy Other, specify
CTENT OF DISEASE	NEW PRIMARY LESION OR RECURRENCE
EEVIOUS BIOPSY/SURGICAL SPECIMENS	New primary Recurrence - regional, describe
CLINICAL OR DIFFERENTIAL DIAGNOSIS	Recurrence - distant, describe PRINCIPAL CLINICIAN
DPERATIVE FINDINGS	

The above Request Information Sheet is published to the RCPA website.

Appendix 2 Guidelines for formatting of a pathology report

Layout

Headings and spaces should be used to indicate subsections of the report, and heading hierarchies should be used where the LIS allows it. Heading hierarchies may be defined by a combination of case, font size, style and, if necessary, indentation.

 Grouping like data elements under headings and using 'white space' assists in rapid transfer of information.⁶²

Descriptive titles and headings should be consistent across the protocol, checklist and report.

When reporting on different tumour types, similar layout of headings and blocks of data should be used, and this layout should be maintained over time.

• Consistent positioning speeds data transfer and, over time, may reduce the need for field descriptions or headings, thus reducing unnecessary information or 'clutter'.

Within any given subsection, information density should be optimised to assist in data assimilation and recall.

- Configuring reports in such a way that they 'chunk' data elements into a single unit will help to improve recall for the clinician. ⁶²
- 'Clutter' should be reduced to a minimum.⁶² Thus, information that is not part of the protocol (e.g. billing information, Snomed codes, etc) should not appear on the reports or should be minimized.
- Injudicious use of formatting elements (e.g. too much bold, underlining or use of footnotes) constitutes clutter and may distract the reader from the key information.

Where a structured report checklist is used as a template for the actual report, any values provided in the checklist but not applying to the case in question must be deleted from the formatted report.

Reports should be formatted with an understanding of the potential for the information to mutate or be degraded as the report is transferred from the LIS to other health information systems.

As a report is transferred between systems:

- text characteristics such as font type, size, bold, italics and colour are often lost
- tables are likely to be corrupted as vertical alignment of text is lost when fixed font widths of the LIS are rendered as proportional fonts on screen or in print
- spaces, tabs and blank lines may be stripped from the report, disrupting the formatting
- supplementary reports may merge into the initial report.

Appendix 3 Example of a pathology report

Page 1 of 2

Citizen, Gerald W. C/O Paradise Close Wreck Bay Resort Nar Nar Goon East, 3181

Copy to: Dr N.G.Chappie Rainforest Cancer Centre. 46 Smith Road,

Woop Woop, 3478

Referred by: Dr V. Brown Suite 3, AJC Medical Centre, Bunyip Crescent Nar Nar Goon West, 3182

Lab Ref: 17/P28460

Referred: 30/8/2017

Male DOB 1/7/1992 MRN M1196785

KIDNEY BIOPSY FOR TUMOUR STRUCTURED REPORT

CLINICAL INFORMATION RECEIVED

Laterality: Right, unifocal
Nature of operation: Core/needle biopsy

Past medical history: Haematuria and abdominal pain

Extent of disease: No known metastases

Pre-operative treatment: Nil

New primary lesion or recurrence: New primary

MACROSCOPIC

Specimen labelled as: Right kidney biopsy of tumour

Nature of specimen: Fresh

Specimen laterality: Right, unifocal

Operative procedure: Core/needle biopsy

Number of cores: 2

Length: A = 22mm

B = 7mm

Tumour site: Lower pole
Colour: Yellow

Block identification key: A: upper B: lower
Other macroscopic comment: Nil of significance

MICROSCOPIC

Histological tumour type: Clear cell renal cell carcinoma

Histological tumour grade - WHO/ISUP: WHO/ISUP Grade 3 - Nucleoli conspicuous

and eosinophilic at 100x magnification

Sarcomatoid morphology: Not identified Rhabdoid morphology: Not identified Necrosis: Not identified Lymphovascular invasion: Not identified Co-existing pathology non-neoplastic kidney: None identified

ANCILLARY TESTS Not performed

Page 2 of 2

Diagnostic Summary

Core/needle biopsy:

Right kidney, lower pole Clear cell renal cell carcinoma WHO/ISUP grade 3

Reported by Dr Bernard Beckstein Authorised 4/9/2017

Appendix 4 World Health Organization (WHO) classification of renal neoplasia

- Clear cell renal cell carcinoma
- Multilocular clear cell renal cell neoplasm of low malignant potential
- · Papillary renal cell carcinoma
 - o Type 1
 - o Type 2
 - o Oncocytic
 - o NOS
- Chromophobe renal cell carcinoma
 - o Hybrid oncocytic chromophobe tumour
- Collecting duct carcinoma
- Renal medullary carcinoma
- MiT family translocation renal cell carcinoma
 - o Xp11 translocation renal cell carcinoma
 - o t(6;11) renal cell carcinoma
- · Mucinous tubular and spindle cell carcinoma
- Tubulocystic renal cell carcinoma
- Acquired cystic disease associated renal cell carcinoma
- Clear cell papillary/tubulopapillary renal cell carcinoma
- Hereditary leiomyomatosis and renal cell carcinoma-associated renal cell carcinoma
- · Succinate dehydrogenase (SDH) deficient renal carcinoma
- · Renal cell carcinoma, unclassified

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