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Cohort Profile: The Upper Gastrointestinal Cancer Registry (UGICR) - a clinical quality registry to monitor and improve care in upper gastrointestinal cancers

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Cohort Profile: The Upper Gastrointestinal Cancer Registry (UGICR) – a clinical quality registry to monitor and improve care in upper gastrointestinal cancers

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Abstract

Purpose

The Upper Gastrointestinal Cancer Registry (UGICR) was developed to monitor and improve the quality of care provided to patients with upper gastrointestinal cancers in Australia. Here we describe the development of a population-based, prospective, upper gastrointestinal cancer clinical quality registry.

Participants

The UGICR supports four cancer modules: pancreatic, oesophagogastric, biliary, and primary liver cancer. The pancreatic cancer module was the first module to be implemented, with others being established in a staged approach. Individuals are recruited to the registry if they are aged 18 years or older, have received care for their cancer at a participating public/private hospital or private clinic in Australia, and do not opt-out of participation.

Findings to date

The registry has human research ethics committee (HREC) approval as a multi-site project with National Mutual Acceptance (NMA) from Monash Health. The UGICR is governed by a multi-disciplinary steering committee which provides clinical governance and oversees clinical working parties. The role of the working parties is to develop quality indicators based on best practice for each registry module, develop the minimum datasets and provide guidance in analysing and reporting of results. Data are captured from existing data sources (population-based cancer incidence registries, pathology databases, and hospital coded data) and manually from clinical records. Data collectors directly enter information into a secure web-based REDCap data collection platform. The first module developed was the pancreatic cancer module which began with a pilot phase and subsequently, we used a formal modified-Delphi consensus process to establish a core set of quality indicators for pancreatic cancer. A detailed description of the methods of the modified Delphi process and the selected indicators has been published separately.

Future plans

The UGICR will provide regular reports of risk-adjusted, benchmarked performance on a range of quality indicators that will highlight variations in care and clinical outcomes at a health service level. The registry has also been developed with the view to collect Patient-Reported Outcomes (PROs), which will further add to our understanding of the care of patients with these cancers.

Article Summary

Strengths & Limitations of this Study

- The UGICR is the first clinical quality registry in Australia, designed to capture information on UGI cancers with the aim to improve practice by monitoring and providing benchmarked reports to participating sites.
- We describe the development of a clinical quality registry for upper gastrointestinal (UGI) cancers, including the establishment of governance, recruitment framework, clinical quality indicators, minimum data set, data access policy and reporting structure.
- This registry was developed as per the Australian Commission on Quality and Safety in Health Care's (ACSQHC) Framework for Australian clinical quality registries and follows ACSQHC's Australian Operating Principles for Clinical Quality Registries and can be used as a model for researchers developing CQRs.
- The time consuming and labour-intensive site governance approval process in Australia is a major limitation for rollout of the registry.

Keywords

pancreatic cancer, oesophageal cancer, gastric cancer, liver cancer, biliary cancer, upper gastrointestinal cancers, clinical registry, quality improvement, quality of care, database, population health

INTRODUCTION

The five most common upper gastrointestinal (UGI) cancers in Australia are pancreas, oesophagus, stomach, liver (hepatocellular carcinoma) and biliary cancers; the combined incidence is over 12,000 and there are approximately 8,000 deaths annually.[1,2] The five-year relative survival rates of UGI cancers are among the worst of all tumour types: 7.7% in pancreas; 17.3% in liver; 19.2% in biliary; 20.1% in oesophagus; and 28.5% in stomach.[2] The dismal prognosis of these cancers can be largely attributed to their presentation at an advanced disease stage. Additionally, older age is a risk factor for mortality from these tumours, and significant cardiac and respiratory comorbidities may limit treatment options. As a result, only 15% of pancreas, 43% of liver, 20% of oesophagus, and 50% of stomach cancers are potentially resectable at diagnosis.[3,4]

Resection, with radical lymph node dissection where appropriate, remains the principal potentially curative therapy for all localised UGI cancers. Disease management is almost invariably multimodal and may include chemotherapy and radiotherapy as neo-adjuvant, adjuvant or palliative therapy, and the provision of optimal supportive care.[5-9]

The aggressive nature of these cancers and the complexity of treatment often decrease health-related quality of life.[10] Advances in surgical techniques and perioperative care have resulted in operative mortality falling to less than 5% in major centres.[11] However surgery remains a morbid procedure with postoperative complications resulting in prolonged hospital admission, adversely impacting on overall quality of life and the ability to undergo any adjuvant therapies.[12] In those surviving one to two years following curative treatment, health-related quality of life generally recovers to baseline. However, there are still major challenges faced by survivors. For those having palliative or supportive therapy only, quality of life frequently deteriorates throughout the disease trajectory.[10]

Local or distant cancer recurrence occurs frequently following resection for all UGI cancers. A third of patients diagnosed with stomach[13] and half of all patients diagnosed with oesophageal[14] cancer develop recurrent disease within two years. In pancreatic cancer, where only 10%-15% of tumours are considered resectable, the local recurrence rate ranges from 10%-40% and distant recurrence is as high as 88%.[15]

Variation in Management, Treatment & Outcome

There is evidence that variability exists in the management and outcomes of UGI cancers. For example: not all patients are presented to a multi-disciplinary team meeting;[16] there are disparities in the utilisation of surgical resection and associated disease-specific survival based on where patients live;[17] there is wide variation in histopathological assessment of margins and the proportion that have clear margins;[15] the duration of surgery, post-operative complication rates and their management differ between public and private hospitals;[18,19] administration of adjuvant chemotherapy or radiotherapy is variable, often due to morbidity associated with postoperative complications;[20] and the 30-day postoperative mortality is lower in hospitals performing more resections each year.[21,22] Patients with UGI cancers have significant unmet needs pertaining to quality of life, finance, relationships, and family or caregiver distress; these are often exacerbated by a lack of understanding of the health system.[23,24] In pancreatic cancer, over 50% of participants (n=136) in an Australian-based study reported moderate to high unmet physical or psychological needs.[25]

Measuring Quality of Care with Clinical Quality Registries

To identify, understand and reduce unwarranted clinical variation and ensure that all patients receive optimal care, it is important to collect high-quality disease-specific data. Clinical Quality Registries (CQRs) support continuous improvements in patient outcomes by monitoring quality of care and providing risk-adjusted feedback to the relevant clinical community. These data describe patterns of treatment in order to identify variation, and can

provide a framework for research.[26] Successful implementation of CQRs has been achieved in a range of disciplines include trauma, cardiac, transplant and bariatric surgery,[27] joint replacement,[28] and cancer care (e.g. prostate). [29]

The Australian Commission on Safety and Quality in Health Care (ACSQHC) supports the development of CQRs in Australia through the provision of the national framework for CQRs.[30] The framework details the necessary principles, guidelines and standards for best practice design, build, operation and security of CQRs. A recent evaluation of the cost-effectiveness of CQRs determined that when funded sufficiently with robust operating procedures, CQRs provide a substantial return on investment.[31] In prioritising the development of CQRs in Australia, the ACSQHC ranked the development of registries for high-burden cancers only behind those monitoring ischemic heart disease and musculoskeletal disorders.[32] Pancreatic cancer is ranked fourth as a high-burden cancer in terms of its impact on disability-adjusted life years behind lung, bowel and breast cancer.[33] It was predicted to be the third leading cause of cancer deaths in the United States in 2018 and by 2030 is predicted to be the second commonest cause of cancer associated mortality.[3]

Although a number of generic population-based cancer registries exist, there are no clinical quality registries specific to the five aforementioned UGI cancers. Disease-specific registries[34,35] and audit databases[36] provide much needed evidence about the management of patients with these cancers. However, little prospective data has been published from multi-institution databases and/or registries regarding the quality of UGI cancer care across the disease trajectory.

Rationale for the UGICR

Improvements in cancer outcomes for patients with UGI cancer will understandably come through establishment of models of care that are informed by close attention to clinical and patient-reported quality measures and standardisation of treatment which comply with agreed

best practice. Given the lack of Australian population-level data regarding patient outcomes from UGI cancers, it was considered that a registry established to monitor treatment and outcomes of patients with cancers arising in the oesophagus, stomach, pancreas, liver and biliary system will improve management of these diseases. Furthermore, while detailed guidelines exist for each of these cancers, gaps remain regarding optimal care and management of these patient groups.[5-9,37]

The Upper Gastrointestinal Cancer Registry (UGICR) is a clinical quality registry established with the aims to:

(1) assess patterns of care and identify variations in clinical and patient reported outcomes;
(2) benchmark performance and provide feedback to service providers using a targeted quality improvement approach, to drive improvements in current practice;
(3) provide confidence to public, clinician and wider stakeholders on the delivery of high quality service;
(4) advance knowledge of best treatment protocols by facilitating future clinical, health service, psychosocial and biomedical research.

Cohort description

Overview

The UGICR is a multi-centre, population-based, non-interventional prospective cohort study that commenced in 2015.

Ethical approval

The registry has human research ethics committee (HREC) approval as a multi-site project with National Mutual Acceptance (NMA) from Monash Health (Ref: 15482A). Ethics approval has also been obtained from Monash University, Cancer Council Victoria, the

Aboriginal Health and Medical Research Council of New South Wales and a number of private hospitals not recognising the NMA scheme.

Governance

The UGICR is governed by a Steering Committee and, currently, two clinical working parties with the responsibility of each outlined in *Figure 1*. The Steering Committee performs in accordance with the Australian Framework for Clinical Quality Registries.[30]

A central research team provides operational oversights. A Principal Investigator (PI) at each participating hospital is responsible for ensuring that research activities undertaken at their site are conducted in accordance with the HREC approval, the research protocol, site registry agreements, and related policy documentation. At each site patients are identified for recruitment and data collection occurs.

Figure 1 here

Registry design

The UGICR has a multi-modular design with pancreatic, oesophagogastric (OG), biliary and liver cancer modules. Data are entered into REDCap (Research Electronic Data Capture), a secure web-based application, hosted and managed by Helix (Monash University).[38] The registry was developed in REDCap and all data are held securely on a Monash University server which has been accredited under the information security standard ISO27001.[39]

Participant Recruitment and Consent

The full recruitment schema is outlined in *Figure 2*. Eligible patients are identified within each jurisdiction through state-based cancer registries or by individual health services. Eligibility criteria are listed in *Table 1*. The UGICR uses an opt-out approach to minimise selection bias.[40]

Figure 2 here

Table 1: Eligibility Criteria

All Modules		
Inclusion	(i)	Patient has been assessed or received care for a confirmed primary oesophageal, gastric, liver, biliary, gallbladder or pancreatic cancer with some limited exclusions specified in each module (see below)
	(ii)	Patient is 18 years of age or older at time of diagnosis
	(iii)	Patient has a diagnosis date on or after 1st January 2016

Module Specific			
Modules		**Tumour Sites**	**Tumour Cell Types**
Pancreatic	*Inclusion*	Pancreas Periampullary region Ampulla of Vater Biliary origin Intestinal origin Distal bile duct	Ductal adenocarcinoma Cholangiocarcinoma Acinar cell carcinoma Acinar cell cystadenocarcinoma IPMN (invasive) Pancreatoblastoma Serous cystadenocarcinoma
	Exclusion	Non-distal bile duct	Neuroendocrine neoplasms Premalignant lesions Mesenchymal tumours Solid pseudopapilliary carcinoma IPMN (non-invasive)
Oesophagogastric	*Inclusion*	Oesophagus (lower two thirds) Gastro-oesophageal junction Stomach	Carcinoma Adenocarcinoma Squamous cell carcinoma Other subtypes
	Exclusion	Upper third of oesophagus	Neuroendocrine neoplasms Lymphomas Mesenchymal tumours
Biliary	*Inclusion*	Perihilar (hilar) bile duct Intrahepatic bile duct Gallbladder	Carcinoma Cholangiocarcinoma Adenosquamous carcinoma Squamous cell carcinoma Cholangiosarcoma
	Exclusion	Distal bile duct	Neuroendocrine neoplasms Mesenchymal tumours
Liver*	*Inclusion*	Liver	Hepatocellular carcinoma
	Exclusion	Intrahepatic bile duct	Cholangiocarcinoma Mesenchymal tumours Germ cell tumours Lymphomas

Abbreviations: IPMN, Intraductal Papillary Mucinous Neoplasm

*Liver module eligibility criteria still to be finalised

Eligible participants are mailed an introductory letter explaining the study and an information booklet outlining details of the registry, its purpose, possible outcomes of the research and the opt-out process. Participants are given two weeks to opt out of the registry before their consent is assumed, after which we commence collection of clinical and personal data covering diagnosis to end-of-life care. Patients can withdraw their consent from participation in the registry at any point by telephoning or emailing the UGICR office, as outlined in the participant information booklet. A waiver of consent applies where patients deemed eligible require an interpreter, have significant cognitive impairment, or where there is evidence that the patient is deceased.

Findings to date

Data Set

The first module developed was the pancreatic cancer module, which began with a pilot phase during which we collected data for a provisional set of quality indicators in three Victorian sites from 2016-2017. Subsequently, we used a formal modified-Delphi consensus process to establish a core set of quality indicators for pancreatic cancer. This process involved 19 pancreatic cancer care experts from three states in Australia. A detailed description of the methods of the modified Delphi process and the selected indicators has been published separately.[41] In addition, a review was undertaken of the Australian Optimal Care Pathways (OCP) for pancreatic cancer[42] and oesophagogastric cancer[43] to ensure that indicators are aligned with the seven themes described in the OCP (prevention and early detection; presentation, initial investigations and referral; diagnosis, staging and treatment planning; treatment; care after initial treatment and recovery; managing recurrent, residual, or metastatic disease; end-of-life care). An outline of this process for pancreatic cancer is provided in *Table 2*.

Table 2: Pancreatic cancer optimal care pathway mapped to modified-Delphi quality indicators

PANCREATIC CANCER OPTIMAL CARE PATHWAY (OCP)	OCP ELEMENTS	MAPPED QUALITY INDICATORS FROM MODIFIED-DELPHI CONSENSUS [41]
STEP ONE: Prevention and early detection	1.1 Prevention 1.2 Risk factors 1.3 Early detection	NIL
STEP TWO: Presentation, initial investigations and referral	2.1 Signs and symptoms 2.2 Assessments by GP or medical practitioner 2.3 Referral	• Documented baseline CA19-9 level before treatment • Documented ECOG and/or ASA at presentation • Time from referral to definitive treatment within 60 days
	2.4, 3.5, 4.6, 5.4, 6.6, 7.3 Support and communication	NIL
STEP THREE: Diagnosis, assessment and treatment planning	3.1 Diagnostic workup 3.2 Staging 3.3 Treatment planning	• Documented pancreatic protocol CT or MRI scan for diagnosis and/or staging • Operability of tumour is clearly defined and documented as either operable/resectable, borderline resectable, locally advanced (unresectable) or metastatic (unresectable) • Disease management for all patients discussed at a MDT meeting
	3.4 , 4.4, 5.3, 6.5, 7.2 Research and clinical Trials	• Number of patients included in a clinical trial
	3.1, 3.2 Timeframe	• Time from referral to definitive treatment within 60 days
STEP FOUR: Treatment	4.1 Treatment intent	NIL
	4.2.1 Surgery (Curative)	• All patients who did not undergo surgery should have a valid reason documented • Number of patients undergoing pancreatic cancer surgery in a level 1-4 hospital
	4.2.1 Chemotherapy or chemo-radiation	• Adjuvant chemotherapy administered following surgery or a reason documented for not undergoing treatment
	4.2.2, 4.3 Treatment of unresectable pancreatic cancer / palliative care	• Chemotherapy ± chemo-radiation offered to patients with locally advanced disease, or a reason documented for not undergoing treatment • Number of patients who saw a medical or radiation oncologist or a reason documented for not doing so
	4.5 Complementary or alternative therapies	NIL
STEP FIVE: Care after initial treatment and recovery	5.1 Survivorship 5.2 Post-treatment care planning	• All patients having completed treatment followed up by a specialist every three to six months for up to 2 years
STEP SIX: Managing recurrent, residual and metastatic disease	6.1 Signs and symptoms of recurrent, residual or metastatic disease	
STEP SEVEN: End-of-life care	6.4 Palliative care 7.1 Multidisciplinary palliative care	• All patients with metastatic disease referred to (or seen by) palliative care specialist

Footnote: Some elements in each step of the pathway are overlapping. Elements 6.2 & 6.3 readdress steps 3 and 4. Please note: The purpose of this document is to provide a broad overview of the areas within the OCP that the developed pancreatic cancer quality indicators measure. Only the key indicators that map to the elements are listed.

The minimum data set was established to enable quality indicators to be calculated. Data items and definitions were aligned with national specifications where appropriate and a comprehensive data dictionary was developed for each module. The core data items are outlined in *Table 3*.

Table 3: UGICR minimum dataset[#]

Participant details Title First name Middle name(s) Surname Recruiting hospital Medical Record Number Date of birth Sex Medicare number Department of Veteran Affairs number Country of birth Preferred language Interpreter required Indigenous status Contact details Phone number(s) Email address Postal Address Residential Address at diagnosis Next of kin and contact details General Practitioner details Deceased status Date of death Cause of death	**Diagnosis and staging** (prior to anti-tumour treatment) Diagnosis date Date mass first seen on imaging Diagnostic imaging tests completed[^] Pathology testing prior to anti-tumour treatment Cytology date Histology date Primary site of tumour Tumour morphology Clinical disease stage (TNM) Resectability of tumour at diagnosis CA 19-9 measured Discussion at a multidisciplinary team meeting Date earliest multidisciplinary team meeting discussion Diagnosing hospital **Surgery** Date of operation Type of resection Surgical approach Reason resection surgery abandoned Date of return to theatre Re-admitted to hospital within 90 days of surgery (excluding same day chemotherapy) Date of readmission Died in surgical admission Name of consultant surgeon Hospital where surgery was performed Resection pathology Maximum dimension of tumour Number of lymph nodes examined Number of lymph nodes positive Closest reported margin Pathologic staging (pTNM) Histology	**Chemotherapy** Treatment intent (Neoadjuvant/Adjuvant/Definitive/Palliative)[*] Date chemotherapy commenced Chemotherapy agent(s) administered Name of medical oncologist Hospital providing chemotherapy **Radiotherapy** Treatment intent (Neoadjuvant/Adjuvant/Definitive/Palliative)[*] Date radiotherapy commenced Radiation oncologist Radiotherapy technique Body sites treated Total dose given (Gy) Number of fractions Name of radiation oncologist Hospital providing radiotherapy **Restaging after neoadjuvant therapy** Date neoadjuvant therapy completed Resectability of tumour Clinical disease (TNM) **Other treatment and end-of-life care** Referral to or contact with palliative care Date of referral to palliative care ≥2 ED presentations in the last 30 days prior to death ≥14 days in acute hospital during last 30 days of life Died within 30 days of dose of chemotherapy

[#] More detailed, module specific data dictionaries have been developed. [^]Varies between modules [*]All related data items collected for first cycle of each type of treatment intent

The OG module has been developed by the OG working party following a literature review, and a consensus method was used to agree upon the quality indicator set. The registry has future plans to begin the collection of Patient Reported Outcomes (PROs) and Patient Reported Experiences (PREs) to provide valuable patient perspectives. As an initial step, a systematic review evaluating Patient Reported Outcome Measures (PROMs) in pancreatic cancer has been undertaken by the UGICR team to define which PROMs are most appropriate for this group of patients.

Data collection

If the participant has not opted out of the registry, data collectors abstract diagnosis, surgical, pathology and treatment data directly from the participant's electronic and/or hard copy medical records from participating sites or from clinician rooms. Data collection begins within four months of recruitment with at least annual follow-up until end-of-life.

Reporting

The registry will produce risk-adjusted benchmarked reports that will feed back de-identified data to participating sites on the associated quality indicators. To provide fair and meaningful benchmarked reports, we have undertaken a review of risk models to identify demographic and baseline clinical variables (focusing on those over which clinicians have no control e.g. age, sex, disease stage) that predict patient outcomes for the purposes of risk-adjustment. The data from the registry will also permit validation of current predictive risk models and enable further refinement of these tools. Publicly available annual reports that provide an overview of quality of care and the registry's activities will be published. A UGICR website (www.ugicr.org.au) has been developed to provide information about the registry to patients, clinicians and other stakeholders. This will be updated to include results as they become available.

Strengths and Limitations

The UGICR is Australia's first UGI cancer CQR. The aims of the registry are to monitor quality of care, benchmark clinical and patient-reported outcomes against best practice, and provide high-quality population-based data for clinical research. Registries such as the UGICR provide much needed real-world evidence outside the context of randomised control trials about disease epidemiology, treatment patterns, burden of illness, survival outcomes, clinical variation, and treatment safety.[44]

In recent decades, there has been increasing integration of PROMs into cancer registries to collect outcomes such as overall quality of life, functional and psychosocial well-being, lifestyle behaviours, and supportive care needs.[45] Clinicians and patients may place different emphasis on symptom impacts and expectations from their treatment.[46] The collection of PROMs is an important step in understanding patients' experience of their symptoms and management, and the impact of the disease and its treatment on their quality of life. The UGICR will determine and integrate the most relevant PROMs for each UGI cancer type following thorough examination of the literature.

Through the accumulation of significant and consistent data on UGI cancers, the registry will assess how clinical management compares with best practice and communicate this to clinicians through the PIs or relevant hospital departments. Further, the UGICR provides a platform for longer-term clinical follow-up, randomised clinical trials and sub-studies exploring treatment outcomes and linking outcomes to tumour tissue characteristics.

An important consideration is the maturity of each module before useful quality indicator reports can be provided to participating hospitals, as some UGI cancers have a relatively low incidence in comparison to other cancers.[2] The working groups in collaboration with

statisticians will determine an analysis plan for each indicator with due consideration to data completeness and risk adjustment methods.

Identified challenges

The UGICR has faced some key challenges affecting its establishment and implementation. The introduction of the NMA scheme has significantly streamlined the ethics process for all public hospitals in Australia, except in the Northern Territory, making the process to gain approval for CQRs more manageable. However, obtaining governance approval at each site continues to be both labour intensive and time consuming.[47,48] Further, separate HREC approval is frequently required to access data from private hospitals and clinics.

Funding is another challenge faced by CQRs. As with many healthcare initiatives, the financial burden can be a major impediment.[26] Data from CQRs are held in positive regard by clinicians, health managers and government. However, further funding will be required to progress national rollout of the registry.

Other identified barriers include reluctance of some healthcare providers to supply source data, and poor interoperability between clinical information systems leading to duplication of data entry. Where data are of high quality, such as for diagnosis and procedure codes, administrative data is appropriate, but there are limited data for comorbidities and risk factors.[49] While automation of data collection from existing data sources would be ideal, this is hampered by inconsistent documentation and a lack of standardisation.[50]

Collaboration

The UGICR aims to capture whole of population, real-world data that monitors and aspires to improve the quality of care provided to patients with UGI cancers. The registry is currently recruiting hospitals to increase population capture and selecting the most relevant instruments for measuring PROs and PREs for inclusion in each module. The biliary module is entering its pilot phase and the liver module is to be developed. Monash University is the UGICR's

data custodian and is accountable for the privacy, security and integrity of patient information held within the registry. Participating sites can request a copy of their own patient-level data. Researchers may access registry data following a formal submission to the UGICR data custodian and approval by the UGICR Steering Committee. They are required to complete a request form detailing their research aims and methods, potential impact on healthcare, and provide evidence relevant HREC approval before de-identified data will be released. The registry will harness new opportunities for data linkage with technologies such as the electronic medical records and collaborate with existing data repositories (e.g. biomedical) to evolve and fulfil its aim of providing quality evidence.

Declarations

Ethics approval

This project has received human research ethics committee (HREC) approval from the following HRECs: Monash Health (Ref: 15482A) under the National Mutual Acceptance (NMA) scheme (HREC/15/MonH/134); Cancer Council Victoria (HREC 1611); Epworth HealthCare (EH2017-227), Aboriginal Health & Medical Research Council (1387/18) and is registered with Monash University (CF16/119-2016000051).

Patient and Public Involvement

The UGICR uses an opt-out approach to minimise selection bias and participants are given two weeks to opt out of the registry before their consent is assumed. Patients can withdraw their consent from participation in the registry at any point. A waiver of consent applies where patients deemed eligible require an interpreter, have significant cognitive impairment, or where there is evidence that the patient is deceased. This approach has been approved by the aforementioned ethics committees.

Consent for publication

Not Applicable

Availability of data and material

Not Applicable

Competing interests

None declared

Data sharing statement

This study describes attributes of the registry and contains no patient-level data

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Authors' Contributions

AM and JH are joint first authors on this manuscript. SE, WB, DC, CP, JK, LL, TL, JM, MN and JZ are part of the UGICR Steering Committee. SE, WB, DC, CP, JK, LL, TL, MN, AA, PB, PC, JC, CD, PE, DG, AH, MH, BK, NM, MM, RN, JP, IP, MS, JS, PT and JZ are part of the working parties. RS and JH developed the registry protocol in consultation with the UGICR Steering Committee and working parties. All authors reviewed and provided feedback on the drafts of the manuscript and approved the final version.

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Figures

Figure 1 Title: UGICR governance structure

Fig 1 legend: HCC= hepatocellular carcinoma

Figure 2 Title: Registry Recruitment Schema

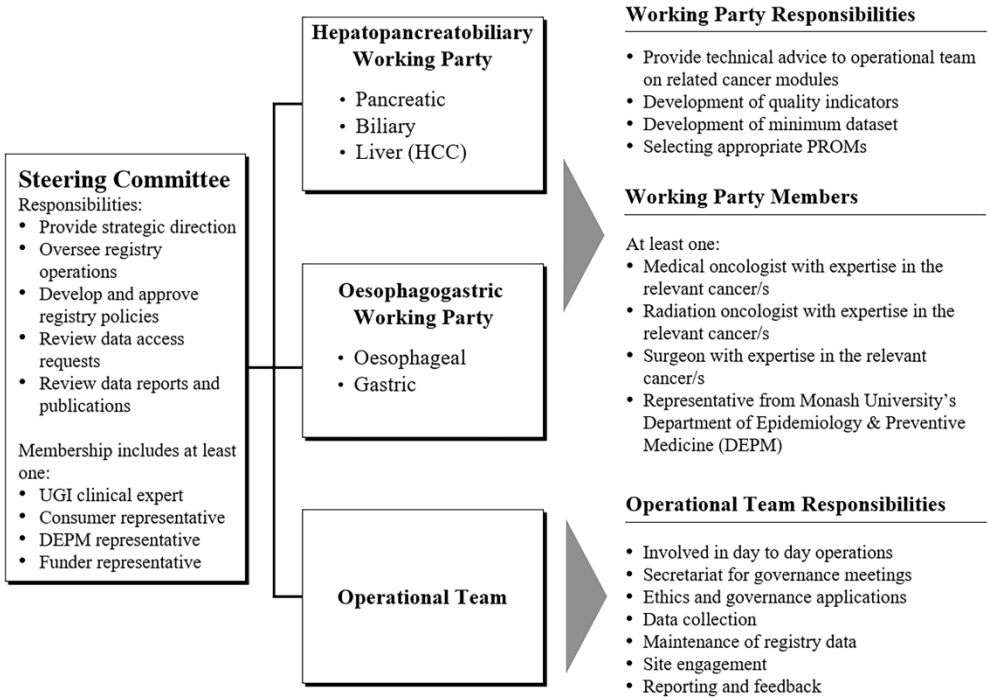

Figure 1: UGICR governance structure / HCC= hepatocellular carcinoma

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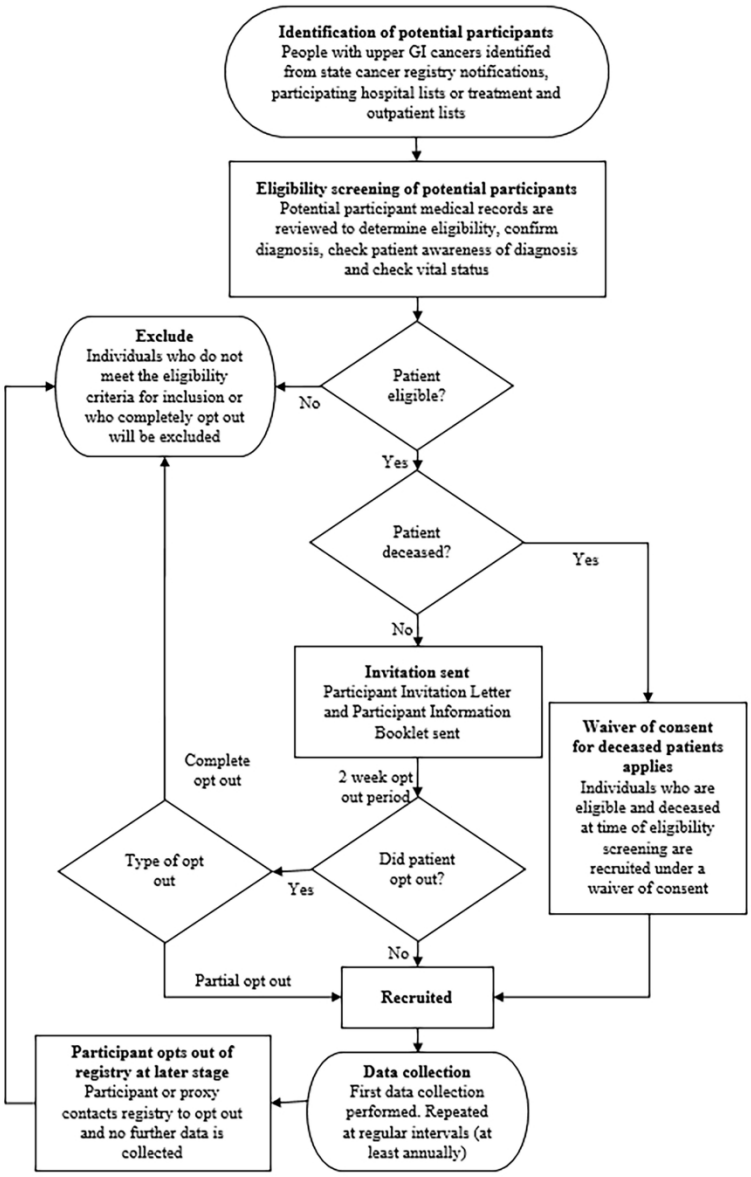

Figure 2 Title: Registry Recruitment Schema

134x208mm (300 x 300 DPI)

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Cohort Profile: The Upper Gastrointestinal Cancer Registry (UGICR) – a clinical quality registry to monitor and improve care in upper gastrointestinal cancers

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ABSTRACT (300 words)

Purpose

The Upper Gastrointestinal Cancer Registry (UGICR) was developed to monitor and improve the quality of care provided to patients with upper gastrointestinal cancers in Australia.

Participants

It supports four cancer modules: pancreatic, oesophagogastric, biliary, and primary liver cancer. The pancreatic cancer (PC) module was the first module to be implemented, with others being established in a staged approach. Individuals are recruited to the registry if they are aged 18 years or older, have received care for their cancer at a participating public/private hospital or private clinic in Australia, and do not opt out of participation.

Findings to Date

The UGICR is governed by a multi-disciplinary steering committee which provides clinical governance and oversees clinical working parties. The role of the working parties is to develop quality indicators based on best practice for each registry module, develop the minimum datasets and provide guidance in analysing and reporting of results. Data are captured from existing data sources (population-based cancer incidence registries, pathology databases, and hospital coded data) and manually from clinical records. Data collectors directly enter information into a secure web-based REDCap data collection platform. The PC module began with a pilot phase and subsequently, we used a formal modified-Delphi consensus process to establish a core set of quality indicators for PC. The second module developed was the oesophagogastric cancer (OGC) module. Results of the one year pilot phases for PC and OGC modules are included in this cohort profile.

Future plans

The UGICR will provide regular reports of risk-adjusted, benchmarked performance on a range of quality indicators that will highlight variations in care and clinical outcomes at a

health service level. The registry has also been developed with the view to collect Patient-Reported Outcomes (PROs), which will further add to our understanding of the care of patients with these cancers.

ARTICLE SUMMARY

Strengths & Limitations of this Study

- The UGICR is the first CQR in Australia, designed to capture information on UGI cancers with the aim to improve practice by monitoring and providing benchmarked reports to participating sites.
- We describe the development of a CQR for UGI cancers, including the establishment of governance, recruitment framework, clinical quality indicators, minimum data set, data access policy and reporting structure.
- This registry was developed as per the Australian Commission on Quality and Safety in Health Care's (ACSQHC) Framework for Australian CQRs and follows ACSQHC's Australian Operating Principles for CQRs and can be used as a model for researchers developing CQRs.
- The time consuming and labour-intensive site governance approval process in Australia is a major limitation for rollout of the registry.

Keywords

pancreatic cancer, oesophageal cancer, gastric cancer, liver cancer, biliary cancer, upper gastrointestinal cancers, clinical registry, quality improvement, quality of care, database, population health

INTRODUCTION

The five most common upper gastrointestinal (UGI) cancers in Australia are pancreas, oesophagus, stomach, liver (hepatocellular carcinoma) and biliary cancers; the combined incidence is approximately 10,000 and there are around 7,500 deaths annually.[1] The five-year

relative survival rates of UGI cancers are among the worst of all tumour types: 9.8% in pancreas; 18.5% in liver; 20.1% in biliary; 22% in oesophagus; and 30.3% in stomach.[1] The dismal prognosis of these cancers can be largely attributed to their presentation at an advanced disease stage. Additionally, older age is a risk factor for mortality from these tumours, and significant cardiac and respiratory comorbidities may limit treatment options. As a result, only 15% of pancreas, 43% of liver, 20% of oesophagus, and 50% of stomach cancers are potentially resectable at diagnosis.[2,3]

Resection, with radical lymph node dissection where appropriate, remains the principal potentially curative therapy for all localised UGI cancers. Disease management is almost invariably multimodal and may include chemotherapy and radiotherapy as neo-adjuvant, adjuvant or palliative therapy, and the provision of optimal supportive care.[4-8]

The aggressive nature of these cancers and the complexity of treatment often decrease health-related quality of life.[9] Advances in surgical techniques and perioperative care have resulted in operative mortality falling to less than 5% in major centres.[10] However surgery remains a morbid procedure with postoperative complications resulting in prolonged hospital admission, adversely impacting on overall quality of life and the ability to undergo any adjuvant therapies.[11] In those surviving one to two years following curative treatment, health-related quality of life generally recovers to baseline. However, there are still major challenges faced by survivors. For those having palliative or supportive therapy only, quality of life frequently deteriorates throughout the disease trajectory.[9]

Local or distant cancer recurrence occurs frequently following resection for all UGI cancers. A third of patients diagnosed with stomach[12] and half of all patients diagnosed with oesophageal[13] cancer develop recurrent disease within two years. In pancreatic cancer (PC),

where only 10%-15% of tumours are considered resectable, the local recurrence rate ranges from 10%-40% and distant recurrence is as high as 88%.[14]

Variation in Management, Treatment & Outcome

There is evidence that variability exists in the management and outcomes of UGI cancers. For example: not all patients are presented to a multi-disciplinary team meeting;[15] there are disparities in the utilisation of surgical resection and associated disease-specific survival based on where patients live;[16] there is wide variation in histopathological assessment of margins and the proportion that have clear margins;[14] the duration of surgery, post-operative complication rates and their management differ between public and private hospitals;[17,18] administration of adjuvant chemotherapy or radiotherapy is variable, often due to morbidity associated with postoperative complications;[19] and the 30-day postoperative mortality is lower in hospitals performing more resections each year.[20,21] Patients with UGI cancers have significant unmet needs pertaining to quality of life, finance, relationships, and family or caregiver distress; these are often exacerbated by a lack of understanding of the health system.[22,23] In PC, over 50% of participants (n=136) in an Australian-based study reported moderate to high unmet physical or psychological needs.[24]

Measuring Quality of Care with Clinical Quality Registries

To identify, understand and reduce unwarranted clinical variation and ensure that all patients receive optimal care, it is important to collect high-quality disease-specific data. Clinical Quality Registries (CQRs) support continuous improvements in patient outcomes by monitoring quality of care and providing risk-adjusted feedback to the relevant clinical community. These data describe patterns of treatment in order to identify variation, and can provide a framework for research.[25] Successful implementation of CQRs has been achieved in a range of disciplines include trauma, cardiac, transplant and bariatric surgery,[26] joint replacement,[27] and cancer care (e.g. prostate).[28]

The Australian Commission on Safety and Quality in Health Care (ACSQHC) supports the development of CQRs in Australia through the provision of the national framework for CQRs.[29] The framework details the necessary principles, guidelines and standards for best practice design, build, operation and security of CQRs. A recent evaluation of the cost-effectiveness of CQRs determined that when funded sufficiently with robust operating procedures, CQRs provide a substantial return on investment.[30] In prioritising the development of CQRs in Australia, the ACSQHC ranked the development of registries for high-burden cancers only behind those monitoring ischemic heart disease and musculoskeletal disorders.[31] Pancreatic cancer is ranked fourth as a high-burden cancer in terms of its impact on disability-adjusted life years behind lung, bowel and breast cancer.[32] It was predicted to be the third leading cause of cancer deaths in the United States in 2018 and by 2030 is predicted to be the second commonest cause of cancer associated mortality.[2]

Although a number of generic population-based cancer registries exist, there are no CQRs specific to the five aforementioned UGI cancers. Disease-specific registries[33,34] and audit databases[35] provide much needed evidence about the management of patients with these cancers. However, little prospective data has been published from multi-institution databases and/or registries regarding the quality of UGI cancer care across the disease trajectory.

Rationale for the UGICR

Improvements in cancer outcomes for patients with UGI cancer will understandably come through establishment of models of care that are informed by close attention to clinical and patient-reported quality measures and standardisation of treatment which comply with agreed best practice. Given the lack of Australian population-level data regarding patient outcomes from UGI cancers, it was considered that a registry established to monitor treatment and outcomes of patients with cancers arising in the oesophagus, stomach, pancreas, liver and biliary system will improve management of these diseases. Furthermore, while detailed

guidelines exist for each of these cancers, gaps remain regarding optimal care and management of these patient groups.[4-8,36]

The Upper Gastrointestinal Cancer Registry (UGICR) is a CQR established with the aims to:

(1) assess patterns of care and identify variations in clinical and patient reported outcomes;
(2) benchmark performance and provide feedback to service providers using a targeted quality improvement approach, to drive improvements in current practice;
(3) provide confidence to public, clinician and wider stakeholders on the delivery of high quality service;
(4) advance knowledge of best treatment protocols by facilitating future clinical, health service, psychosocial and biomedical research.

COHORT DESCRIPTION

Overview

The UGICR is a multi-centre, population-based, non-interventional prospective cohort study. It was established in 2015 in Victoria and has since expanded to the state of New South Wales, Australia.

Ethical approval

The registry has human research ethics committee (HREC) approval as a multi-site project with National Mutual Acceptance (NMA) from Monash Health (Ref: 15482A). Ethics approval has also been obtained from Monash University, Cancer Council Victoria, the Aboriginal Health and Medical Research Council of New South Wales and a number of private hospitals not recognising the NMA scheme.

Governance

The UGICR is governed by a Steering Committee and, currently, two clinical working parties with the responsibility of each outlined in *Figure 1*. The Steering Committee performs in accordance with the Australian Framework for CQRs.[29]

A central research team provides operational oversights. A Principal Investigator (PI) at each participating hospital is responsible for ensuring that research activities undertaken at their site are conducted in accordance with the HREC approval, the research protocol, site registry agreements, and related policy documentation. At each site patients are identified for recruitment and data collection occurs.

Figure 1 here

Registry design

The UGICR has a multi-modular design with pancreatic, oesophagogastric (OG), liver and biliary cancer modules. Data are entered into REDCap (Research Electronic Data Capture), a secure web-based application, hosted and managed by Helix (Monash University).[37] The registry was developed in REDCap and all data are held securely on a Monash University server which has been accredited under the information security standard ISO27001.[38]

Participant Recruitment and Consent

The full recruitment schema is outlined in *Figure 2*. Eligible patients are identified within each jurisdiction through state-based cancer registries or by individual health services. Eligibility criteria are listed in *Table 1*. The UGICR uses an opt-out approach to minimise selection bias.[39]

Figure 2 here

Table 1: Eligibility Criteria

		All Modules
Inclusion	(i)	Patient has a confirmed primary pancreatic, oesophageal, gastric, liver, biliary or gallbladder cancer with some limited exclusions specified in each module

		(see below)	
	(ii)	Patient has been assessed or received care at a participating public or private hospital or private clinician rooms	
	(iii)	Patient is 18 years of age or older at time of diagnosis	
	(iv)	Patient has a diagnosis date on or after 1st January 2016 (apart from one centre which commenced recruitment in November 2015	
Module Specific			
Modules		**Tumour Sites**	**Tumour Cell Types**
Pancreatic	*Inclusion*	Pancreas Periampullary region Ampulla of Vater Biliary origin Intestinal origin Distal bile duct	Ductal adenocarcinoma Cholangiocarcinoma Acinar cell carcinoma Acinar cell cystadenocarcinoma IPMN (invasive) Pancreatoblastoma Serous cystadenocarcinoma
	Exclusion	Non-distal bile duct	Neuroendocrine neoplasms Premalignant lesions Mesenchymal tumours Solid pseudopapilliary carcinoma IPMN (non-invasive)
Oesophagogastric	*Inclusion*	Oesophagus (lower two thirds) Gastro-oesophageal junction Stomach	Carcinoma Adenocarcinoma Squamous cell carcinoma Other subtypes
	Exclusion	Upper third of oesophagus	Neuroendocrine neoplasms Lymphomas Mesenchymal tumours
Biliary	*Inclusion*	Perihilar (hilar) bile duct Intrahepatic bile duct Gallbladder	Carcinoma Cholangiocarcinoma Adenosquamous carcinoma Squamous cell carcinoma Cholangiosarcoma
	Exclusion	Distal bile duct	Neuroendocrine neoplasms Mesenchymal tumours
Liver*	*Inclusion*	Liver	Hepatocellular carcinoma
	Exclusion	Intrahepatic bile duct	Cholangiocarcinoma Mesenchymal tumours Germ cell tumours Lymphomas

Abbreviations: IPMN, Intraductal Papillary Mucinous Neoplasm, *Liver module eligibility criteria still to be finalised

Eligible participants are mailed an introductory letter explaining the study and an information booklet outlining details of the registry, its purpose, possible outcomes of the research and the opt-out process. Participants are given two weeks to opt out of the registry before their

participation is assumed, after which we commence collection of clinical and personal data covering diagnosis to end-of-life care. Patients can withdraw their consent from participation in the registry at any point by telephoning or emailing the UGICR office, as outlined in the participant information booklet. A waiver of consent applies where patients deemed eligible require an interpreter, have significant cognitive impairment, or where there is evidence that the patient is deceased.

FINDINGS TO DATE

Data Set

The first module developed was the PC module, which began with a pilot phase of approximately one year, during which we collected data for a provisional set of quality indicators in three Victorian sites from 2016-2017. The second module developed using a similar pilot phase was the OG module. Subsequently, we used a formal modified-Delphi consensus process to establish a core set of quality indicators for PC. This process involved 19 PC care experts from three states in Australia. A detailed description of the methods of the modified Delphi process and the selected indicators has been published separately.[40] In addition, a review was undertaken of the Australian Optimal Care Pathways (OCP) for PC[41] and OGC[42] to ensure that indicators are aligned with the seven themes described in the OCP (prevention and early detection; presentation, initial investigations and referral; diagnosis, staging and treatment planning; treatment; care after initial treatment and recovery; managing recurrent, residual, or metastatic disease; end-of-life care). An outline of this process for PC is provided in *Table 2*. There are currently no clinical quality indicators in the UGICR that measure care for the prevention and early detection of PC. However, the UGICR is participating in a collaborative project, Symptom-UGI: Upper Gastrointestinal Cancer Symptom Study, to map the patient pathways from onset of symptoms to cancer diagnosis.

Details of this study can be found within the UGICR website (https://ugicr.org.au/associated-studies/).

Table 2: PC Optimal Care Pathway Mapped to Modified-Delphi Quality Indicators

PC OPTIMAL CARE PATHWAY (OCP)	OCP ELEMENTS	MAPPED QUALITY INDICATORS FROM MODIFIED-DELPHI CONSENSUS [41]
STEP ONE: Prevention and early detection	1.1 Prevention 1.2 Risk factors 1.3 Early detection	NIL
STEP TWO: **Presentation, initial investigations and referral**	2.1 Signs and symptoms 2.2 Assessments by GP or medical practitioner 2.3 Referral	• Documented baseline CA19-9 level before treatment • Documented ECOG and/or ASA at presentation • Time from referral to definitive treatment within 60 days
	2.4, 3.5, 4.6, 5.4, 6.6, 7.3 Support and communication	NIL
STEP THREE: **Diagnosis, assessment and treatment planning**	3.1 Diagnostic workup 3.2 Staging 3.3 Treatment planning	• Documented pancreatic protocol CT or MRI scan for diagnosis and/or staging • Operability of tumour is clearly defined and documented as either operable/resectable, borderline resectable, locally advanced (unresectable) or metastatic (unresectable) • Disease management for all patients discussed at a MDT meeting
	3.4 , 4.4, 5.3, 6.5, 7.2 Research and clinical Trials	• Number of patients included in a clinical trial
	3.1, 3.2 Timeframe	• Time from referral to definitive treatment within 60 days
STEP FOUR: **Treatment**	4.1 Treatment intent	NIL
	4.2.1 Surgery (Curative)	• All patients who did not undergo surgery should have a valid reason documented • Number of patients undergoing PC surgery in a level 1-4 hospital
	4.2.1 Chemotherapy or chemo-radiation	• Adjuvant chemotherapy administered following surgery or a reason documented for not undergoing treatment
	4.2.2, 4.3 Treatment of unresectable PC / palliative care	• Chemotherapy ± chemo-radiation offered to patients with locally advanced disease, or a reason documented for not undergoing treatment • Number of patients who saw a medical or radiation oncologist or a reason documented for not doing so
	4.5 Complementary or alternative therapies	NIL
STEP FIVE: Care after initial treatment and recovery	5.1 Survivorship 5.2 Post-treatment care planning	• All patients having completed treatment followed up by a specialist every three to six months for up to 2 years
STEP SIX: Managing recurrent, residual and metastatic disease	6.1 Signs and symptoms of recurrent, residual or metastatic disease	
STEP SEVEN: End-of-life care	6.4 Palliative care 7.1 Multidisciplinary palliative care	• All patients with metastatic disease referred to (or seen by) palliative care specialist

Footnote: Some elements in each step of the pathway are overlapping. Elements 6.2 & 6.3 readdress steps 3 and 4. Please note: The purpose of this document is to provide a broad overview of the areas within the OCP that the developed PC quality indicators measure. Only the key indicators that map to the elements are listed.

The minimum data set was established to enable quality indicators to be calculated. Data items and definitions were aligned with national specifications where appropriate and a comprehensive data dictionary was developed for each module. The core data items are outlined in *Table 3*.

Table 3: UGICR Minimum Dataset[#]

Participant details Title First name Middle name(s) Surname Recruiting hospital Medical Record Number Date of birth Sex Medicare number Department of Veteran Affairs number Country of birth Preferred language Interpreter required Indigenous status Contact details Phone number(s) Email address Postal address Residential address at diagnosis Next of kin and contact details General Practitioner details Deceased status Date of death Cause of death	**Diagnosis and staging** (prior to anti-tumour treatment) Diagnosis date Date mass first seen on imaging Diagnostic imaging tests completed[^] Pathology testing prior to anti-tumour treatment Cytology date Histology date Primary site of tumour Tumour morphology Clinical disease stage (TNM) Resectability of tumour at diagnosis CA 19-9 measured Discussion at a multidisciplinary team meeting Date earliest multidisciplinary team meeting discussion Diagnosing hospital **Surgery** Date of operation Type of resection Surgical approach Reason resection surgery abandoned Date of return to theatre Re-admitted to hospital within 90 days of surgery (excluding same day chemotherapy) Date of readmission Died in surgical admission Name of consultant surgeon Hospital where surgery was performed Resection pathology Maximum dimension of tumour Number of lymph nodes examined Number of lymph nodes positive Closest reported margin Pathologic staging (pTNM) Histology	**Chemotherapy** Treatment intent (Neoadjuvant/Adjuvant/Curativetive/Palliative)[*] Date chemotherapy commenced Chemotherapy agent(s) administered Name of medical oncologist Hospital providing chemotherapy **Radiotherapy** Treatment intent (Neoadjuvant/Adjuvant/Curativetive/Palliative)[*] Date radiotherapy commenced Radiation oncologist Radiotherapy technique Body sites treated Total dose given (Gy) Number of fractions Name of radiation oncologist Hospital providing radiotherapy **Restaging after neoadjuvant therapy** Date neoadjuvant therapy completed Resectability of tumour Clinical disease (TNM) **Other treatment and end-of-life care** Referral to or contact with palliative care Date of referral to palliative care ≥2 ED presentations in the last 30 days prior to death ≥14 days in acute hospital during last 30 days of life Died within 30 days of dose of chemotherapy

[#] More detailed, module specific data dictionaries have been developed. [^]Varies between modules [*]All related data items collected for first cycle of each type of treatment intent

The OGC module has been developed by the OGC working party following a literature review, and a consensus method was used to agree upon the quality indicator set. The registry has future plans to begin the collection of Patient Reported Outcomes (PROs) and Patient Reported Experiences (PREs) to provide valuable patient perspectives. As an initial step, a systematic review evaluating Patient Reported Outcome Measures (PROMs) in PChas been undertaken by the UGICR team to define which PROMs are most appropriate for this group of patients.

Data collection

If the participant has not opted out of the registry, data collectors abstract diagnosis, surgical, pathology and treatment data directly from the participant's electronic and/or hard copy medical records from participating sites or from clinician rooms. Data collection begins close to the time of recruitment with at least annual follow-up until end-of-life.

Results from the pilot studies from the PC and OGC modules.

The results of the pilot phase for both PC and OGC modules are displayed in Table 4. Of the 123 participants eligible for the PC module and 189 for the OGC module, 8 (6.5%) and 9 (4.8%) opted out of the registry, respectively. Clinical stage at diagnosis was not well documented in both the PC module (n = 80, 70%) and OGC cancer module (n = 82, 46%) and is an area for future quality improvement. Around 20% of the pancreatic cohort received surgery as first treatment which is broadly representative of surgical treatment in patients with PC[43]. Further, 73 participants in the PC and 94 participants in the OGC module had documented reasons for no surgery. The pilot results for both modules identified areas for improving data completeness, definitions, items and structure of data collection forms. Following the pilot phase, the registry focused on improving these areas before expanding to other participating hospitals.

Table 4: PC and OGC Module Data from Pilot Data Collection

Variable	PC Module n (%)	OGC Module n (%)
Recruited	**115**	**180**
Recruited via invitation letter	88 (76.5)	120 (66.7)
Recruited via waiver of consent (deceased)	27 (23.5)	60 (33.3)
Sex		
Male	56 (48.7)	132 (73.3)
Female	59 (51.3)	48 (26.7)
Age at diagnosis (years)		
<50	6 (5.2)	11 (6.1)
50-59	14 (12.2)	22 (12.2)
60-69	30 (26.1)	54 (30.0)
70-79	38 (33.0)	54 (30.0)
≥80	22 (19.1)	33 (18.3)
Missing	5 (4.3)	6 (3.3)
Resectability at diagnosis		
Resectable	25 (21.7)	58 (32.2)
Borderline resectable	3 (2.6)	11 (6.1)
Unresectable	67 (58.3)	64 (35.6)
Locally Advanced (LA)	*24 (20.9)*	*6* (3.3)
Metastatic (Mets)	*43 (37.4)*	*58* (32.2)
Not documented	14 (12.2)	-
Unknown	-	41 (22.8)
Missing	6 (5.2)	6 (3.3)
Clinical stage at diagnosis		
I or II	5 (4.3)	33 (18.3)
III	-	7 (3.9)
IV	18 (15.7)	50 (27.8)
Complete TNM[a] not documented	80 (69.6)	82 (45.6)
Missing	12 (10.4)	8 (4.4)
First treatment		
Neoadjuvant therapy	4 (3.5)	60 (33.3)
Attempted or completed resection surgery	27 (23.5)	13 (7.2)
Curative intent ChemoTx and/or RT[b]	-	7 (3.9)
Palliative intent ChemoTx and/or RT[b]	37 (32.2)	55 (30.6)
No treatment	29 (25.2)	23 (12.8)
Unknown	-	16 (8.9)
Missing	18 (15.7)	6 (3.3)
Reasons for no surgery[c]		
LA or Mets	62	60
Advanced age	1	6
Comorbidities	7	9
Patient declined	1	12
Patient died prior to surgery	0	7
Performance status	-	4

Variable	PC Module n (%)	OGC Module n (%)
Other reason	1	-
Reason not documented	4	3
Participant data collection status		
Complete	51 (44.3)	107 (59.4)
Incomplete	64 (55.7)	73 (40.6)
Data entry sub-form completeness		
Demographics	113 (98.2)	180 (100.0)
Vital status and tumour recurrence	58 (50.4)	145 (80.6)
Diagnosis details	97 (84.3)	165 (91.7)
Biliary stents	94 (81.7)	-
Surgery	102 (88.7)	168 (93.3)
Pathology of resection sample	102 (88.7)	-
Neoadjuvant therapy	104 (90.4)	-
Adjuvant therapy	98 (85.2)	-
Therapy for locally advanced disease	95 (82.6)	-
Therapy for metastatic disease	77 (67.0)	-
Other treatment and trials	80 (70.0)	-
Treatment summary	- -	167 (92.8)
Restaging after neoadjuvant therapy	- -	167 (92.8)
Chemotherapy details	- -	162 (90.0)
Radiotherapy details	- -	163 (90.6)
End-of-life details	- -	81 (45.0)

[a] TNM system of classification of cancer, [b]ChemoTx and/or RT = Chemotherapy and/or radiotherapy [c]Reason for no surgery: Participants may have more than one reason documented

Population Coverage

Population coverage in Victoria is based on data from the Victorian Cancer Registry. The population coverage in the pilot phase was 19% for the PC module and 11% for the OGC module. Current coverage is 73% for PC and 55% for the OGC module. In New South Wales, data is currently only being collected on the PC module with an estimated population coverage of 55%.

Reporting

The registry will produce risk-adjusted benchmarked reports that will feed back de-identified data to participating sites on the associated quality indicators. To provide fair and meaningful benchmarked reports, we have undertaken a review of risk models to identify demographic and baseline clinical variables (focusing on those over which clinicians have no control e.g. age, sex, disease stage) that predict patient outcomes for the purposes of risk-adjustment. The

data from the registry will also permit validation of current predictive risk models and enable further refinement of these tools. Publicly available annual reports that provide an overview of quality of care and the registry's activities will be published. A UGICR website (https://ugicr.org.au/) has been developed to provide information about the registry to patients, clinicians and other stakeholders. This will be updated to include results as they become available.

STRENGTHS AND LIMITATIONS

The UGICR is Australia's first UGI cancer CQR. The aims of the registry are to monitor quality of care, benchmark clinical and patient-reported outcomes against best practice, and provide high-quality population-based data for clinical research. Registries such as the UGICR provide much needed real-world evidence outside the context of randomised control trials about disease epidemiology, treatment patterns, burden of illness, survival outcomes, clinical variation, and treatment safety.[44]

In recent decades, there has been increasing integration of PROMs into cancer registries to collect outcomes such as overall quality of life, functional and psychosocial well-being, lifestyle behaviours, and supportive care needs.[45] Clinicians and patients may place different emphasis on symptom impacts and expectations from their treatment.[46] The collection of PROMs is an important step in understanding patients' experience of their symptoms and management, and the impact of the disease and its treatment on their quality of life. The UGICR will determine and integrate the most relevant PROMs for each UGI cancer type following thorough examination of the literature.

Through the accumulation of significant and consistent data on UGI cancers, the registry will assess how clinical management compares with best practice and communicate this to clinicians through the PIs or relevant hospital departments. Further, the UGICR provides a

platform for longer-term clinical follow-up, randomised clinical trials and sub-studies exploring treatment outcomes and linking outcomes to tumour tissue characteristics.

An important consideration is the maturity of each module before useful quality indicator reports can be provided to participating hospitals, as some UGI cancers have a relatively low incidence in comparison to other cancers.[1] The working groups in collaboration with statisticians will determine an analysis plan for each indicator with due consideration to data completeness and risk adjustment methods.

Identified challenges

The UGICR has faced some key challenges affecting its establishment and implementation. The introduction of the NMA scheme has significantly streamlined the ethics process for all public hospitals in Australia, except in the Northern Territory, making the process to gain approval for CQRs more manageable. However, obtaining governance approval at each site continues to be both labour intensive and time consuming.[47,48] Further, separate HREC approval is frequently required to access data from private hospitals and clinics.

Funding is another challenge faced by CQRs. As with many healthcare initiatives, the financial burden can be a major impediment.[25] Data from CQRs are held in positive regard by clinicians, health managers and government. However, further funding will be required to progress national rollout of the registry.

Other identified barriers include reluctance of some healthcare providers to supply source data, and poor interoperability between clinical information systems leading to duplication of data entry. Where data are of high quality, such as for diagnosis and procedure codes, administrative data is appropriate, but there are limited data for comorbidities and risk factors.[49] While automation of data collection from existing data sources would be ideal, this is hampered by inconsistent documentation and a lack of standardisation.[50]

Collaboration

The UGICR aims to capture whole of population, real-world data that monitors and aspires to improve the quality of care provided to patients with UGI cancers. The registry is currently recruiting hospitals to increase population capture and selecting the most relevant instruments for measuring PROs and PREs for inclusion in each module. The biliary module is entering its pilot phase and the liver module is to be developed. Monash University is the UGICR's data custodian and is accountable for the privacy, security and integrity of patient information held within the registry. Participating sites can request a copy of their own patient-level data. Researchers may access registry data following a formal submission to the UGICR data custodian and approval by the UGICR Steering Committee. They are required to complete a request form detailing their research aims and methods, potential impact on healthcare, and provide evidence relevant HREC approval before de-identified data will be released. The registry will harness new opportunities for data linkage with technologies such as the electronic medical records and collaborate with existing data repositories (e.g. biomedical) to evolve and fulfil its aim of providing quality evidence.

DECLARATIONS

Ethics approval

This project has received human research ethics committee (HREC) approval from the following HRECs: Monash Health (Ref: 15482A) under the National Mutual Acceptance (NMA) scheme (HREC/15/MonH/134); Cancer Council Victoria (HREC 1611); Epworth HealthCare (EH2017-227), Aboriginal Health & Medical Research Council (1387/18) and is registered with Monash University (CF16/119-2016000051).

Patient and Public Involvement

Consumer representatives are involved at the level of the steering committee and provide oversight on the relevant modules as they are developed by the UGICR. Consumers

representatives will also be involved in future studies which include the selection of a core-set of PROMs.

Consent for publication

Not Applicable

Availability of data and material

Not Applicable

Competing interests

None declared

Data sharing statement

This study describes attributes of the registry and contains no patient-level data

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Authors' Contributions

AM and JH are joint first authors on this manuscript. SE, WB, DC, CP, JK, LL, TL, JM, MN and JZ are part of the UGICR Steering Committee. SE, LI, WB, DC, CP, JK, LL, TL, MN, AA, PB, PC, JC, CD, PE, DG, AH, MH, BK, NM, MM, RN, JP, IP, MS, JS, PT and JZ are part of the working parties. RS and JH developed the registry protocol in consultation with the UGICR Steering Committee and working parties. All authors reviewed and provided feedback on the drafts of the manuscript and approved the final version.

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FIGURE TITLES AND LEGEND

Figure 1 Title: UGICR governance structure

Fig 1 legend: HCC= hepatocellular carcinoma

Figure 2 Title: Registry Recruitment Schema

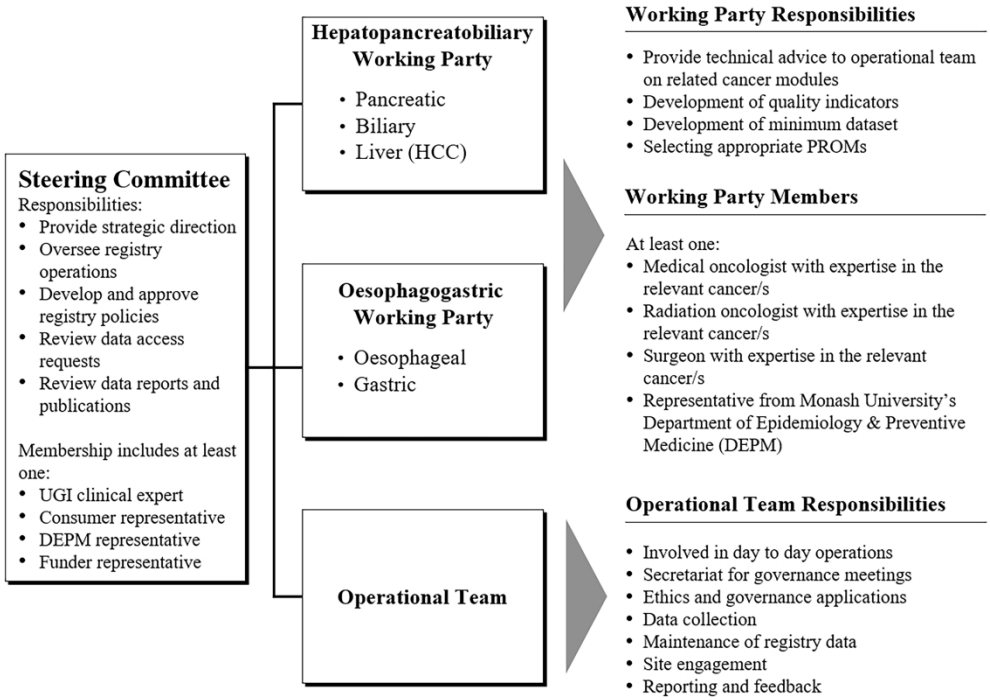

Figure 1: UGICR governance structure / HCC= hepatocellular carcinoma

296x206mm (300 x 300 DPI)

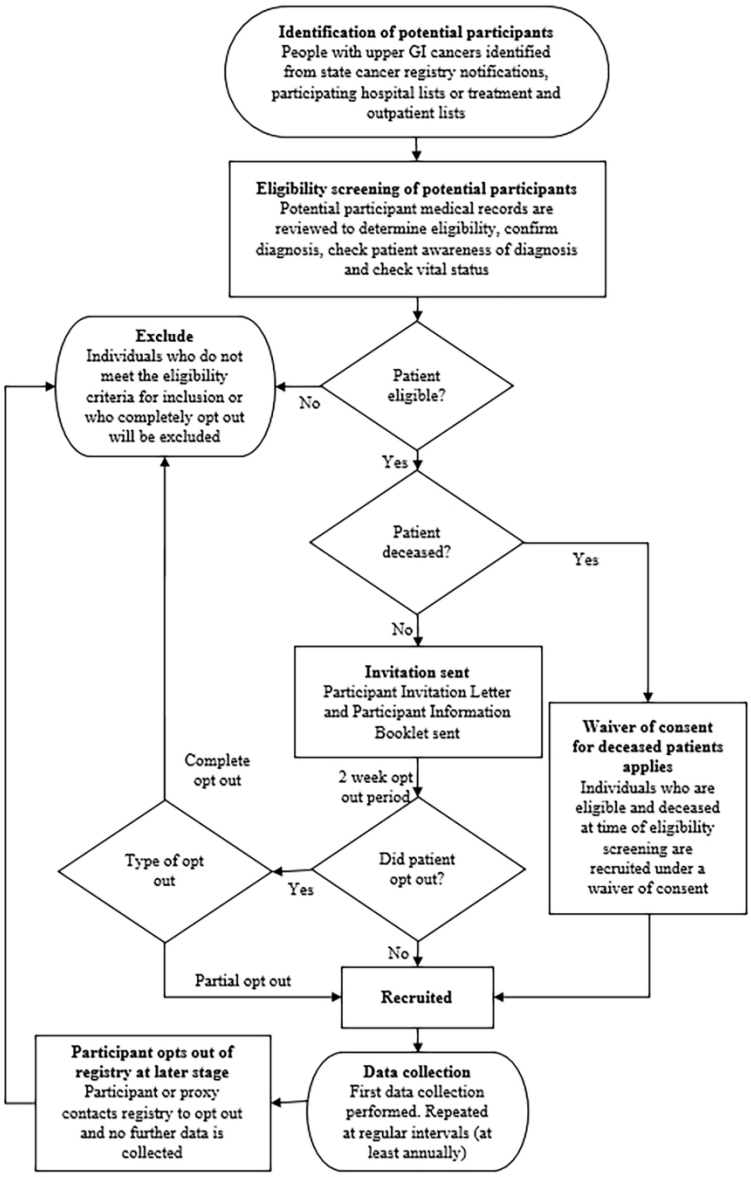

Figure 2 Title: Registry Recruitment Schema

134x208mm (300 x 300 DPI)