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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.

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 multidisciplinary steering committee that 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 Research Electronic Data Capture (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 1 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.

Strengths and limitations of this study

- The Upper Gastrointestinal Cancer Registry is the first clinical quality registry (CQR) in Australia, designed to capture information on upper gastrointestinal (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.

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 7500 deaths annually.[1] The 5-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 neoadjuvant, 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 1–2 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 2 years. In pancreatic cancer (PC), where only 10%–15% of tumours are considered resectable, the local recurrence rate ranges from 10% to 40% and distant recurrence is as high as 88%.[14]

There is evidence that variability exists in the management and outcomes of UGI cancers. For example, not all patients are presented to a multidisciplinary 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, postoperative 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 (CQRs)

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. 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 (eg, 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 ischaemic heart disease and musculoskeletal disorders.[31] PC 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 USA in 2018 and by 2030 is predicted to be the second most common 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 have been published from multi-institution databases and/or registries regarding the quality of UGI cancer care across the disease trajectory.

Rationale for the Upper Gastrointestinal Cancer Registry (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 that 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,

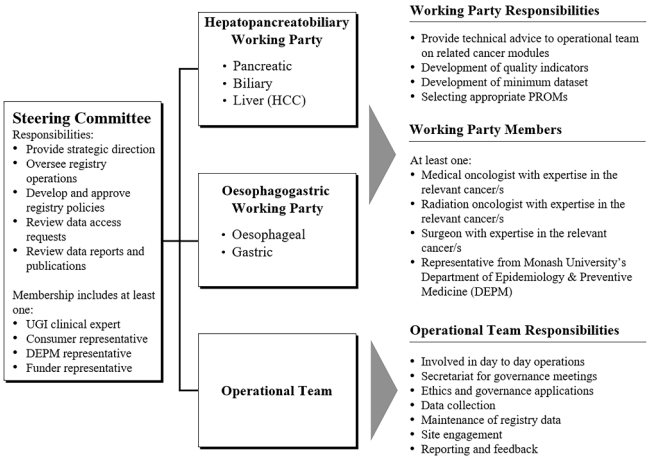

Figure 1 UGICR governance structure. HCC, hepatocellular carcinoma; PROMs, patient reported outcome measures; UGI, upper gastrointestinal.

gaps remain regarding optimal care and management of these patient groups.[4–8 36]

The 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 multicentre, 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.

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 at each participating hospital is responsible for ensuring that research activities undertaken at their site are conducted in accordance with the human research ethics committee (HREC) approval, the research protocol, site registry agreements and related policy documentation. At each site, patients are identified for recruitment and data collection occurs.

Registry design

The UGICR has a multimodular design with pancreatic, oesophagogastric (OG), liver and biliary cancer modules.

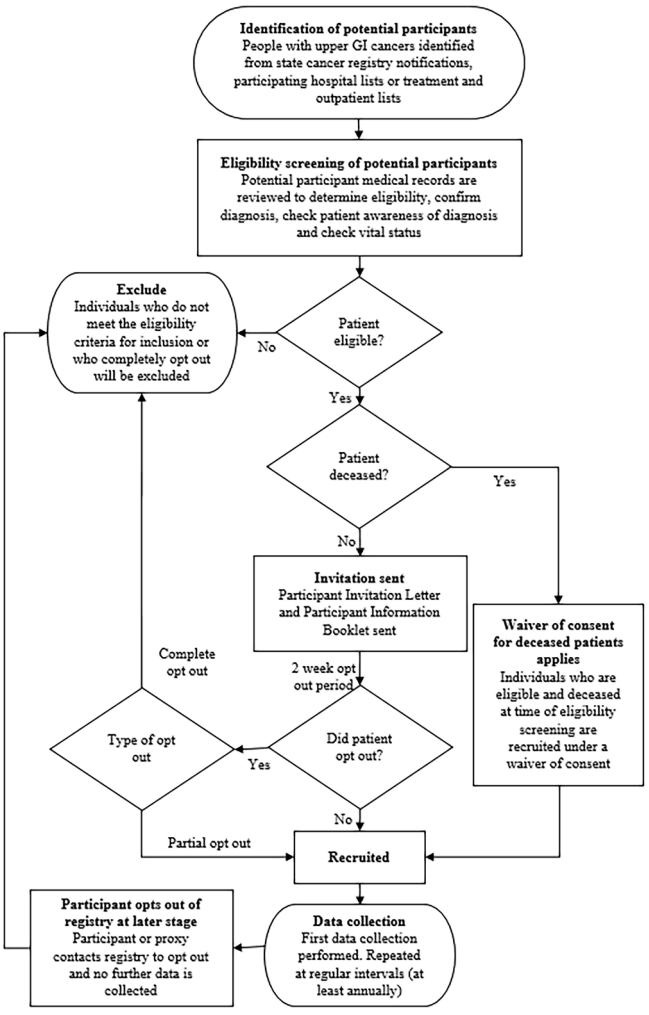

Figure 2 Registry recruitment schema. GI, gastrointestinal.

Data are entered into Research Electronic Data Capture (REDCap), 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 that 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]

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 2 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

Table 1 Eligibility criteria

All modules			
Inclusion	1. Patient has a confirmed primary pancreatic, oesophageal, gastric, liver, biliary or gall bladder cancer with some limited exclusions specified in each module (see below). 2. Patient has been assessed or received care at a participating public or private hospital or private clinician rooms. 3. Patient is 18 years of age or older at time of diagnosis. 4. Patient has a diagnosis date on or after 1 January 2016 (apart from one centre that 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. Gall bladder.	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.

*Liver module eligibility criteria still to be finalised.
IPMN, intraductal papillary mucinous neoplasm.

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 1 year, during which we collected data for a provisional set of quality indicators in three Victorian sites from 2016 to 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,

Table 2 PC Optimal Care Pathway (OCP) mapped to modified Delphi quality indicators

PC OCP	OCP elements	Mapped quality indicators from modified Delphi consensus[40]
Step 1: Prevention and early detection	1.1 Prevention. 1.2 Risk factors. 1.3 Early detection.	Nil
Step 2: Presentation, initial investigations and referral	2.1 Signs and symptoms. 2.2 Assessments by general practitioner 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 and 7.3 Support and communication	Nil
Step 3: 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 an MDT meeting.
	3.4, 4.4, 5.3, 6.5 and 7.2 Research and clinical trials	► Number of patients included in a clinical trial.
	3.1 and 3.2 Timeframe	► Time from referral to definitive treatment within 60 days.
Step 4: 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 chemoradiation.	► Adjuvant chemotherapy administered following surgery or a reason documented for not undergoing treatment.
	4.2.2 and 4.3 Treatment of unresectable PC/ palliative care.	► Chemotherapy±chemoradiation 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 5: Care after initial treatment and recovery Step 6: Managing recurrent, residual and metastatic disease	5.1 Survivorship. 5.2 Post-treatment care planning. 6.1 Signs and symptoms of recurrent, residual or metastatic disease.	► All patients having completed treatment followed up by a specialist every 3–6 months for up to 2 years.
Step 7: 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.

Some elements in each step of the pathway are overlapping. Elements 6.2 and 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.
ASA, American Society of Anesthesiologists (performance status); ECOG, Eastern Cooperative Oncology Group (performance status); MDT, Multidisciplinary Team.

staging and treatment planning; treatment; care after initial treatment and recovery; managing recurrent, residual or metastatic disease; and 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/).

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.

The OGC module has been developed by the OGC working party following a literature review, and a consensus method was used to agree on 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 PC 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 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] Furthermore, 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.

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 are 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 deidentified 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, for example, age, sex and 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. Furthermore, the UGICR provides a platform for longer term clinical follow-up, randomised clinical trials and substudies 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 with other

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 antitumour 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
Readmitted 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.
ED, Emergency Department; TNM (staging), Tumour, Node, Metastasis ; UGICR, Upper Gastrointestinal Cancer Registry.

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* 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	–	7 (3.9)
Palliative intent ChemoTx and/or RT	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†		
LA or Mets	62	60
Advanced age	1	6
Comorbidities	7	9
Patient declined	1	12
Patient died prior to surgery	0	7

Continued

Table 4 Continued

Variable	PC module n (%)	OGC module n (%)
Performance status	–	4
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 subform 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)

*TNM system of classification of cancer.
†Reason for no surgery: participants may have more than one reason documented.
ChemoTX, chemotherapy; RT, radiotherapy.

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 National Mutual Acceptance (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] Furthermore, 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 deidentified 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 (eg, biomedical) to evolve and fulfil its aim of providing quality evidence.

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