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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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3 **1 Cohort Profile: The Upper Gastrointestinal Cancer Registry (UGICR) – a clinical**
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5 **2 quality registry to monitor and improve care in upper gastrointestinal cancers**
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44 **Abstract**

45 **Purpose**

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

50 **Participants**

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

56 **Findings to date**

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

70 **Future plans**

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

76 **Article Summary**

77 **Strengths & Limitations of this Study**

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

90 **Keywords**

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

94

95 INTRODUCTION

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

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

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

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3 119 Local or distant cancer recurrence occurs frequently following resection for all UGI cancers.
4
5 120 A third of patients diagnosed with stomach¹³ and half of all patients diagnosed with
6
7 121 oesophageal¹⁴ cancer develop recurrent disease within two years. In pancreatic cancer, where
8
9 122 only 10%-15% of tumours are considered resectable, the local recurrence rate ranges from
10
11 123 10%-40% and distant recurrence is as high as 88%.¹⁵
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15 124 **Variation in Management, Treatment & Outcome**

16
17 125 There is evidence that variability exists in the management and outcomes of UGI cancers. For
18
19 126 example: not all patients are presented to a multi-disciplinary team meeting;¹⁶ there are
20
21 127 disparities in the utilisation of surgical resection and associated disease-specific survival
22
23 128 based on where patients live;¹⁷ there is wide variation in histopathological assessment of
24
25 129 margins and the proportion that have clear margins;¹⁵ the duration of surgery, post-operative
26
27 130 complication rates and their management differ between public and private hospitals;^{18,19}
28
29 131 administration of adjuvant chemotherapy or radiotherapy is variable, often due to morbidity
30
31 132 associated with postoperative complications;²⁰ and the 30-day postoperative mortality is
32
33 133 lower in hospitals performing more resections each year.^{21,22} Patients with UGI cancers have
34
35 134 significant unmet needs pertaining to quality of life, finance, relationships, and family or
36
37 135 caregiver distress; these are often exacerbated by a lack of understanding of the health
38
39 136 system.^{23,24} In pancreatic cancer, over 50% of participants (n=136) in an Australian-based
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41 137 study reported moderate to high unmet physical or psychological needs.²⁵
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48 138 **Measuring Quality of Care with Clinical Quality Registries**

49
50 139 To identify, understand and reduce unwarranted clinical variation and ensure that all patients
51
52 140 receive optimal care, it is important to collect high-quality disease-specific data. Clinical
53
54 141 Quality Registries (CQRs) support continuous improvements in patient outcomes by
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56 142 monitoring quality of care and providing risk-adjusted feedback to the relevant clinical
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58 143 community. These data describe patterns of treatment in order to identify variation, and can
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2
3 144 provide a framework for research.²⁶ Successful implementation of CQRs has been achieved
4
5 145 in a range of disciplines include trauma, cardiac, transplant and bariatric surgery,²⁷ joint
6
7 146 replacement,²⁸ and cancer care (e.g. prostate).²⁹
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10 147 The Australian Commission on Safety and Quality in Health Care (ACSQHC) supports the
11
12 148 development of CQRs in Australia through the provision of the national framework for
13
14 149 CQRs.³⁰ The framework details the necessary principles, guidelines and standards for best
15
16 150 practice design, build, operation and security of CQRs. A recent evaluation of the cost-
17
18 151 effectiveness of CQRs determined that when funded sufficiently with robust operating
19
20 152 procedures, CQRs provide a substantial return on investment.³¹ In prioritising the
21
22 153 development of CQRs in Australia, the ACSQHC ranked the development of registries for
23
24 154 high-burden cancers only behind those monitoring ischemic heart disease and
25
26 155 musculoskeletal disorders.³² Pancreatic cancer is ranked fourth as a high-burden cancer in
27
28 156 terms of its impact on disability-adjusted life years behind lung, bowel and breast cancer.³³ It
29
30 157 was predicted to be the third leading cause of cancer deaths in the United States in 2018 and
31
32 158 by 2030 is predicted to be the second commonest cause of cancer associated mortality.³
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39 159 Although a number of generic population-based cancer registries exist, there are no clinical
40
41 160 quality registries specific to the five aforementioned UGI cancers. Disease-specific
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43 161 registries^{34,35} and audit databases³⁶ provide much needed evidence about the management of
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45 162 patients with these cancers. However, little prospective data has been published from multi-
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47 163 institution databases and/or registries regarding the quality of UGI cancer care across the
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49 164 disease trajectory.
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53 165 **Rationale for the UGICR**

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55 166 Improvements in cancer outcomes for patients with UGI cancer will understandably come
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57 167 through establishment of models of care that are informed by close attention to clinical and
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59 168 patient-reported quality measures and standardisation of treatment which comply with agreed
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3 169 best practice. Given the lack of Australian population-level data regarding patient outcomes
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5 170 from UGI cancers, it was considered that a registry established to monitor treatment and
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7 171 outcomes of patients with cancers arising in the oesophagus, stomach, pancreas, liver and
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10 172 biliary system will improve management of these diseases. Furthermore, while detailed
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12 173 guidelines exist for each of these cancers, gaps remain regarding optimal care and
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15 174 management of these patient groups.^{5-9,37}

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18 175 The Upper Gastrointestinal Cancer Registry (UGICR) is a clinical quality registry established
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20 176 with the aims to:

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23 177 (1) assess patterns of care and identify variations in clinical and patient reported outcomes;
24
25 178 (2) benchmark performance and provide feedback to service providers using a targeted
26
27 179 quality improvement approach, to drive improvements in current practice;
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29
30 180 (3) provide confidence to public, clinician and wider stakeholders on the delivery of high
31
32 181 quality service;
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34 182 (4) advance knowledge of best treatment protocols by facilitating future clinical, health
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36 183 service, psychosocial and biomedical research.

38 39 184 **Cohort description**

40 41 185 *Overview*

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44 186 The UGICR is a multi-centre, population-based, non-interventional prospective cohort study
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46 187 that commenced in 2015.

47 48 188 *Ethical approval*

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51 189 The registry has human research ethics committee (HREC) approval as a multi-site project
52
53 190 with National Mutual Acceptance (NMA) from Monash Health (Ref: 15482A). Ethics
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55 191 approval has also been obtained from Monash University, Cancer Council Victoria, the
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3 192 Aboriginal Health and Medical Research Council of New South Wales and a number of
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5 193 private hospitals not recognising the NMA scheme.
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8 194 *Governance*

9
10 195 The UGICR is governed by a Steering Committee and, currently, two clinical working parties
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12 196 with the responsibility of each outlined in *Figure 1*. The Steering Committee performs in
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14 197 accordance with the Australian Framework for Clinical Quality Registries.³⁰
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18 198 A central research team provides operational oversights. A Principal Investigator (PI) at each
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20 199 participating hospital is responsible for ensuring that research activities undertaken at their
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22 200 site are conducted in accordance with the HREC approval, the research protocol, site registry
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24 201 agreements, and related policy documentation. At each site patients are identified for
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26 202 recruitment and data collection occurs.
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29 203 ***Figure 1 here***

30 204 *Registry design*

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32 205 The UGICR has a multi-modular design with pancreatic, oesophagogastric (OG), biliary and
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34 206 liver cancer modules. Data are entered into REDCap (Research Electronic Data Capture), a
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36 207 secure web-based application, hosted and managed by Helix (Monash University).³⁸ The
37
38 208 registry was developed in REDCap and all data are held securely on a Monash University
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40 209 server which has been accredited under the information security standard ISO27001.³⁹
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43 210 *Participant Recruitment and Consent*

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45 211 The full recruitment schema is outlined in *Figure 2*. Eligible patients are identified within
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47 212 each jurisdiction through state-based cancer registries or by individual health services.
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49 213 Eligibility criteria are listed in *Table 1*. The UGICR uses an opt-out approach to minimise
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51 214 selection bias.⁴⁰
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54 215 ***Figure 2 here***
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216 Table 1: Eligibility Criteria

| All Modules | | | |
|-------------------------|------------------|---|---|
| <i>Inclusion</i> | (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 | <i>Inclusion</i> | 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 |
| | <i>Exclusion</i> | Non-distal bile duct | Neuroendocrine neoplasms Premalignant lesions Mesenchymal tumours Solid pseudopapillary carcinoma IPMN (non-invasive) |
| Oesophagogastric | <i>Inclusion</i> | Oesophagus (lower two thirds) Gastro-oesophageal junction Stomach | Carcinoma Adenocarcinoma Squamous cell carcinoma Other subtypes |
| | <i>Exclusion</i> | Upper third of oesophagus | Neuroendocrine neoplasms Lymphomas Mesenchymal tumours |
| Biliary | <i>Inclusion</i> | Perihilar (hilar) bile duct Intrahepatic bile duct Gallbladder | Carcinoma Cholangiocarcinoma Adenosquamous carcinoma Squamous cell carcinoma Cholangiosarcoma |
| | <i>Exclusion</i> | Distal bile duct | Neuroendocrine neoplasms Mesenchymal tumours |
| Liver* | <i>Inclusion</i> | Liver | Hepatocellular carcinoma |
| | <i>Exclusion</i> | Intrahepatic bile duct | Cholangiocarcinoma Mesenchymal tumours Germ cell tumours Lymphomas |

217 Abbreviations: IPMN, Intraductal Papillary Mucinous Neoplasm

218 *Liver module eligibility criteria still to be finalised

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3 219 Eligible participants are mailed an introductory letter explaining the study and an information
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5 220 booklet outlining details of the registry, its purpose, possible outcomes of the research and the
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8 221 opt-out process. Participants are given two weeks to opt out of the registry before their
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10 222 consent is assumed, after which we commence collection of clinical and personal data
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12 223 covering diagnosis to end-of-life care. Patients can withdraw their consent from participation
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14 224 in the registry at any point by telephoning or emailing the UGICR office, as outlined in the
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16 225 participant information booklet. A waiver of consent applies where patients deemed eligible
17
18 226 require an interpreter, have significant cognitive impairment, or where there is evidence that
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20 227 the patient is deceased.

24 228 **Findings to date**

26 229 *Data Set*

28 230 The first module developed was the pancreatic cancer module, which began with a pilot
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30 231 phase during which we collected data for a provisional set of quality indicators in three
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32 232 Victorian sites from 2016-2017. Subsequently, we used a formal modified-Delphi consensus
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34 233 process to establish a core set of quality indicators for pancreatic cancer. This process
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36 234 involved 19 pancreatic cancer care experts from three states in Australia. A detailed
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38 235 description of the methods of the modified Delphi process and the selected indicators has
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40 236 been published separately.⁴¹ In addition, a review was undertaken of the Australian Optimal
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42 237 Care Pathways (OCP) for pancreatic cancer⁴² and oesophagogastric cancer⁴³ to ensure that
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44 238 indicators are aligned with the seven themes described in the OCP (prevention and early
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46 239 detection; presentation, initial investigations and referral; diagnosis, staging and treatment
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48 240 planning; treatment; care after initial treatment and recovery; managing recurrent, residual, or
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50 241 metastatic disease; end-of-life care). An outline of this process for pancreatic cancer is
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52 242 provided in *Table 2*.

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244 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • Number of patients included in a clinical trial |
| | 3.1, 3.2 Timeframe | <ul style="list-style-type: none"> • Time from referral to definitive treatment within 60 days |
| STEP FOUR: Treatment | 4.1 Treatment intent | NIL |
| | 4.2.1 Surgery (Curative) | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • All patients with metastatic disease referred to (or seen by) palliative care specialist |
| | 7.1 Multidisciplinary palliative care | |

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.

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3 246 The minimum data set was established to enable quality indicators to be calculated. Data
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5 247 items and definitions were aligned with national specifications where appropriate and a
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7 248 comprehensive data dictionary was developed for each module. The core data items are
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10 249 outlined in *Table 3*.
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250 Table 3: UGICR minimum dataset#

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

252 # 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

253 intent

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3 254 The OG module has been developed by the OG working party following a literature review,
4
5 255 and a consensus method was used to agree upon the quality indicator set. The registry has
6
7 256 future plans to begin the collection of Patient Reported Outcomes (PROs) and Patient
8
9 257 Reported Experiences (PREs) to provide valuable patient perspectives. As an initial step, a
10
11 258 systematic review evaluating Patient Reported Outcome Measures (PROMs) in pancreatic
12
13 259 cancer has been undertaken by the UGICR team to define which PROMs are most
14
15 260 appropriate for this group of patients.
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19 261 *Data collection*

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21 262 If the participant has not opted out of the registry, data collectors abstract diagnosis, surgical,
22
23 263 pathology and treatment data directly from the participant's electronic and/or hard copy
24
25 264 medical records from participating sites or from clinician rooms. Data collection begins
26
27 265 within four months of recruitment with at least annual follow-up until end-of-life.
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31 266 *Reporting*

32
33 267 The registry will produce risk-adjusted benchmarked reports that will feed back de-identified
34
35 268 data to participating sites on the associated quality indicators. To provide fair and meaningful
36
37 269 benchmarked reports, we have undertaken a review of risk models to identify demographic
38
39 270 and baseline clinical variables (focusing on those over which clinicians have no control e.g.
40
41 271 age, sex, disease stage) that predict patient outcomes for the purposes of risk-adjustment. The
42
43 272 data from the registry will also permit validation of current predictive risk models and enable
44
45 273 further refinement of these tools. Publicly available annual reports that provide an overview
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47 274 of quality of care and the registry's activities will be published. A UGICR website
48
49 275 (www.ugicr.org.au) has been developed to provide information about the registry to patients,
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51 276 clinicians and other stakeholders. This will be updated to include results as they become
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53 277 available.
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278 **Strengths and Limitations**

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

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

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

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

1
2
3 301 statisticians will determine an analysis plan for each indicator with due consideration to data
4
5 302 completeness and risk adjustment methods.

8 303 *Identified challenges*

10 304 The UGICR has faced some key challenges affecting its establishment and implementation.

12 305 The introduction of the NMA scheme has significantly streamlined the ethics process for all
13
14 306 public hospitals in Australia, except in the Northern Territory, making the process to gain
15
16 307 approval for CQRs more manageable. However, obtaining governance approval at each site
17
18 308 continues to be both labour intensive and time consuming.^{47,48} Further, separate HREC
19
20 309 approval is frequently required to access data from private hospitals and clinics.

24 310 Funding is another challenge faced by CQRs. As with many healthcare initiatives, the
25
26 311 financial burden can be a major impediment.²⁶ Data from CQRs are held in positive regard by
27
28 312 clinicians, health managers and government. However, further funding will be required to
29
30 313 progress national rollout of the registry.

34 314 Other identified barriers include reluctance of some healthcare providers to supply source
35
36 315 data, and poor interoperability between clinical information systems leading to duplication of
37
38 316 data entry. Where data are of high quality, such as for diagnosis and procedure codes,
39
40 317 administrative data is appropriate, but there are limited data for comorbidities and risk
41
42 318 factors.⁴⁹ While automation of data collection from existing data sources would be ideal, this
43
44 319 is hampered by inconsistent documentation and a lack of standardisation.⁵⁰

48 320 *Collaboration*

50 321 The UGICR aims to capture whole of population, real-world data that monitors and aspires to
51
52 322 improve the quality of care provided to patients with UGI cancers. The registry is currently
53
54 323 recruiting hospitals to increase population capture and selecting the most relevant instruments
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56 324 for measuring PROs and PREs for inclusion in each module. The biliary module is entering
57
58 325 its pilot phase and the liver module is to be developed. Monash University is the UGICR's

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3 326 data custodian and is accountable for the privacy, security and integrity of patient information
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5
6 327 held within the registry. Participating sites can request a copy of their own patient-level data.
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8 328 Researchers may access registry data following a formal submission to the UGICR data
9
10 329 custodian and approval by the UGICR Steering Committee. They are required to complete a
11
12 330 request form detailing their research aims and methods, potential impact on healthcare, and
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14 331 provide evidence relevant HREC approval before de-identified data will be released. The
15
16 332 registry will harness new opportunities for data linkage with technologies such as the
17
18 333 electronic medical records and collaborate with existing data repositories (e.g. biomedical) to
19
20 334 evolve and fulfil its aim of providing quality evidence.
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23 335 **Declarations**

24 336 **Ethics approval**

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26 337 This project has received human research ethics committee (HREC) approval from the
27
28 338 following HRECs: Monash Health (Ref: 15482A) under the National Mutual Acceptance
29
30 339 (NMA) scheme (HREC/15/MonH/134); Cancer Council Victoria (HREC 1611); Epworth
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32 340 HealthCare (EH2017-227), Aboriginal Health & Medical Research Council (1387/18) and is
33
34 341 registered with Monash University (CF16/119-2016000051).
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40 342 **Patient and Public Involvement**

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42 343 The UGICR uses an opt-out approach to minimise selection bias and participants are given
43
44 344 two weeks to opt out of the registry before their consent is assumed. Patients can withdraw
45
46 345 their consent from participation in the registry at any point. A waiver of consent applies
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48 346 where patients deemed eligible require an interpreter, have significant cognitive impairment,
49
50 347 or where there is evidence that the patient is deceased. This approach has been approved by
51
52 348 the aforementioned ethics committees.
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56 349 **Consent for publication**

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58 350 Not Applicable
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3 351 [Availability of data and material](#)
4

5 352 Not Applicable
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7 353 [Competing interests](#)
8

9 354 None declared
10

11 355 [Data sharing statement](#)
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13
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15

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17

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27

28 363 steering committee representation.
29

30 364 [Authors' Contributions](#)
31

32 365 AM and JH are joint first authors on this manuscript. SE, WB, DC, CP, JK, LL, TL, JM, MN
33

34 366 and JZ are part of the UGICR Steering Committee. SE, WB, DC, CP, JK, LL, TL, MN, AA,
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37

38 368 the working parties. RS and JH developed the registry protocol in consultation with the
39

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Figures

Figure 1 Title: UGICR governance structure

Fig 1 legend: HCC= hepatocellular carcinoma

Figure 2 Title: Registry Recruitment Schema

For peer review only

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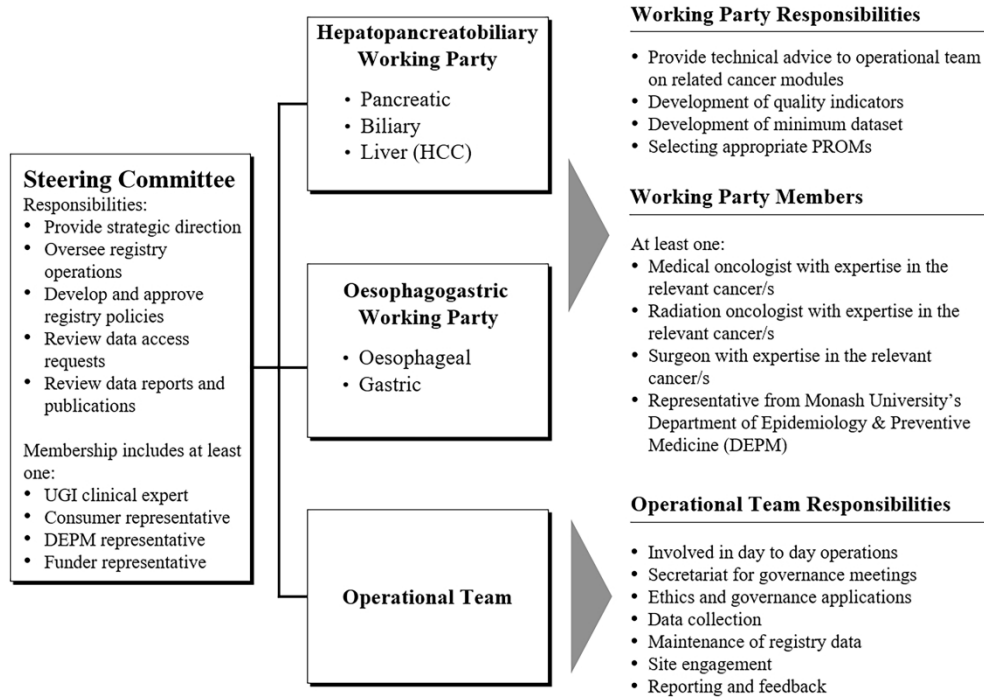


Figure 1: UGICR governance structure / HCC= hepatocellular carcinoma

296x206mm (300 x 300 DPI)

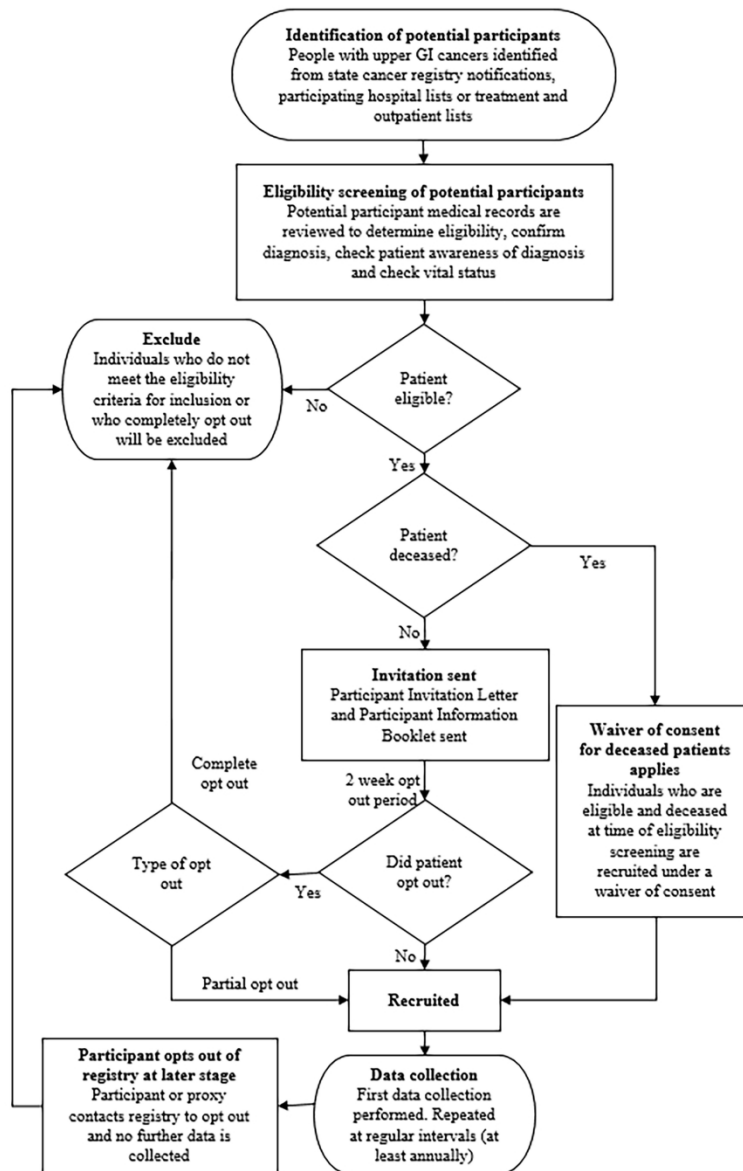


Figure 2 Title: Registry Recruitment Schema

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BMJ Open

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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| Primary Subject | Oncology |

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|----------------------------|---|
| Heading: | |
| Secondary Subject Heading: | Public health, Epidemiology |
| Keywords: | Hepatobiliary tumours < ONCOLOGY, Gastrointestinal tumours < GASTROENTEROLOGY, Gastrointestinal tumours < ONCOLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Pancreatic disease < GASTROENTEROLOGY, Oesophageal disease < GASTROENTEROLOGY |
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3 **1 Cohort Profile: The Upper Gastrointestinal Cancer Registry (UGICR) – a clinical**
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5 **2 quality registry to monitor and improve care in upper gastrointestinal cancers**
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44 ABSTRACT (300 words)

45 Purpose

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

48 Participants

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

54 Findings to Date

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

66 Future plans

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

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3 69 health service level. The registry has also been developed with the view to collect Patient-
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5 70 Reported Outcomes (PROs), which will further add to our understanding of the care of
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8 71 patients with these cancers.

10 72 **ARTICLE SUMMARY**

12 73 **Strengths & Limitations of this Study**

- 15 74 • The UGICR is the first CQR in Australia, designed to capture information on UGI
16
17 75 cancers with the aim to improve practice by monitoring and providing benchmarked
18
19 76 reports to participating sites.
- 22 77 • We describe the development of a CQR for UGI cancers, including the establishment of
23
24 78 governance, recruitment framework, clinical quality indicators, minimum data set, data
25
26 79 access policy and reporting structure.
- 29 80 • This registry was developed as per the Australian Commission on Quality and Safety in
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31 81 Health Care's (ACSQHC) Framework for Australian CQRs and follows ACSQHC's
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33 82 Australian Operating Principles for CQRs and can be used as a model for researchers
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35 83 developing CQRs.
- 38 84 • The time consuming and labour-intensive site governance approval process in Australia
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40 85 is a major limitation for rollout of the registry.

42 86 **Keywords**

45 87 pancreatic cancer, oesophageal cancer, gastric cancer, liver cancer, biliary cancer, upper
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47 88 gastrointestinal cancers, clinical registry, quality improvement, quality of care, database,
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49 89 population health

52 90 **INTRODUCTION**

55 91 The five most common upper gastrointestinal (UGI) cancers in Australia are pancreas,
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57 92 oesophagus, stomach, liver (hepatocellular carcinoma) and biliary cancers; the combined
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59 93 incidence is approximately 10,000 and there are around 7,500 deaths annually.¹ The five-year

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3 94 relative survival rates of UGI cancers are among the worst of all tumour types: 9.8% in
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5 95 pancreas; 18.5% in liver; 20.1% in biliary; 22% in oesophagus; and 30.3% in stomach.¹ The
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7
8 96 dismal prognosis of these cancers can be largely attributed to their presentation at an
9
10 97 advanced disease stage. Additionally, older age is a risk factor for mortality from these
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12 98 tumours, and significant cardiac and respiratory comorbidities may limit treatment options.
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14 99 As a result, only 15% of pancreas, 43% of liver, 20% of oesophagus, and 50% of stomach
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16
17 100 cancers are potentially resectable at diagnosis.^{2,3}

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20 101 Resection, with radical lymph node dissection where appropriate, remains the principal
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22 102 potentially curative therapy for all localised UGI cancers. Disease management is almost
23
24 103 invariably multimodal and may include chemotherapy and radiotherapy as neo-adjuvant,
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27 104 adjuvant or palliative therapy, and the provision of optimal supportive care.⁴⁻⁸

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30 105 The aggressive nature of these cancers and the complexity of treatment often decrease health-
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32 106 related quality of life.⁹ Advances in surgical techniques and perioperative care have resulted
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34 107 in operative mortality falling to less than 5% in major centres.¹⁰ However surgery remains a
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37 108 morbid procedure with postoperative complications resulting in prolonged hospital
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39 109 admission, adversely impacting on overall quality of life and the ability to undergo any
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41 110 adjuvant therapies.¹¹ In those surviving one to two years following curative treatment, health-
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43 111 related quality of life generally recovers to baseline. However, there are still major challenges
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46 112 faced by survivors. For those having palliative or supportive therapy only, quality of life
47
48 113 frequently deteriorates throughout the disease trajectory.⁹

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51 114 Local or distant cancer recurrence occurs frequently following resection for all UGI cancers.
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53 115 A third of patients diagnosed with stomach¹² and half of all patients diagnosed with
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56 116 oesophageal¹³ cancer develop recurrent disease within two years. In pancreatic cancer (PC),
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3 117 where only 10%-15% of tumours are considered resectable, the local recurrence rate ranges
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5 118 from 10%-40% and distant recurrence is as high as 88%.¹⁴
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7 119 **Variation in Management, Treatment & Outcome**

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9
10 120 There is evidence that variability exists in the management and outcomes of UGI cancers. For
11
12 121 example: not all patients are presented to a multi-disciplinary team meeting;¹⁵ there are
13
14 122 disparities in the utilisation of surgical resection and associated disease-specific survival
15
16 123 based on where patients live;¹⁶ there is wide variation in histopathological assessment of
17
18 124 margins and the proportion that have clear margins;¹⁴ the duration of surgery, post-operative
19
20 125 complication rates and their management differ between public and private hospitals;^{17,18}
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22 126 administration of adjuvant chemotherapy or radiotherapy is variable, often due to morbidity
23
24 127 associated with postoperative complications;¹⁹ and the 30-day postoperative mortality is
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26 128 lower in hospitals performing more resections each year.^{20,21} Patients with UGI cancers have
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28 129 significant unmet needs pertaining to quality of life, finance, relationships, and family or
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30 130 caregiver distress; these are often exacerbated by a lack of understanding of the health
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32 131 system.^{22,23} In PC, over 50% of participants (n=136) in an Australian-based study reported
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34 132 moderate to high unmet physical or psychological needs.²⁴
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40 133 **Measuring Quality of Care with Clinical Quality Registries**

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43 134 To identify, understand and reduce unwarranted clinical variation and ensure that all patients
44
45 135 receive optimal care, it is important to collect high-quality disease-specific data. Clinical
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47 136 Quality Registries (CQRs) support continuous improvements in patient outcomes by
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49 137 monitoring quality of care and providing risk-adjusted feedback to the relevant clinical
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51 138 community. These data describe patterns of treatment in order to identify variation, and can
52
53 139 provide a framework for research.²⁵ Successful implementation of CQRs has been achieved
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55 140 in a range of disciplines include trauma, cardiac, transplant and bariatric surgery,²⁶ joint
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57 141 replacement,²⁷ and cancer care (e.g. prostate).²⁸
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3 142 The Australian Commission on Safety and Quality in Health Care (ACSQHC) supports the
4
5 143 development of CQRs in Australia through the provision of the national framework for
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7 144 CQRs.²⁹ The framework details the necessary principles, guidelines and standards for best
8
9 145 practice design, build, operation and security of CQRs. A recent evaluation of the cost-
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11 146 effectiveness of CQRs determined that when funded sufficiently with robust operating
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13 147 procedures, CQRs provide a substantial return on investment.³⁰ In prioritising the
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15 148 development of CQRs in Australia, the ACSQHC ranked the development of registries for
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17 149 high-burden cancers only behind those monitoring ischemic heart disease and
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19 150 musculoskeletal disorders.³¹ Pancreatic cancer is ranked fourth as a high-burden cancer in
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21 151 terms of its impact on disability-adjusted life years behind lung, bowel and breast cancer.³² It
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23 152 was predicted to be the third leading cause of cancer deaths in the United States in 2018 and
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25 153 by 2030 is predicted to be the second commonest cause of cancer associated mortality.²
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31 154 Although a number of generic population-based cancer registries exist, there are no CQRs
32
33 155 specific to the five aforementioned UGI cancers. Disease-specific registries^{33,34} and audit
34
35 156 databases³⁵ provide much needed evidence about the management of patients with these
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37 157 cancers. However, little prospective data has been published from multi-institution databases
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39 158 and/or registries regarding the quality of UGI cancer care across the disease trajectory.

159 Rationale for the UGICR

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

1
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3 167 guidelines exist for each of these cancers, gaps remain regarding optimal care and
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5 168 management of these patient groups.^{4-8,36}
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8 169 The Upper Gastrointestinal Cancer Registry (UGICR) is a CQR established with the aims to:
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10
11 170 (1) assess patterns of care and identify variations in clinical and patient reported outcomes;
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13 171 (2) benchmark performance and provide feedback to service providers using a targeted
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15 172 quality improvement approach, to drive improvements in current practice;
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18 173 (3) provide confidence to public, clinician and wider stakeholders on the delivery of high
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20 174 quality service;
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22 175 (4) advance knowledge of best treatment protocols by facilitating future clinical, health
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24 176 service, psychosocial and biomedical research.
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28 177 **COHORT DESCRIPTION**

29 178 **Overview**

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31 179 The UGICR is a multi-centre, population-based, non-interventional prospective cohort study.
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33 180 It was established in 2015 in Victoria and has since expanded to the state of New South
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35 181 Wales, Australia.
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39 182 **Ethical approval**

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41 183 The registry has human research ethics committee (HREC) approval as a multi-site project
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43 184 with National Mutual Acceptance (NMA) from Monash Health (Ref: 15482A). Ethics
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45 185 approval has also been obtained from Monash University, Cancer Council Victoria, the
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48 186 Aboriginal Health and Medical Research Council of New South Wales and a number of
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50 187 private hospitals not recognising the NMA scheme.
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188 Governance

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

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

197 *Figure 1 here*

198 Registry design

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

204 Participant Recruitment and Consent

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

209 *Figure 2 here*

210 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 | <i>Inclusion</i> | 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 |
| | <i>Exclusion</i> | Non-distal bile duct | Neuroendocrine neoplasms Premalignant lesions Mesenchymal tumours Solid pseudopapillary carcinoma IPMN (non-invasive) |
| Oesophagogastric | <i>Inclusion</i> | Oesophagus (lower two thirds) Gastro-oesophageal junction Stomach | Carcinoma Adenocarcinoma Squamous cell carcinoma Other subtypes |
| | <i>Exclusion</i> | Upper third of oesophagus | Neuroendocrine neoplasms Lymphomas Mesenchymal tumours |
| Biliary | <i>Inclusion</i> | Perihilar (hilar) bile duct Intrahepatic bile duct Gallbladder | Carcinoma Cholangiocarcinoma Adenosquamous carcinoma Squamous cell carcinoma Cholangiosarcoma |
| | <i>Exclusion</i> | Distal bile duct | Neuroendocrine neoplasms Mesenchymal tumours |
| Liver* | <i>Inclusion</i> | Liver | Hepatocellular carcinoma |
| | <i>Exclusion</i> | Intrahepatic bile duct | Cholangiocarcinoma Mesenchymal tumours Germ cell tumours Lymphomas |

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

213 Eligible participants are mailed an introductory letter explaining the study and an information

214 booklet outlining details of the registry, its purpose, possible outcomes of the research and the

215 opt-out process. Participants are given two weeks to opt out of the registry before their

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3 216 participation is assumed, after which we commence collection of clinical and personal data
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5 217 covering diagnosis to end-of-life care. Patients can withdraw their consent from participation
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7 218 in the registry at any point by telephoning or emailing the UGICR office, as outlined in the
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9 219 participant information booklet. A waiver of consent applies where patients deemed eligible
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11 220 require an interpreter, have significant cognitive impairment, or where there is evidence that
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13 221 the patient is deceased.
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16 222 **FINDINGS TO DATE**

17 223 **Data Set**

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19 224 The first module developed was the PC module, which began with a pilot phase of
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21 225 approximately one year, during which we collected data for a provisional set of quality
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23 226 indicators in three Victorian sites from 2016-2017. The second module developed using a
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25 227 similar pilot phase was the OG module. Subsequently, we used a formal modified-Delphi
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27 228 consensus process to establish a core set of quality indicators for PC. This process involved
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29 229 19 PC care experts from three states in Australia. A detailed description of the methods of the
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31 230 modified Delphi process and the selected indicators has been published separately.⁴⁰ In
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33 231 addition, a review was undertaken of the Australian Optimal Care Pathways (OCP) for PC⁴¹
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35 232 and OGC⁴² to ensure that indicators are aligned with the seven themes described in the OCP
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37 233 (prevention and early detection; presentation, initial investigations and referral; diagnosis,
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39 234 staging and treatment planning; treatment; care after initial treatment and recovery; managing
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41 235 recurrent, residual, or metastatic disease; end-of-life care). An outline of this process for PC
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43 236 is provided in *Table 2*. There are currently no clinical quality indicators in the UGICR that
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45 237 measure care for the prevention and early detection of PC. However, the UGICR is
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47 238 participating in a collaborative project, Symptom-UGI: Upper Gastrointestinal Cancer
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49 239 Symptom Study, to map the patient pathways from onset of symptoms to cancer diagnosis.
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240 Details of this study can be found within the UGICR website (<https://ugicr.org.au/associated->
241 [studies/](#)).

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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 | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> Number of patients included in a clinical trial |
| | 3.1, 3.2 Timeframe | <ul style="list-style-type: none"> Time from referral to definitive treatment within 60 days |
| STEP FOUR: Treatment | 4.1 Treatment intent | NIL |
| | 4.2.1 Surgery (Curative) | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> Adjuvant chemotherapy administered following surgery or a reason documented for not undergoing treatment |
| | 4.2.2, 4.3 Treatment of unresectable PC / palliative care | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> All patients with metastatic disease referred to (or seen by) palliative care specialist |
| | 7.1 Multidisciplinary palliative care | |

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.

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3 244 The minimum data set was established to enable quality indicators to be calculated. Data
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5 245 items and definitions were aligned with national specifications where appropriate and a
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7 246 comprehensive data dictionary was developed for each module. The core data items are
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10 247 outlined in *Table 3*.
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248 Table 3: UGICR Minimum Dataset[#]

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

250 # 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
251 intent

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3 252 The OGC module has been developed by the OGC working party following a literature
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5 253 review, and a consensus method was used to agree upon the quality indicator set. The registry
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8 254 has future plans to begin the collection of Patient Reported Outcomes (PROs) and Patient
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10 255 Reported Experiences (PREs) to provide valuable patient perspectives. As an initial step, a
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12 256 systematic review evaluating Patient Reported Outcome Measures (PROMs) in PC has been
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15 257 undertaken by the UGICR team to define which PROMs are most appropriate for this group
16
17 258 of patients.

19 259 [Data collection](#)

21 260 If the participant has not opted out of the registry, data collectors abstract diagnosis, surgical,
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23 261 pathology and treatment data directly from the participant's electronic and/or hard copy
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25 262 medical records from participating sites or from clinician rooms. Data collection begins close
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28 263 to the time of recruitment with at least annual follow-up until end-of-life.

31 264 [Results from the pilot studies from the PC and OGC modules.](#)

33 265 The results of the pilot phase for both PC and OGC modules are displayed in Table 4. Of the
34
35 266 123 participants eligible for the PC module and 189 for the OGC module, 8 (6.5%) and 9
36
37 267 (4.8%) opted out of the registry, respectively. Clinical stage at diagnosis was not well
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39 268 documented in both the PC module (n = 80, 70%) and OGC cancer module (n = 82, 46%)
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41
42 269 and is an area for future quality improvement. Around 20% of the pancreatic cohort received
43
44 270 surgery as first treatment which is broadly representative of surgical treatment in patients
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46 271 with PC⁴³. Further, 73 participants in the PC and 94 participants in the OGC module had
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48 272 documented reasons for no surgery. The pilot results for both modules identified areas for
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50 273 improving data completeness, definitions, items and structure of data collection forms.
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53 274 Following the pilot phase, the registry focused on improving these areas before expanding to
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55 275 other participating hospitals.
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276 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) |
| <i>Locally Advanced (LA)</i> | 24 (20.9) | 6 (3.3) |
| <i>Metastatic (Mets)</i> | 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) |

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

279 Population Coverage

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

285 Reporting

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

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3 291 data from the registry will also permit validation of current predictive risk models and enable
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5 292 further refinement of these tools. Publicly available annual reports that provide an overview
6
7 293 of quality of care and the registry's activities will be published. A UGICR website
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10 294 (<https://ugicr.org.au/>) has been developed to provide information about the registry to
11
12 295 patients, clinicians and other stakeholders. This will be updated to include results as they
13
14
15 296 become available.

17 297 **STRENGTHS AND LIMITATIONS**

18
19 298 The UGICR is Australia's first UGI cancer CQR. The aims of the registry are to monitor
20
21 299 quality of care, benchmark clinical and patient-reported outcomes against best practice, and
22
23 300 provide high-quality population-based data for clinical research. Registries such as the
24
25 301 UGICR provide much needed real-world evidence outside the context of randomised control
26
27 302 trials about disease epidemiology, treatment patterns, burden of illness, survival outcomes,
28
29 303 clinical variation, and treatment safety.⁴⁴

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34 304 In recent decades, there has been increasing integration of PROMs into cancer registries to
35
36 305 collect outcomes such as overall quality of life, functional and psychosocial well-being,
37
38 306 lifestyle behaviours, and supportive care needs.⁴⁵ Clinicians and patients may place different
39
40 307 emphasis on symptom impacts and expectations from their treatment.⁴⁶ The collection of
41
42 308 PROMs is an important step in understanding patients' experience of their symptoms and
43
44 309 management, and the impact of the disease and its treatment on their quality of life. The
45
46 310 UGICR will determine and integrate the most relevant PROMs for each UGI cancer type
47
48 311 following thorough examination of the literature.

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53 312 Through the accumulation of significant and consistent data on UGI cancers, the registry will
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55 313 assess how clinical management compares with best practice and communicate this to
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57 314 clinicians through the PIs or relevant hospital departments. Further, the UGICR provides a

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3 315 platform for longer-term clinical follow-up, randomised clinical trials and sub-studies
4
5 316 exploring treatment outcomes and linking outcomes to tumour tissue characteristics.
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8 317 An important consideration is the maturity of each module before useful quality indicator
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10 318 reports can be provided to participating hospitals, as some UGI cancers have a relatively low
11
12 319 incidence in comparison to other cancers.¹ The working groups in collaboration with
13
14 320 statisticians will determine an analysis plan for each indicator with due consideration to data
15
16 321 completeness and risk adjustment methods.
17

322 Identified challenges

323 The UGICR has faced some key challenges affecting its establishment and implementation.
324 The introduction of the NMA scheme has significantly streamlined the ethics process for all
325 public hospitals in Australia, except in the Northern Territory, making the process to gain
326 approval for CQRs more manageable. However, obtaining governance approval at each site
327 continues to be both labour intensive and time consuming.^{47,48} Further, separate HREC
328 approval is frequently required to access data from private hospitals and clinics.
329 Funding is another challenge faced by CQRs. As with many healthcare initiatives, the
330 financial burden can be a major impediment.²⁵ Data from CQRs are held in positive regard by
331 clinicians, health managers and government. However, further funding will be required to
332 progress national rollout of the registry.
333 Other identified barriers include reluctance of some healthcare providers to supply source
334 data, and poor interoperability between clinical information systems leading to duplication of
335 data entry. Where data are of high quality, such as for diagnosis and procedure codes,
336 administrative data is appropriate, but there are limited data for comorbidities and risk
337 factors.⁴⁹ While automation of data collection from existing data sources would be ideal, this
338 is hampered by inconsistent documentation and a lack of standardisation.⁵⁰

339 Collaboration

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

354 DECLARATIONS

355 Ethics approval

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

361 Patient and Public Involvement

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

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3 364 representatives will also be involved in future studies which include the selection of a core-
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5 365 set of PROMs.

8 366 [Consent for publication](#)

10 367 Not Applicable

12 368 [Availability of data and material](#)

14 369 Not Applicable

17 370 [Competing interests](#)

19 371 None declared

21 372 [Data sharing statement](#)

24 373 This study describes attributes of the registry and contains no patient-level data

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34 380 steering committee representation.

42 381 [Authors' Contributions](#)

44 382 AM and JH are joint first authors on this manuscript. SE, WB, DC, CP, JK, LL, TL, JM, MN
45 383 and JZ are part of the UGICR Steering Committee. SE, LI, WB, DC, CP, JK, LL, TL, MN,
46 384 AA, PB, PC, JC, CD, PE, DG, AH, MH, BK, NM, MM, RN, JP, IP, MS, JS, PT and JZ are
47 385 part of the working parties. RS and JH developed the registry protocol in consultation with
48 386 the UGICR Steering Committee and working parties. All authors reviewed and provided
49 387 feedback on the drafts of the manuscript and approved the final version.

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6
7
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9
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11
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13
14 393 ongoing data to the UGICR.
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FIGURE TITLES AND LEGEND

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Figure 1 Title: UGICR governance structure

Fig 1 legend: HCC= hepatocellular carcinoma

Figure 2 Title: Registry Recruitment Schema

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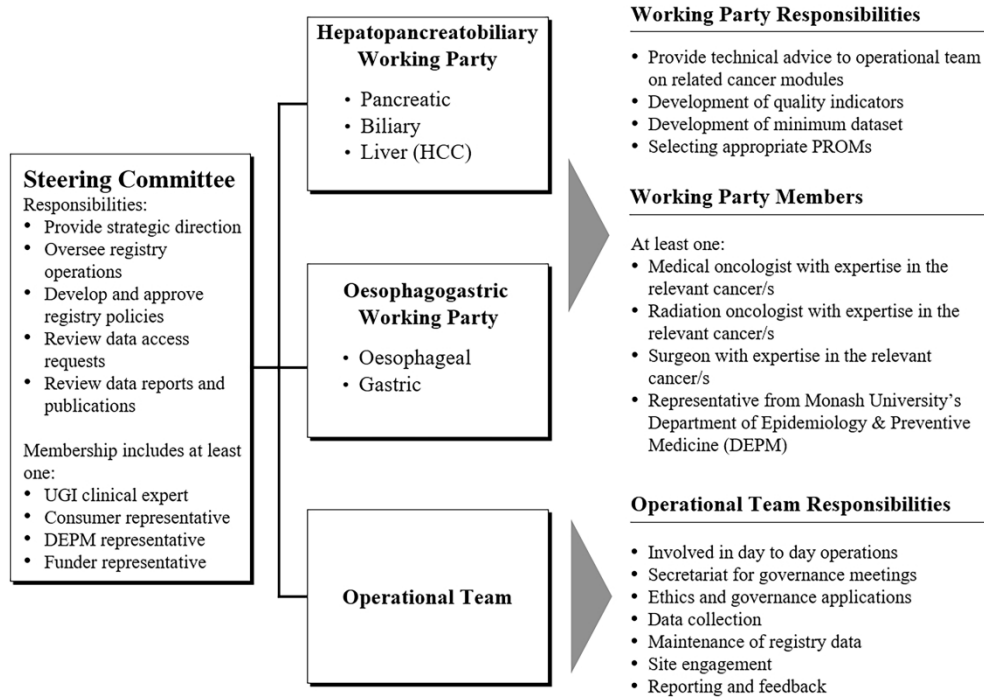


Figure 1: UGICR governance structure / HCC= hepatocellular carcinoma

296x206mm (300 x 300 DPI)

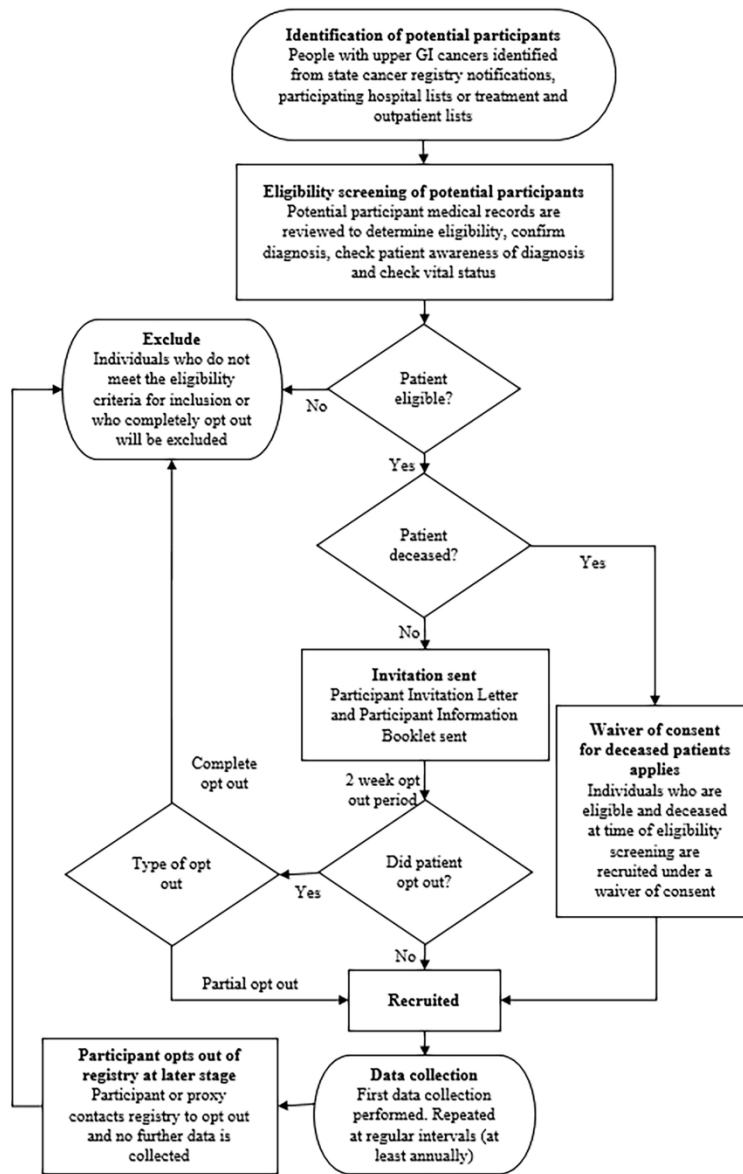


Figure 2 Title: Registry Recruitment Schema

134x208mm (300 x 300 DPI)