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Provision of Interventional Oncology Services in the United Kingdom: Pilot Study

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Manuscripts

1 Provision of Interventional Oncology Services in the United Kingdom: Pilot Study

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42 79 discussion with other authors and approving the manuscript for publication in discussion with the
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44 80 other authors.
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81 **Abstract**

82 **Objective:**

83 To map out the current provision of interventional oncology (IO) services in the United Kingdom.

84

85 **Design:**

86 Multi-centre survey

87

88 **Setting:**

89 All NHS Trusts in England and Scottish, Welsh and Northern Ireland health boards.

90

91 **Participants:**

92 Interventional Radiology departments in all NHS trusts/ health boards in the United Kingdom.

93

94 **Results**

95 A total of 179 NHS trusts/health boards were contacted. We received 100% response rate. 144
96 trusts (80%) provided IO services or had a formal pathway of referral in place for patients to a
97 recipient trust. 21 trusts (12%) had plans to provide an IO service or formal referral pathway in the
98 next 12 months only. 14 trusts (8%) did not have a pathway of referral and no plans to implement
99 one.

100 70 trusts (39%) offered both supportive and disease-modifying procedures. 73 trusts (41%)
101 provided only supportive procedures. Of these, 43 (59%) had a referral pathway for disease-
102 modifying IO procedures, either from a regional cancer network or through interventional radiology
103 networks. 14 (8%) did not have a pathway of referral and no plans to implement one.

104

105 **Conclusion**

106 The provision of IO services in the UK is promising however collaborative networks are necessary
107 to ensure disease-modifying IO procedures are made accessible to all patients and to facilitate
108 larger registry data for research with commissioning of new services.

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1
2 110 **Article Summary**

3
4 111 **Strengths and limitations of this study**

- 5
6 112 • 100% response rate from 179 Acute NHS Trusts and Health Boards throughout the United
7
8 113 Kingdom
- 9
10 114 • Provides comprehensive map of Interventional Oncology (IO) Services throughout the UK to
11
12 115 allow for more integrated cancer pathways on a national level.
- 13
14 116 • Map of the provision and geographic variation in disease modifying procedures such as tumour
15
16 117 ablation, which will allow for future planning of new IO services.
- 17
18 118 • Identifies types of supportive IO treatments, which are less routinely available apart from in
19
20 119 larger tertiary centres and therefore highlights areas to target for IO training.
- 21
22 120 • Limitations include those inherent to survey/ questionnaire format, such as subjective bias.
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1
2 125 **Introduction**

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4 126 More than 1-in-3 people will develop cancer in their lifetime[1]. Since the NHS Cancer Plan in
5
6 127 2000, the Department of Health has strived to improve diagnosis and treatment[1]. As part of the
7
8 128 NHS plans to deliver world-class cancer services, there is a drive to achieve better outcomes by
9
10 129 ensuring all patients have access to the best treatments available[2]. Wide variation remains in
11
12 130 performance across the country with major differences in access to cancer services[1].

13
14 131

15
16 132 Interventional oncology (IO), image guided procedures used to diagnose and treat oncological
17
18 133 patients, is fast becoming the four pillar of oncological care alongside medical, surgical and
19
20 134 radiation oncology. The Royal College of Radiologists have set out best practice guidance for the
21
22 135 incorporation of interventional oncology into all cancer services nationally[3]. There remains a
23
24 136 significant shortage of interventional radiologists, who are the primary contributors towards IO, with
25
26 137 almost half of services in England unable to provide a local or networked out of hours access to
27
28 138 Interventional Radiology (IR)[4]. Undoubtedly this shortfall will have consequences on the provision
29
30 139 of elective IO services in the UK and potentially affect patient care through limitations to access.

31
32 140 The current provision of Interventional Oncology services throughout the UK is unknown, therefore
33
34 141 NHS commissioners are unable to realistically factor IO into national cancer pathways as evident
35
36 142 in a previous Department of Health publication[1] which did not acknowledge IO as a treatment
37
38 143 option for patients out with surgery, chemotherapy and radiotherapy.

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40 144

41
42 145 The primary objective of this national survey was to map out the current provision of interventional
43
44 146 oncology services in the UK. We also sought to uncover formal patient referral pathways, the types
45
46 147 of IO procedures offered and any limitations to providing IO. Ultimately, we aim to develop IO
47
48 148 networks and improve access to these treatments for cancer patients.

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50 149

51
52 150 The survey was designed and undertaken in collaboration with the Interventional Oncology United
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54 151 Kingdom (IOUK) group, a specialist interest group of the British Society of Interventional Radiology
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56 152 (BSIR).

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1
2 154 **Method**

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4 155 No research ethics committee approval was required for this service redesign data-gathering
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6 156 project. No patient identifiable data was gathered.

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8 157

9
10 158 All NHS Foundation Trusts in England[5] and all health boards in Scotland, Wales and Northern
11
12 159 Ireland were contacted by email (see supplementary material). This was followed by a telephone
13
14 160 follow-up of all hospital radiology departments that did not complete the survey within 2 weeks of
15
16 161 the first email being sent out. Telephone follow-up was conducted by a single radiologist (JZ). The
17
18 162 survey could be completed by any of the following: Head of department of radiology/ interventional
19
20 163 radiology, any consultant radiologist (diagnostic or interventional) or superintendent radiographer
21
22 164 who has insight into the local provision of services.

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24 165

25
26 166 The surveys key points were:

- 27
28 167 • Are IO procedures offered in the trust?
29
30 168 • If so, are these supportive treatments only or both supportive and disease-modifying?
31
32 169 • We asked about the types of procedures undertaken
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34 170 • If not, is there an agreed formal pathway to another recipient trust?
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36 171 • If there was no agreed pathway, was there a plan to provide IO or a pathway in the next 12
37
38 172 months?
39
40 173 • What barriers are there to setting up an IO service?
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44
45 175 The full survey can be found in the online supplementary file.

46
47 176 Supportive and symptomatic procedures were defined as those providing relief from tumour-
48
49 177 related symptoms but do not modify the underlying malignant disease process and includes
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51 178 diagnostic tests such as image guided biopsy which 'support' the provision of definitive
52
53 179 treatment[3]. Disease modifying procedures were defined as those where the intent is to modify
54
55 180 malignant progression and/or modify the prognosis and includes image-guided ablation, trans-
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57 181 arterial chemoembolisation (TACE) and selective internal radiation therapy (SIRT).
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1
2 183 Following the initial survey we followed up all trusts/ health boards which only offered supportive
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4 184 treatments to see if there were formal referral pathways for disease-modifying procedures.
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6 185 A formal referral pathway was defined as an existing mechanism of referral through a multi-
7
8 186 disciplinary team responsible for the patient, usually through a pre-existing local oncology or
9
10 187 radiology network.

11
12 188

13 14 189 **Results**

15
16 190 A total of 179 NHS trusts or health boards were contacted throughout the United Kingdom. We
17
18 191 received 100% response rate. The responses came from consultant interventional and diagnostic
19
20 192 radiologists and superintendent radiographers who had insight into the local provision of services.
21
22 193 144 trusts (80%) provided IO services or had a formal pathway of referral in place for patients to a
23
24 194 recipient trust (Figure 1). 21 trusts (12%) had plans to provide an IO service or formal referral
25
26 195 pathway in the next 12 months only. 14 trusts (8%) did not have a pathway of referral and no plans
27
28 196 to implement one. 70 trusts (39%) offered both supportive and disease-modifying procedures on
29
30 197 site (Figure 2). 73 trusts (41%) provided only supportive procedures on site. One trust had a
31
32 198 formal referral pathway for supportive IO. Only 19 (11%) institutions had an interventional oncology
33
34 199 lead.

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36 200

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38 201 The number of trusts providing each supportive/ symptomatic IO procedure and disease-modifying
39
40 202 procedure are shown in table 1 and table 2. These are represented in graphical form in Figure 3.
41
42 203 Figure 4 and 5 show the maps of the trusts providing each type of disease-modifying procedure.

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46 205 For England only, a total of 153 NHS Foundation trusts in England were contacted. 127 (83%)
47
48 206 trusts provided IO services or had a formal pathway of referral to another agreed recipient trust for
49
50 207 IO procedures (Figure 1). Out of the 26 that did not have a formal referral pathway, 21 (14%) trusts
51
52 208 had plans to provide an IO service or formal referral pathway for patients to have IO at another
53
54 209 trust within the next 12 months. 5 (3%) trusts did not have a pathway and had no plans of providing
55
56 210 IO or a referral pathway in the next 12 months (Figure 1). 57 out of 127 (45%) trusts providing IO

1 211 offered both supportive and disease modifying procedures (Figure 2). 70 out of 127 (55%)
2
3 212 provided only supportive procedures.

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5 213

6
7 214 For Scotland, 10 out of 14 health boards provided IO or had a formal pathway of referral to a
8
9 215 specialist hospital in another health board (Glasgow or Edinburgh). Of these, 8 health boards
10
11 216 provided both supportive and disease-modifying IO while 2 provided only supportive IO. 4 health
12
13 217 boards (29%) did not provide IO and did not have plans to provide a pathway in the next 12
14
15 218 months.

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19 220 For Wales, 6 out of 7 health boards (86%) provided IO or had a referral pathway in place. 4 Welsh
20
21 221 health boards (57%) provided both types of IO, one health board provided only supportive IO and
22
23 222 one had a formal referral pathway. One Welsh health board did not offer IO or have a referral
24
25 223 pathway implemented in the next 12 months.

26
27 224 Only 1 out of 5 health boards in Northern Ireland (Belfast Health and Social Care Trust) provided
28
29 225 IO (both types).

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31 226

32
33 227 Out of the 70 English NHS trusts and 3 Scottish/ Welsh Health Boards, which provided only
34
35 228 supportive IO, 43 trusts (59%) had a referral pathway to another hospital/ trust for disease-
36
37 229 modifying IO procedures. This was from a local regional cancer network referral initiated following
38
39 230 a formal discussion at the multi-disciplinary team meeting.

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41 231

42
43 232 The most common barriers to providing disease-modifying IO were insufficient funding, lack of
44
45 233 staff, lack of support from other non-radiology clinicians, having a pathway already in place and
46
47 234 problems with recruitment into IR.

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50
51 236 **Discussion**

52
53 237 Overall, the provision of IO in the UK is promising. Based on the Royal College of Radiologists
54
55 238 definition of 'supportive' IO[1], this encompasses many routine procedures that can be carried out
56
57 239 by diagnostic radiologists which is reflected in the excellent availability of these procedures
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1
2 240 throughout the UK. Beyond basic image-guided drainage procedures, the provision of specialist
3
4 241 vascular, gastro-intestinal or biliary 'symptomatic' intervention is less routinely available apart from
5
6 242 in the larger tertiary centers which were also providing disease-modifying IO. This highlights
7
8 243 important areas to target for radiology and IO training.
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10 244

11 245 Given the vital role of IR in the management of critically ill patients, the comprehensive provision of
12
13 246 supportive IO in most parts of the UK reflects the drive to train more radiologists with basic
14
15 247 interventional skills, which are also transferrable to IO[6]. We acknowledge that providing out of
16
17 248 hours IR is not directly related to IO however it will allow for 'supportive' IO to be routinely available
18
19 249 which encompasses many routine procedures that are the backbone of IO, whereas disease-
20
21 250 modifying treatments can be centralized as part of the current NHS model for cancer services[7].
22
23

24 251 There are still NHS trusts/ boards, most noticeably in rural Scotland and Northern Ireland where
25
26 252 provision of IO services appear limited and linking up with neighboring hospitals to set up formal
27
28 253 pathways would be a first step to improving access for patients to disease-modifying IO. What
29
30 254 remains unclear is what the current demand for IO services are generally but particularly in these
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32 255 rural regions, as we have no data to suggest current arrangements are sub-optimal. It would not be
33
34 256 necessary or appropriate for all providers to liaise with IO services, and these should be facilitated
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36 257 through regional cancer networks with more integrated pathways of care[7]. Currently there
37
38 258 appears to be 136 out of 153 acute NHS trusts in England, which are listed to offer acute oncology
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40 259 services[8]. Further work is required to elucidate whether there is any discrepancy in the regional
41
42 260 demand and supply of disease-modifying IO.
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45
46 262 Of the trusts that only offered supportive IO, 59% had a formal referral pathway to another centre
47
48 263 for disease-modifying IO. The perceived barriers from these trusts to starting up elective disease-
49
50 264 modifying services stemmed from shortfalls in funding, staffing and support from other specialties.
51

52 265 With tertiary centres undertaking much higher volumes of disease modifying IO procedures, some
53
54 266 smaller district general hospitals felt unsupported in starting up their own service, from financial
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56 267 considerations when purchasing the equipment to garnering support from allied specialties such as
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58 268 surgery and oncology. This is an important point as it highlights the need for greater awareness of
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1
2 269 the role of the interventional radiologist in oncology care and we must strive to work even closer
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4 270 with oncologists given the new evidence suggesting the added value of combination therapies and
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6 271 incorporation of IO procedures into European cancer guidelines[9]. However, with the current
7
8 272 model of centralizing cancer services, these barriers would only be an issue if cancer centers were
9
10 273 unable to provide IO. To improve patient selection for complex IO procedures, interventional
11
12 274 radiologists should have a regular role in multi-disciplinary team meetings. With only 19 institutions
13
14 275 (11%) currently having a formal IO lead clinician, there is a role for dispersed leadership to achieve
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16 276 structural change in established cancer networks.
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20 278 Local expertise and facilities help determine the IO that is offered. An example is the provision of
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22 279 disease-modifying IO for the liver, which is centred around the national liver transplant units[10].
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24 280 The reasons for this are clear given that image-guided tumour ablation, TACE and SIRT are
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26 281 effective therapies than can be used solely or in combination with chemotherapy or surgery to
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28 282 improve the outcome of such patients who can be complex and should be managed by multi-
29
30 283 disciplinary teams (MDT) [11 12]. Interventional radiologists must endeavor to participate in MDT
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32 284 discussions to educate other clinicians on the role of IO in the management of patients and
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34 285 contribute towards improvement and restructuring of services. This will also open opportunities to
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36 286 undertake collaborative research that will be higher impact and wider reaching to the oncology
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38 287 community.
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41
42 289 The recurrent issue of lack of staffing within IR remains a barrier. Despite the promising provision
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44 290 of supportive IO, most departments are struggling to cope with the demand for basic vascular,
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46 291 urological and biliary procedures, necessary to provide a sustainable out of hours service, without
47
48 292 compounding this with additional workload and need for additional training for disease-modifying
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50 293 IO. Additional need for interventional radiographers and nursing cover for IO services should not
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52 294 be overlooked either to allow a new service to be introduced.
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56 296 Changes to the delivery of healthcare throughout the UK demands that IO treatments can
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58 297 demonstrate not only a therapeutic benefit but also cost-effectiveness. For units with a referral
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1
2 298 pathway for disease-modifying IO, there was a common theme that this set-up was more cost
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4 299 effective than starting a service from scratch. Without knowledge of the actual demand for these IO
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6 300 procedures, there is no answer to this currently, and clinical investigators must incorporate
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8 301 measures of cost-effectiveness and patient-reported outcomes into large-scale studies to provide
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10 302 more robust evidence[13]. Even if these IO treatments can be shown to be equally effective
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12 303 compared with the current standard of care but with significantly less morbidity, then it will allow
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14 304 the specialty to develop further, however current studies have not offered definitive
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16 305 conclusions[14]. Building upon the knowledge of these IO networks will allow better registry data
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18 306 that can be used to derive larger cohorts for future trials and also commissioning of new services.
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21
22 308 The limitations of the present study include those inherent in the survey/ questionnaire format such
23
24 309 as the subjective element depending on whether a superintendent radiographer or consultant
25
26 310 radiologist responded given their underlying experience and knowledge of their radiology services
27
28 311 which could impact on the detail of their survey answers. The strengths of the survey include 100%
29
30 312 response rate from 179 acute NHS trusts/ health boards which allowed a comprehensive map of
31
32 313 both supportive and disease-modifying IO procedures offered in the UK that will help direct
33
34 314 radiology/IO training, future planning of new IO services and allow for more integrated cancer
35
36 315 pathways.
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38 316

39 317 **Conclusion**

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42 318 The provision of IO services in the UK is promising however collaboration and networking is
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44 319 necessary to ensure disease-modifying IO procedures are made accessible to all patients
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46 320 throughout the UK and to facilitate larger registry data for research and commissioning of new
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48 321 services.
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11
12 329 work; no financial relationships with any organisations that might have an interest in the submitted
13
14 330 work in the previous three years; no other relationships or activities that could appear to have
15
16 331 influenced the submitted work
17
18 332
19
20 333 Transparency declaration: I affirm that the manuscript is an honest, accurate, and transparent
21
22 334 account of the study being reported; that no important aspects of the study have been omitted; and
23
24 335 that any discrepancies from the study as planned (and, if relevant, registered) have been
25
26 336 explained.
27
28 337
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30 338 Data sharing: no additional data available.
31
32 339

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2 381 **Figure Legends:**

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4 382 **Figure 1:** UK Map showing the overall provision of interventional oncology (IO) services
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6 383 throughout the UK.

7
8 384 **Figure 2:** UK Map showing what types of IO procedures (supportive and/ or disease modifying
9
10 385 procedures) are undertaken in each NHS trust/ health board.

11
12 386 **Figure 3:** Bar charts showing number of trusts offering: (A) Each type of supportive/symptomatic
13
14 387 IO procedure and (B) Each type of disease-modifying IO procedure.

15
16 388 **Figure 4:** UK Map showing the provision of ablation services: (A) Renal ablation (B) Liver ablation
17
18 389 (C) Bone ablation and (D) Lung ablation.

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20 390 **Figure 5:** UK Map showing the provision of (A) Trans-arterial chemoembolization (TACE) and (B)
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22 391 Selective internal radiation therapy (SIRT).

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397 **Table Legends**

398 **Table 1:** Type of supportive/ symptomatic IO procedure and number of trusts that offer each and
 399 percentage of total number of trusts (n=179).

| Type of supportive/ symptomatic IO procedure | Number of trusts | Percentage (%) |
|---|------------------|----------------|
| Ascitic diversion | 39 | 22 |
| Vena caval stenting | 79 | 44 |
| Enteral tube placement e.g. Radiologically Inserted Gastrostomy (RIG) | 81 | 45 |
| Percutaneous Trans-hepatic Cholangiography (PTC) | 84 | 47 |
| Gastrointestinal stenting | 87 | 49 |
| Vena caval filtration | 88 | 49 |
| Biliary drainage and stenting | 118 | 66 |
| Ureteric stenting | 124 | 69 |
| Central venous catheter | 125 | 70 |
| Image-guided drainage | 128 | 72 |
| Nephrostomy | 129 | 72 |
| Image-guided biopsy | 137 | 77 |

400

401 **Table 2:** Type of disease-modifying IO procedures and number of trusts that offer each and
 402 percentage of total number of trusts (n=179).

403

| Type of disease-modifying IO procedure | Number of trusts | Percentage (%) |
|---|------------------|----------------|
| Prostate ablation | 2 | 1 |
| Selective Internal Radiation Therapy (SIRT) | 17 | 9 |
| Bone ablation | 18 | 10 |
| Lung ablation | 28 | 16 |
| Liver ablation | 39 | 22 |
| Kidney ablation | 39 | 22 |
| Trans-arterial chemoembolization (TACE) | 40 | 22 |

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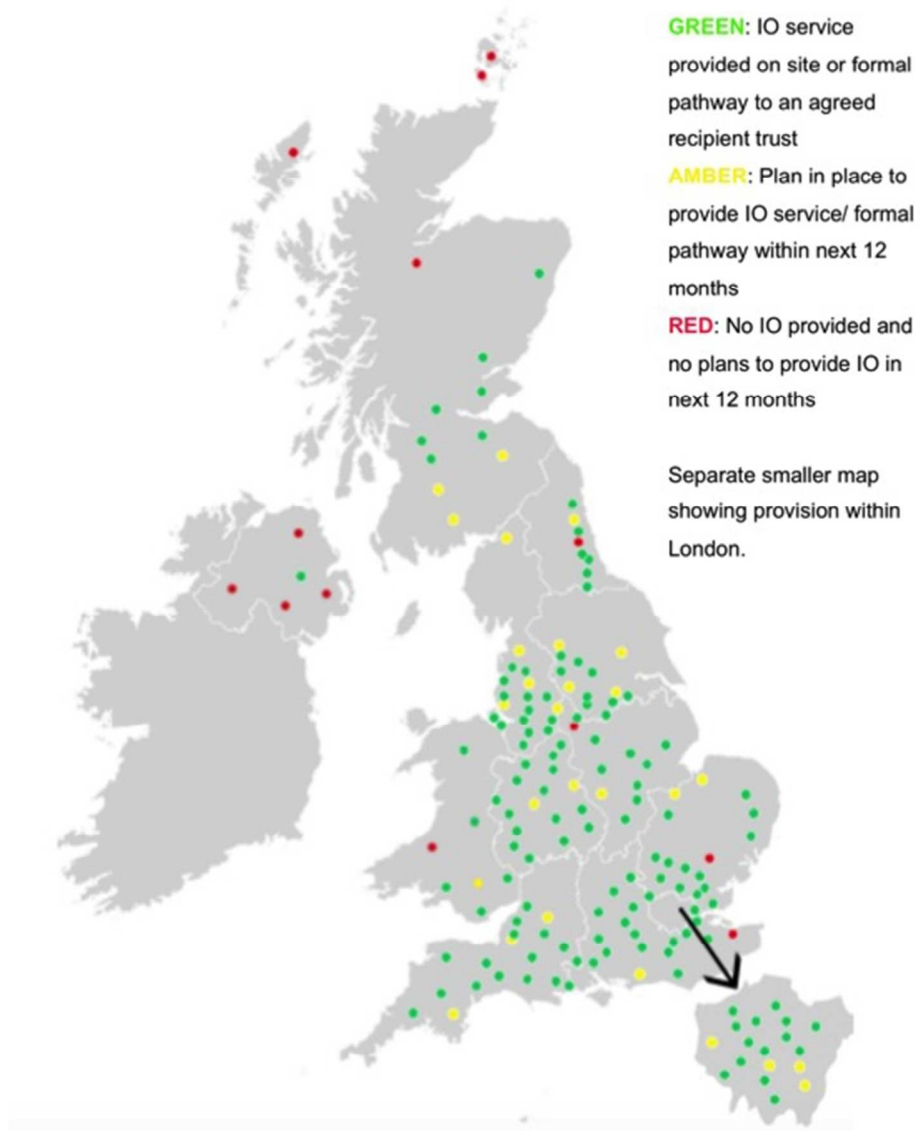


Figure 1: UK Map showing the overall provision of interventional oncology (IO) services throughout the UK.

199x254mm (72 x 72 DPI)

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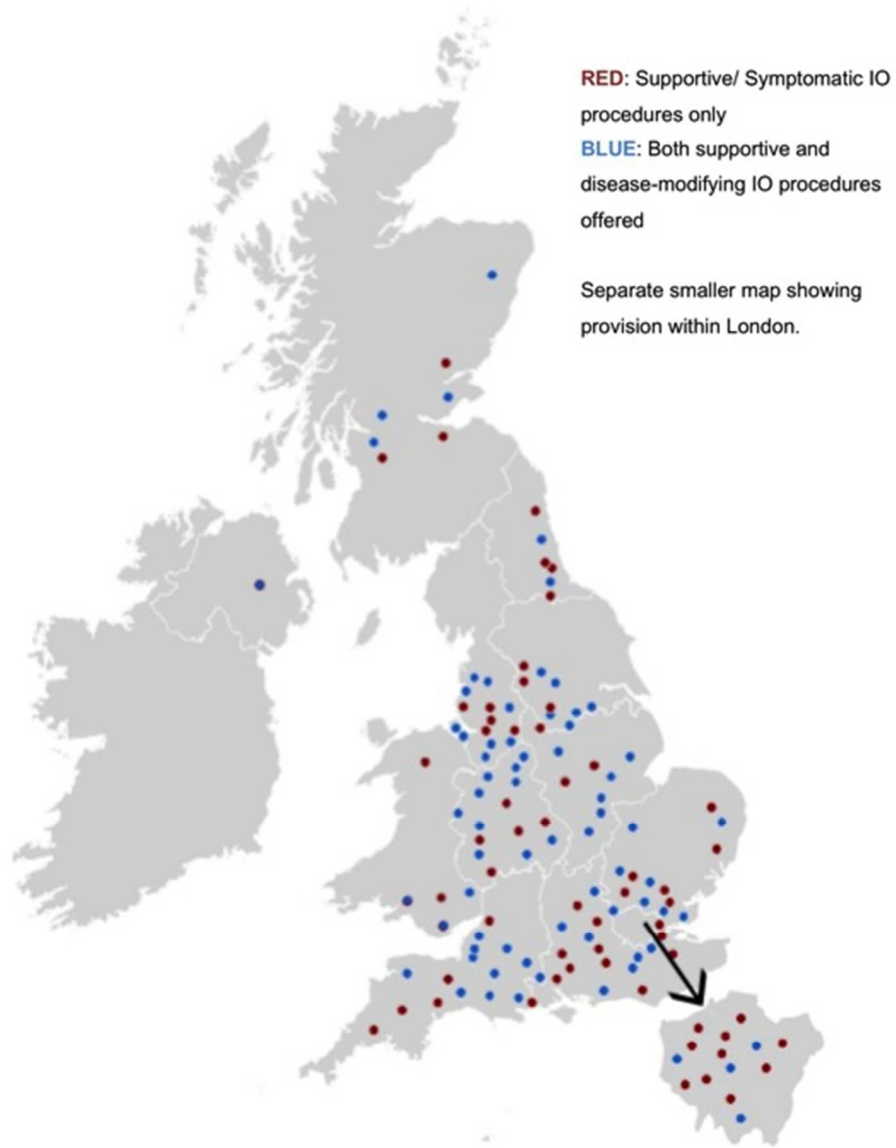


Figure 2: UK Map showing what types of IO procedures (supportive and/ or disease modifying procedures) are undertaken in each NHS trust/ health board.

187x247mm (72 x 72 DPI)

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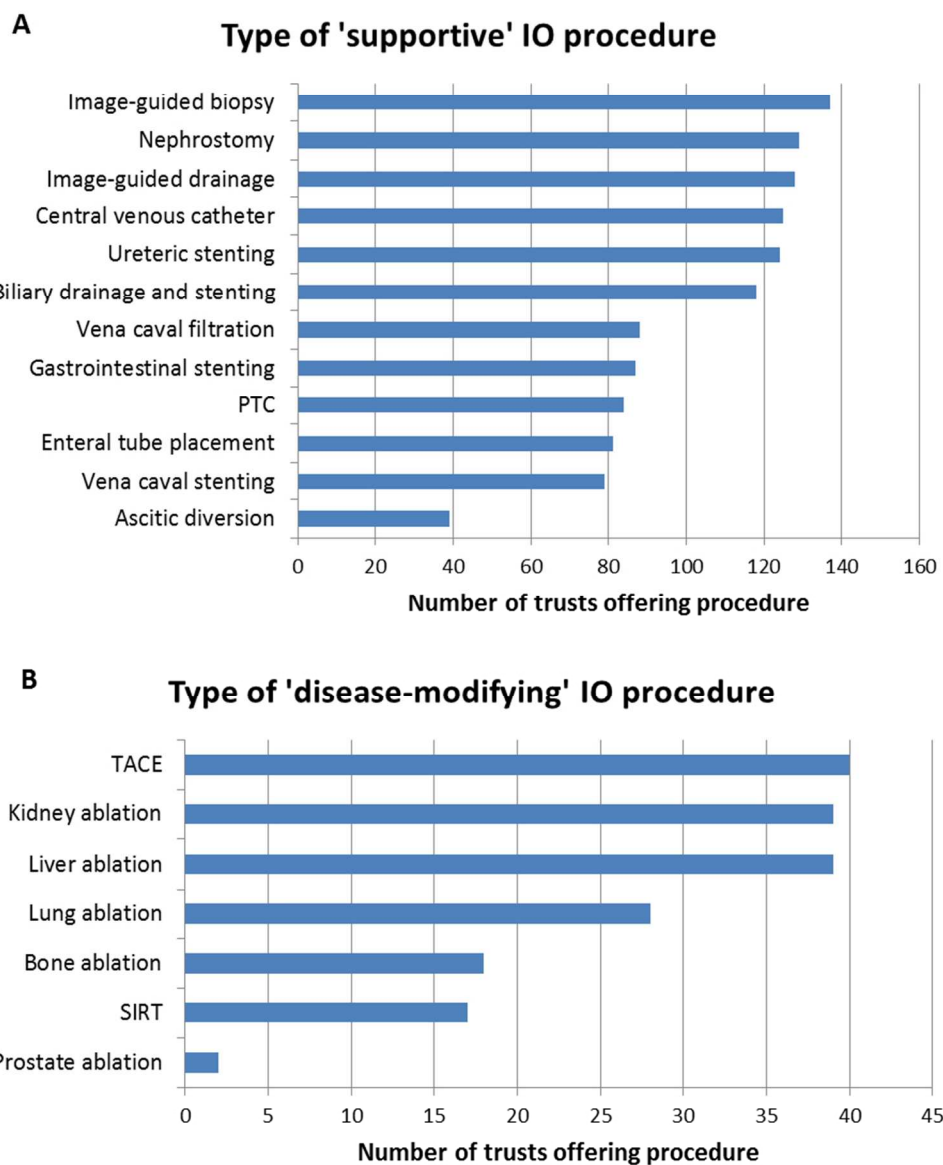


Figure 3: Bar charts showing number of trusts offering: (A) Each type of supportive/symptomatic IO procedure and (B) Each type of disease-modifying IO procedure.

156x189mm (150 x 150 DPI)

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Figure 4: UK Map showing the provision of ablation services: (A) Renal ablation (B) Liver ablation (C) Bone ablation and (D) Lung ablation.

232x299mm (96 x 96 DPI)

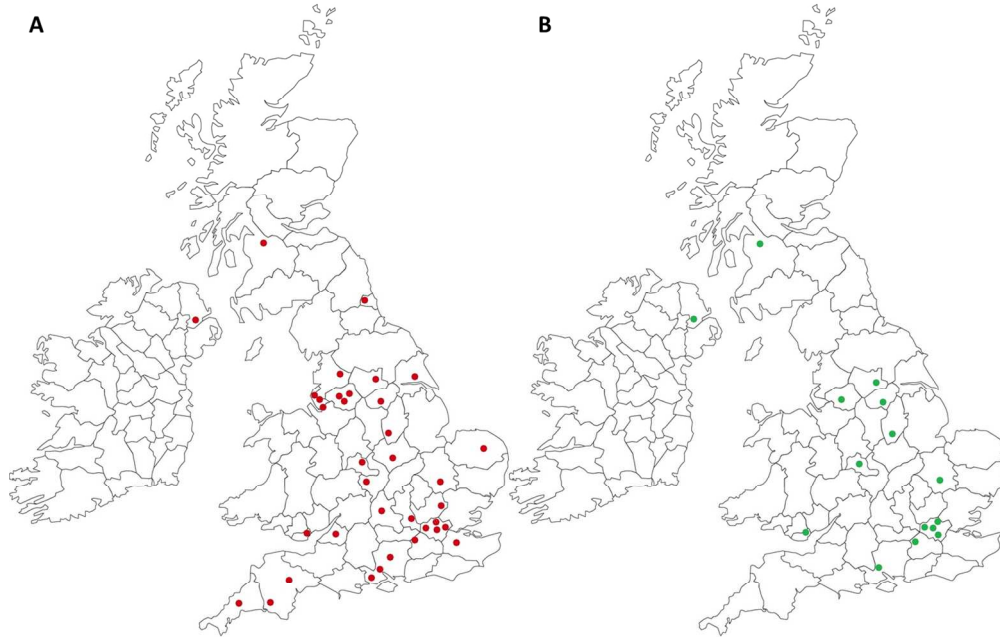


Figure 5: UK Map showing the provision of (A) Trans-arterial chemoembolization (TACE) and (B) Selective internal radiation therapy (SIRT).

259x176mm (150 x 150 DPI)

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Provision of Interventional Oncology Services in the United Kingdom: Pilot Study

SRQR Qualitative Research Checklist Adapted from:
OBrien BC; Harris IB; Beckman TJ; Reed DA; Cook DA. Standards for reporting
qualitative research: a synthesis of recommendations. Academic Medicine.
89(9):1245-51, 2014 Sep. DOI: 10.1097/ACM.0000000000000388

| Number | Topic | Page number in manuscript |
|--------|---|---------------------------------|
| | Title and abstract | |
| S1 | Title | 1 |
| S2 | Abstract | 3 |
| | Introduction | |
| S3 | Problem formation | 5 |
| S4 | Purpose or research question | 5 |
| | Methods | |
| S5 | Qualitative approach and research paradigm | 6 |
| S6 | Researcher characteristics and reflexivity | 6 |
| S7 | Context | 5 |
| S8 | Sampling strategy | 6 |
| S9 | Ethical issues pertaining to human subjects | n/a |
| S10 | Data collection methods | 6 |
| S11 | Data collection instruments and technologies | 6 |
| S12 | Units of study | 6 |
| S13 | Data processing | 6 |
| S14 | Data analysis | 6 |
| S15 | Techniques to enhance trustworthiness | 6 |
| | Results/ findings | |
| S16 | Synthesis and interpretation | 7-8 |
| S17 | Links to empirical data | 7 |
| | Discussion | |
| S18 | Integration with prior work, implications, transferability, and contribution(s) to the field | 8-10 |
| S19 | Limitations | 11 |
| | Other | |
| S20 | Conflicts of Interest | 12 |
| S21 | Funding | 12 |
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BMJ Open

Cross-sectional Study of the Provision of Interventional Oncology Services in the United Kingdom

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SCHOLARONE™
Manuscripts

1 **Cross-sectional Study of the Provision of Interventional Oncology Services in the United**
2 **Kingdom**

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44 50 **Contributorship Statement**

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46 51 Dr Jim Zhong (JZ) was also involved with designing the initial study concept, initial literature
47
48 52 search, designing the survey and questionnaire layout, all data collection and analysis, writing up
49
50 53 the manuscript and revising the manuscript in discussion with other authors. He has prepared the
51
52 54 manuscript for publication.

53
54 55 Dr Peter Atiiga (P A) was also involved with designing the survey and questionnaire layout, the
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56 56 data collection and revising the manuscript in discussion with other authors.
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20 66 Dr David Breen (DB) was also involved with finalizing the initial study concept, reviewing and
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40 76 approving the survey and questionnaire layout, reviewing the data and analysis and approving the
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45
46 79 survey and questionnaire layout, reviewing the results and analysis, and revising the manuscript in
47
48 80 discussion with other authors and approving the manuscript for publication in discussion with the
49
50 81 other authors.

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56
57 84 study.

1
2 85 **Abstract**

3
4 86 **Objective:**

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6 87 To map out the current provision of interventional oncology (IO) services in the United Kingdom.
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10 89 **Design:**

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12 90 Cross-sectional multi-centre study.
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16 92 **Setting:**

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18 93 All National Health Service (NHS) Trusts in England and Scottish, Welsh and Northern Ireland
19
20 94 health boards.
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22 95

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24 96 **Participants:**

25
26 97 Interventional Radiology departments in all NHS trusts/ health boards in the United Kingdom.
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30 99 **Results**

31
32 100 A total of 179 NHS trusts/health boards were contacted. We received a 100% response rate. Only
33
34 101 19 (11%) institutions had an interventional oncology lead. 144 trusts (80%) provided IO services or
35
36 102 had a formal pathway of referral in place for patients to a recipient trust. 21 trusts (12%) had plans
37
38 103 to provide an IO service or formal referral pathway in the next 12 months only. 14 trusts (8%) did
39
40 104 not have a pathway of referral and no plans to implement one.

41
42 105 70 trusts (39%) offered supportive and disease-modifying procedures. 1 trust had a formal referral
43
44 106 pathway for supportive procedures. 73 trusts (41%) provided only supportive procedures
45
46 107 (diagnostic or therapeutic). Of these, 43 (59%) had a referral pathway for disease-modifying IO
47
48 108 procedures, either from a regional cancer network or through interventional radiology networks and
49
50 109 30 trusts (41%) did not have a referral pathway for disease-modifying procedures.
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55 111 **Conclusion**
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2 112 The provision of IO services in the UK is promising however collaborative networks are necessary
3
4 113 to ensure disease-modifying IO procedures are made accessible to all patients and to facilitate
5
6 114 larger registry data for research with commissioning of new services.
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9
10 116 **Article Summary**

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12 117 **Strengths and limitations of this study**

- 13
14 118 • 100% response rate from 179 Acute NHS Trusts and Health Boards throughout the United
15
16 119 Kingdom
17
18 120 • Provides comprehensive map of Interventional Oncology (IO) Services throughout the UK to
19
20 121 allow for more integrated cancer pathways on a national level.
21
22 122 • Map of the provision and geographic variation in disease modifying procedures such as tumour
23
24 123 ablation, which will allow for future planning of new IO services.
25
26 124 • Identifies types of supportive IO treatments, which are less routinely available apart from in
27
28 125 larger tertiary centres and therefore highlights areas to target for IO training.
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30 126 • Limitations include those inherent to survey/ questionnaire format, such as subjective bias.
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131 Introduction

132 More than 1-in-3 people will develop cancer in their lifetime[1]. Since the NHS Cancer Plan in
133 2000, the Department of Health has strived to improve diagnosis and treatment[1]. As part of the
134 NHS Cancer Plan to deliver world-class cancer services, there is a drive to achieve better
135 outcomes by ensuring all patients have access to the best treatments available[2]. Wide variation
136 remains in performance across the country with major differences in access to cancer services[1].

137

138 Interventional oncology (IO) ,the use of image guided techniques to diagnose and treat cancer
139 patients is fast becoming the fourth pillar of oncological care alongside medical, surgical and
140 radiation oncology; The Royal College of Radiologists have set out best practice guidance for the
141 incorporation of interventional oncology into all cancer services nationally[3].

142 Supportive and symptomatic procedures were defined as those providing relief from tumour-
143 related symptoms but not modifying the underlying malignant disease process and include
144 diagnostic tests such as image guided biopsy which ‘support’ the provision of definitive
145 treatment[3]. These may be palliative procedures such as image guided drainage or stent
146 insertion. Disease modifying procedures were defined as those where the intent is to modify
147 malignant progression and/or modify the prognosis and include image-guided ablation, trans-
148 arterial chemoembolisation (TACE) and selective internal radiation therapy (SIRT).

149

150 There remains a significant shortage of interventional radiologists, who are the primary contributors
151 towards IO, with almost half of services in England unable to provide a local or networked out of
152 hours access to Interventional Radiology (IR)[4]. Undoubtedly this shortfall will have consequences
153 on the provision of elective IO services in the UK and potentially affect patient care through
154 limitations to access.

155

156 The current provision of Interventional Oncology services throughout the UK is unknown, therefore
157 NHS commissioners are unable to realistically factor IO into national cancer pathways as evident
158 in a previous Department of Health publication[1] which did not acknowledge IO as a treatment
159 option for patients.

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4 161 The primary objective of this cross sectional study was to map out the current provision of
5
6 162 interventional oncology services in the UK. We also sought to uncover formal patient referral
7
8 163 pathways, the types of IO procedures offered and any limitations to providing IO. Ultimately, we
9
10 164 aim to develop IO networks and improve access to these treatments for cancer patients.

11
12 165

13
14 166 The survey was designed and undertaken in collaboration with the Interventional Oncology United
15
16 167 Kingdom (IOUK) group, a specialist interest group of the British Society of Interventional Radiology
17
18 168 (BSIR).

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21
22 170 **Method**

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24 171 No research ethics committee approval was required for this data-gathering project. No patient
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26 172 identifiable data was captured.

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30 174 This cross-sectional study involved all acute NHS Foundation Trusts in England[5] and all health
31
32 175 boards in Scotland, Wales and Northern Ireland which were contacted by email with the survey
33
34 176 (see supplementary material). This was followed by a telephone follow-up of all hospital radiology
35
36 177 departments that did not complete the survey within 2 weeks of the first email being sent out.
37
38 178 Telephone follow-up was conducted by a single radiologist (JZ). The survey could be completed by
39
40 179 any of the following: The head of department of radiology/ interventional radiology, any consultant
41
42 180 radiologist (diagnostic or interventional) or superintendent radiographer who has insight into the
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44 181 local provision of services.

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48 183 The surveys key points were:

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50 184
- 51 185 • Are IO procedures offered in the trust?
 - 52 186 • If so, are these supportive treatments only or both supportive and disease-modifying?
 - 53 187 • We asked about the types of procedures undertaken
 - 54 188 • If no IO procedures are offered, is there an agreed formal pathway to another recipient trust?
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2 189 • If there was no agreed pathway, was there a plan to provide IO or a pathway in the next 12
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4 190 months?
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6 191 • What barriers are there to setting up an IO service?
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10 193 The full survey can be found in the online supplementary file.
11

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14 195 Following the initial survey we followed up all trusts/ health boards which only offered supportive
15 196 treatments to see if there were formal referral pathways for disease-modifying procedures.

16
17 197 A formal referral pathway was defined as an existing mechanism of referral through a multi-
18 198 disciplinary team responsible for the patient, usually through a pre-existing local oncology or
19 199 radiology network.
20

21 200

22 201 **Results**

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25
26 202 A total of 179 NHS trusts or health boards were contacted throughout the United Kingdom. We
27 203 received 100% response rate. The responses came from consultant interventional and diagnostic
28 204 radiologists and superintendent radiographers who had insight into the local provision of services.

29
30 205 143 trusts (80%) had an IR department in their trust. All trusts with an IR department offered IO
31 206 procedures. Only 19 (11%) institutions had an interventional oncology lead.

32
33 207 144 trusts (80%) provided IO services or had a formal pathway of referral in place for patients to a
34 208 recipient trust (Figure 1 and 2), of which 137 trusts (77%) stated what types of IO services they
35 209 offered. 21 trusts (12%) had plans to provide an IO service or formal referral pathway in the next
36 210 12 months only. 14 trusts (8%) did not have a pathway of referral and no plans to implement one.

37
38 211 70 trusts (39%) offered both supportive and disease-modifying procedures (Figure 3). 1 trust had a
39 212 formal referral pathway for supportive procedures. 73 trusts (41%) provided only supportive
40 213 procedures (diagnostic or therapeutic).
41

42 214

43
44 215 The number of trusts providing each supportive/ symptomatic IO procedure and disease-modifying
45 216 procedure are shown in table 1 and table 2. The 7 trusts that gave no details to which IO
46 217 procedures were offered were excluded when calculating the percentages
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2 218 129 trusts out of 179 (72%) offered therapeutic IO procedures after excluding trusts, which only
3
4 219 offered diagnostic image guided biopsy. Figure 4 and 5 show the maps of the trusts providing each
5
6 220 type of disease-modifying procedure.

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8 221

9
10 222 For England only, a total of 153 NHS Foundation trusts in England were contacted. 127 (83%)
11
12 223 trusts provided IO services or had a formal pathway of referral to another agreed recipient trust for
13
14 224 IO procedures (Figure 1). Out of the 26 that did not have a formal referral pathway, 21 (14%) trusts
15
16 225 had plans to provide an IO service or formal referral pathway for patients to have IO at another
17
18 226 trust within the next 12 months. 5 (3%) trusts did not have a pathway and had no plans of providing
19
20 227 IO or a referral pathway in the next 12 months (Figure 1). 57 out of 127 (45%) trusts providing IO
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22 228 offered both supportive and disease modifying procedures (Figure 3). 70 out of 127 (55%)
23
24 229 provided only supportive procedures.

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28 231 For Scotland, 10 out of 14 health boards provided IO or had a formal pathway of referral to a
29
30 232 specialist hospital in another health board (Glasgow or Edinburgh). Of these, 8 health boards
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32 233 provided both supportive and disease-modifying IO whilst 2 provided only supportive IO. 4 health
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34 234 boards (29%) did not provide IO and did not have plans to provide a pathway in the next 12
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36 235 months.

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40 237 For Wales, 6 out of 7 health boards (86%) provided IO or had a referral pathway in place. 4 Welsh
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42 238 health boards (57%) provided both types of IO, one health board provided only supportive IO and
43
44 239 one had a formal referral pathway. One Welsh health board did not offer IO or have a referral
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46 240 pathway implemented in the next 12 months.

47
48 241 Only 1 out of 5 health boards in Northern Ireland (Belfast Health and Social Care Trust) provided
49
50 242 IO (both types). 4 health boards did not have plans to offer IO or have a referral pathway
51
52 243 implemented in the next 12 months.

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56 245 Out of the 70 English NHS trusts and 3 Scottish/ Welsh Health Boards, which provided only
57
58 246 supportive IO, 43 trusts (59%) had a referral pathway to another hospital/ trust for disease-

1
2 247 modifying IO procedures. This was from a local regional cancer network referral initiated following
3
4 248 a formal discussion at the multi-disciplinary team meeting or through interventional radiology
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6 249 networks. 30 trusts (41%) did not have a referral pathway for disease-modifying procedures.
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10 251 The most common barriers to providing disease-modifying IO were insufficient funding, lack of
11
12 252 staff, lack of support from other non-radiology clinicians, having a pathway already in place and
13
14 253 problems with recruitment into IR.

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16 255 **Discussion**

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20 256 Overall, the provision of IO in the UK is unevenly spread.. Based on the Royal College of
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22 257 Radiologists definition of 'supportive' IO[1], this encompasses many routine procedures that can be
23
24 258 carried out by diagnostic radiologists which is reflected in the excellent availability of these
25
26 259 procedures throughout the UK. Beyond basic image-guided drainage procedures, the provision of
27
28 260 specialist vascular, gastro-intestinal or biliary 'symptomatic' intervention is less routinely available
29
30 261 apart from in the larger tertiary centers which were also providing disease-modifying IO. This
31
32 262 highlights important areas to target nationally for radiology and IO training.
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36 264 Given the vital role of IR in the management of critically ill patients, the comprehensive provision of
37
38 265 supportive IO in most parts of the UK reflects the drive to train more radiologists with basic
39
40 266 interventional skills, which are also transferrable to IO[6]. Only 1 trust without an IR department
41
42 267 offered IO. We were unable to capture if most of the IO procedures were done by the IR
43
44 268 department or not, with institutions occasionally splitting non-vascular (e.g. ablation) and vascular
45
46 269 interventions (e.g. transarterial chemoembolization - TACE) between the diagnostic radiologists
47
48 270 and the interventional radiologists who also have to cover the on-call service for non-oncology
49
50 271 related emergency procedures such as trauma, bleeding or aortic syndromes. A major recruitment
51
52 272 drive currently is the provision of on-call IR services and given the overlap between IO and IR
53
54 273 training, emergency IR provision is therefore linked with the provision of IO services not only for
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56 274 maintaining the availability of supportive services in small district hospitals but also for the
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58 275 provision of disease-modifying IO in specialist centres. Additional need for interventional
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1
2 276 radiographers and nursing cover for IO services should not be overlooked either to allow a new IO
3
4 277 service to be introduced.
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6 278
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8 279 We acknowledge that disease-modifying treatments form a smaller proportion of IO workload and
9
10 280 centralization of this is happening as part of the current NHS model for cancer services[7]. One
11
12 281 argument for this model in the context of IO is to ensure that more complex IO procedures are
13
14 282 undertaken by those who carry out a sufficient number of cases to maintain competency however
15
16 283 this should not preclude suitable patients from being referred due to their geographic location.
17
18 284 There are NHS trusts/ boards, most noticeably in rural Scotland and Northern Ireland where
19
20 285 access to disease-modifying IO services appears limited and linking up with neighboring hospitals
21
22 286 to set up formal referral pathways should be considered. What also remains unclear is what the
23
24 287 current demand for IO services are generally but particularly in these rural regions, as we have no
25
26 288 data to suggest current arrangements are sub-optimal. It would not be necessary or appropriate for
27
28 289 all providers to liaise with IO services, and these should be facilitated through regional cancer
29
30 290 networks with more integrated pathways of care[7]. Currently there appears to be 136 out of 153
31
32 291 acute NHS trusts in England, which are listed to offer acute oncology services[8]. Further work is
33
34 292 required to elucidate whether there is any discrepancy in the regional demand and supply of
35
36 293 disease-modifying IO.
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40 295 The perceived barriers to starting up elective disease-modifying services stemmed from shortfalls
41
42 296 in funding, staffing and support from other specialties. With tertiary centres undertaking much
43
44 297 higher volumes of disease modifying IO procedures, some smaller district general hospitals felt
45
46 298 unsupported in starting up their own service, from financial considerations when purchasing the
47
48 299 equipment to garnering support from allied specialties such as surgery and oncology. This is an
49
50 300 important point as it highlights the need for greater awareness of the role of the interventional
51
52 301 radiologist in oncology care and we must strive to work even closer with oncologists given the new
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54 302 evidence suggesting the added value of combination therapies and incorporation of IO procedures
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56 303 into European cancer guidelines[9]. However, with the current model of centralizing cancer
57
58 304 services, these barriers would only be an issue if cancer centers were unable to provide IO. To
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1
2 305 improve patient selection for complex IO procedures, interventional radiologists should have a
3
4 306 regular role in multi-disciplinary team meetings. With only 19 institutions (11%) currently having a
5
6 307 formal IO lead clinician, there is a role for dispersed leadership to achieve structural change in
7
8 308 established cancer networks.

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12 310 Local expertise and facilities help determine the IO that is offered. An example is the provision of
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14 311 disease-modifying IO for the liver, which is centred around the national liver transplant units[10].
15
16 312 Clearly image-guided tumour ablation, TACE and SIRT are effective therapies than can be used
17
18 313 solely or in combination with chemotherapy or surgery to improve the outcome of such patients.
19
20 314 [11 12]. Participation in MDT discussions will also allow interventional radiologists and radiologists
21
22 315 familiar with IO Techniques to educate other clinicians on the role of IO in the management of
23
24 316 patients and contribute towards improvement and restructuring of services. This will also open
25
26 317 opportunities to undertake collaborative research that will be higher impact and wider reaching to
27
28 318 the oncology community.

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31
32 320 The recurrent issue of lack of staffing within IR remains a barrier. Despite the promising provision
33
34 321 of supportive IO, most departments are struggling to cope with the demand for basic vascular,
35
36 322 urological and biliary procedures, necessary to provide a sustainable out of hours service, without
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38 323 compounding this with additional workload and need for additional training for disease-modifying
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40 324 IO.

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44 326 Changes to the delivery of healthcare throughout the UK demands that IO treatments can
45
46 327 demonstrate not only a therapeutic benefit but also cost-effectiveness. For units with a referral
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48 328 pathway for disease-modifying IO, there was a common theme that this set-up was more cost
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50 329 effective than starting a service from scratch. Without knowledge of the actual demand for these IO
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52 330 procedures, there is no answer to this currently, and clinical investigators must incorporate
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54 331 measures of cost-effectiveness and patient-reported outcomes into large-scale studies to provide
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56 332 more robust evidence[13]. Even if these IO treatments can be shown to be equally effective
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58 333 compared with the current standard of care but with significantly less morbidity, then it will allow
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1
2 334 the specialty to develop further, however current studies have not offered definitive
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4 335 conclusions[14]. Building upon the knowledge of these IO networks will allow better registry data
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6 336 that can be used to derive larger cohorts for future trials and also commissioning of new services.

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10 338 The limitations of the present study include those inherent in the survey/ questionnaire format such
11
12 339 as the subjective element depending on whether a superintendent radiographer or consultant
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14 340 radiologist responded given their underlying experience and knowledge of their radiology services
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16 341 which could impact on the detail of their survey answers. The strengths of the survey include 100%
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18 342 response rate from 179 acute NHS trusts/ health boards which allowed a comprehensive map of
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20 343 both supportive and disease-modifying IO procedures offered in the UK that will help direct
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22 344 radiology/IO training, future planning of new IO services and allow for more integrated cancer
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24 345 pathways.

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28 347 **Conclusion**

29
30 348 The provision of IO services in the UK is promising however collaboration and networking is
31
32 349 necessary to ensure disease-modifying IO procedures are made accessible to all patients
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34 350 throughout the UK and to facilitate improved registry data collection for research and
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36 351 commissioning or funding of new services.

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6 356 All authors have completed the ICMJE uniform disclosure form at

7
8 357 www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted

9
10 358 work; no financial relationships with any organisations that might have an interest in the submitted

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12 359 work in the previous three years; no other relationships or activities that could appear to have

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14 360 influenced the submitted work

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16 361

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18 362 Transparency declaration: I affirm that the manuscript is an honest, accurate, and transparent

19
20 363 account of the study being reported; that no important aspects of the study have been omitted; and

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22 364 that any discrepancies from the study as planned (and, if relevant, registered) have been

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24 365 explained.

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28 367 Data sharing: no additional data available.

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2 413 **Figure Legends:**

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4 414 **Figure 1:** UK Map showing the overall provision of interventional oncology (IO) services
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6 415 throughout the UK.

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8 416 **Figure 2:** Middle pie chart (A) displaying total number/percentage of trusts which offer IO or have a
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10 417 referral pathway, number which plan to set up IO service or referral pathway in the next 12 months
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12 418 (All English trusts) and those without any plans to set up a IO service pathway. The top (B) and
13
14 419 bottom (C) pie charts display the breakdown of healthcare trusts/ health boards by country.

15
16 420 **Figure 3:** UK Map showing what types of IO procedures (supportive and/ or disease modifying
17
18 421 procedures) are undertaken in each NHS trust/ health board.

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20 422 **Figure 4:** UK Map showing the provision of ablation services: (A) Renal ablation (B) Liver ablation
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22 423 (C) Bone ablation and (D) Lung ablation.

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24 424 **Figure 5:** UK Map showing the provision of (A) Trans-arterial chemoembolization (TACE) and (B)
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26 425 Selective internal radiation therapy (SIRT).

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431 **Table Legends**

432 **Table 1:** Type of supportive/ symptomatic IO procedure and number of trusts that offer each and
 433 percentage of total number of trusts that provided information on the types of procedure offered
 434 (n=137). 7 out of 144 who offered IO did not include what procedures were offered and were
 435 excluded from calculations.

| Type of supportive/ symptomatic IO procedure | Number of trusts | Percentage of total (%) |
|---|------------------|-------------------------|
| Image-guided biopsy | 137 | 100 |
| Nephrostomy | 129 | 94 |
| Image-guided drainage | 128 | 93 |
| Central venous catheter | 125 | 91 |
| Ureteric stenting | 124 | 91 |
| Biliary drainage and stenting | 118 | 86 |
| Vena caval filtration | 88 | 64 |
| Gastrointestinal stenting | 87 | 64 |
| Percutaneous Trans-hepatic Cholangiography (PTC) | 84 | 61 |
| Enteral tube placement e.g. Radiologically Inserted Gastrostomy (RIG) | 81 | 59 |
| Vena caval stenting | 79 | 58 |
| Ascitic diversion | 39 | 28 |
| Vertebroplasty | 6 | 4 |
| Isolated perfusion chemotherapy | 5 | 4 |

436

437 **Table 2:** Type of disease-modifying IO procedures and number of trusts that offer each and
 438 percentage of total number of trusts (n=179).

| Type of disease-modifying IO procedure | Number of trusts | Percentage (%) |
|---|------------------|----------------|
| Trans-arterial chemoembolization (TACE) | 40 | 22 |
| Liver ablation | 39 | 22 |
| Kidney ablation | 39 | 22 |
| Lung ablation | 28 | 16 |
| Bone ablation | 18 | 10 |
| Selective Internal Radiation Therapy (SIRT) | 17 | 9 |
| Prostate ablation | 2 | 1 |

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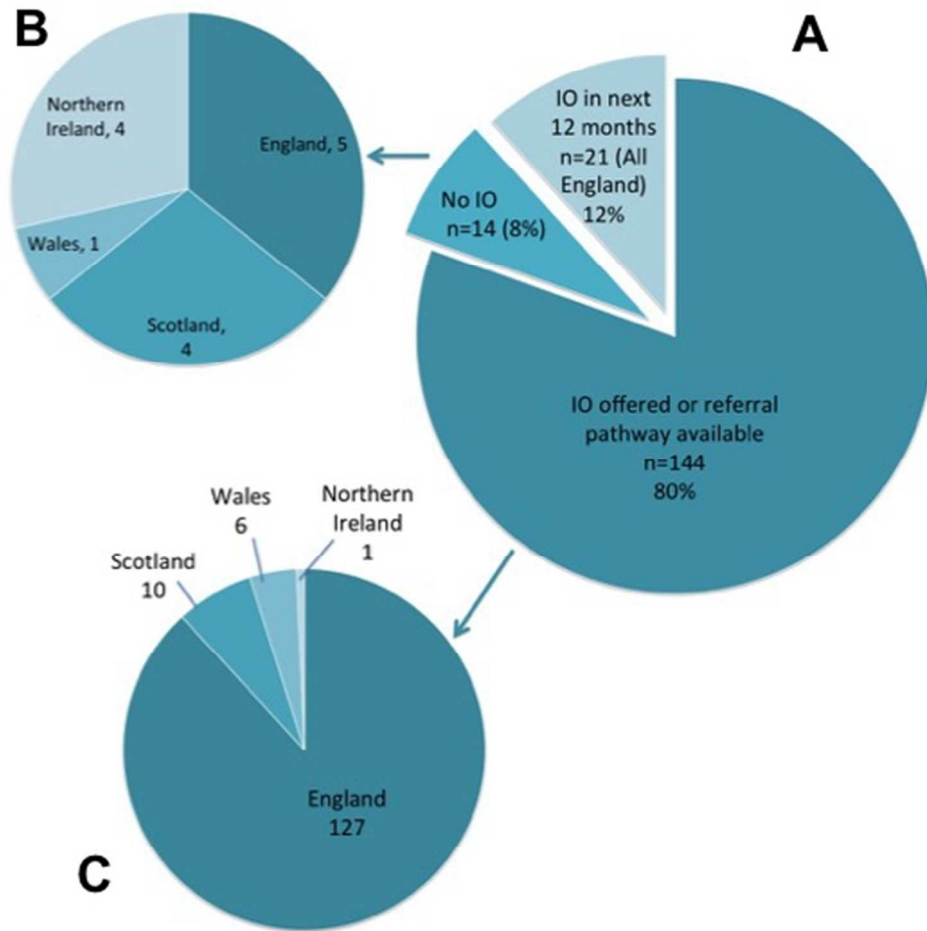
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Figure 1: UK Map showing the overall provision of interventional oncology (IO) services throughout the UK.

94x127mm (300 x 300 DPI)



Middle pie chart (A) displaying total number/percentage of trusts which offer IO or have a referral pathway, number which plan to set up IO service or referral pathway in the next 12 months (All English trusts) and those without any plans to set up a IO service pathway. The top (B) and bottom (C) pie charts display the breakdown of healthcare trusts/ health boards by country.

196x190mm (72 x 72 DPI)



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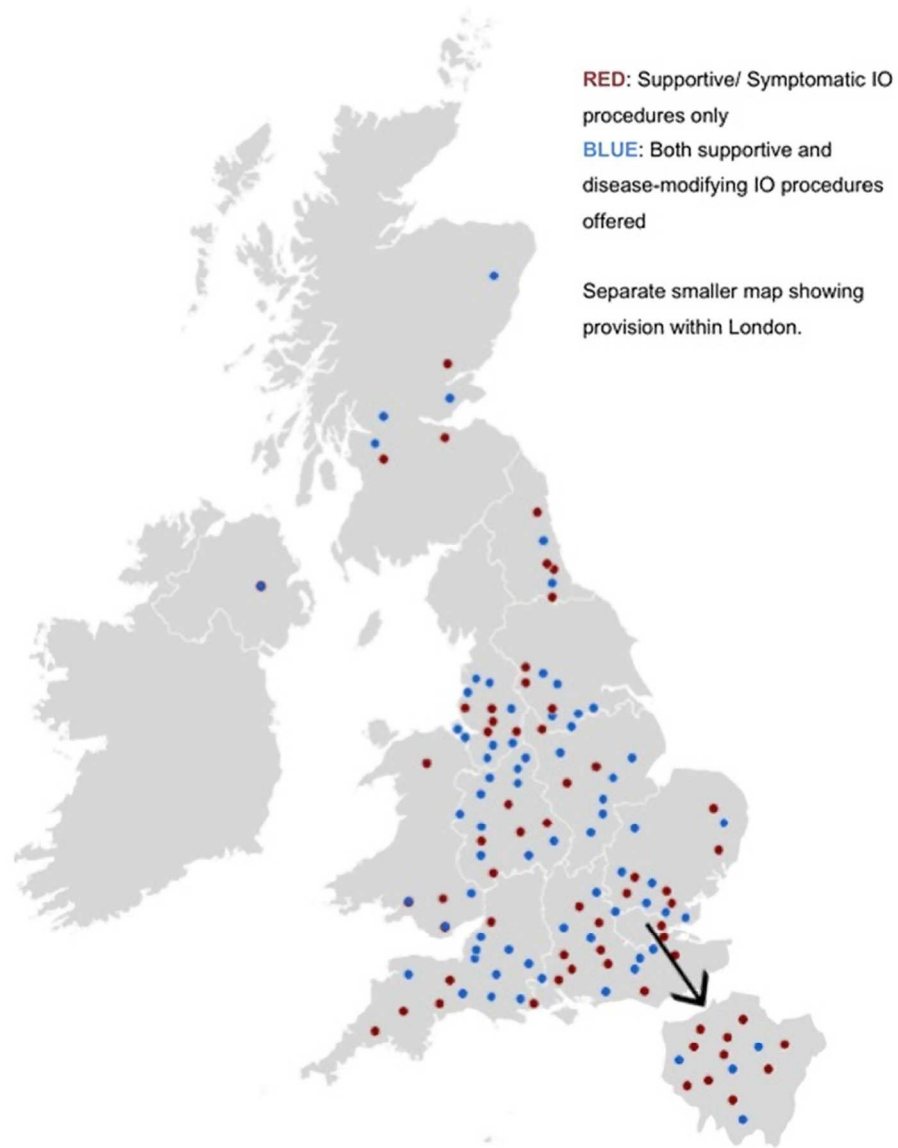


Figure 3: UK Map showing what types of IO procedures (supportive and/ or disease modifying procedures) are undertaken in each NHS trust/ health board.

118x157mm (300 x 300 DPI)



Figure 4: UK Map showing the provision of ablation services: (A) Renal ablation (B) Liver ablation (C) Bone ablation and (D) Lung ablation.

232x299mm (96 x 96 DPI)

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Figure 5: UK Map showing the provision of (A) Trans-arterial chemoembolization (TACE) and (B) Selective internal radiation therapy (SIRT).

259x176mm (150 x 150 DPI)

ew only

Cross-sectional Study of the Provision of Interventional Oncology Services in the United Kingdom

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

| | Item No | Recommendation | Page in Manuscript |
|---------------------------|---------|---|--------------------|
| Title and abstract | 1 | (a) Indicate the study's design with a commonly used term in the title or the abstract | 1 |
| | | (b) Provide in the abstract an informative and balanced summary of what was done and what was found | 4 |
| Introduction | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 6 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 6 |
| Methods | | | |
| Study design | 4 | Present key elements of study design early in the paper | 7 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 7 |
| Participants | 6 | (a) Give the eligibility criteria, and the sources and methods of selection of participants | 7 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 7 |
| Data sources/measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 7 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 13 |
| Study size | 10 | Explain how the study size was arrived at | 7 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 7 |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding | 7 |
| | | (b) Describe any methods used to examine subgroups and interactions | 7 |
| | | (c) Explain how missing data were addressed | 7 |
| | | (d) If applicable, describe analytical methods taking account of sampling strategy | n/a |
| | | (e) Describe any sensitivity analyses | n/a |
| Results | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 8 |
| | | (b) Give reasons for non-participation at each stage | n/a |
| | | (c) Consider use of a flow diagram | n/a |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 8 |

| | | | |
|--------------------------|-----|--|-------|
| | | (b) Indicate number of participants with missing data for each variable of interest | n/a |
| Outcome data | 15* | Report numbers of outcome events or summary measures | 8-10 |
| Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | n/a |
| | | (b) Report category boundaries when continuous variables were categorized | 8-10 |
| | | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | n/a |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | 9-10 |
| Discussion | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 10-13 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 12-13 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 10-13 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 11-13 |
| Other information | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 3 |

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Cross-sectional Study of the Provision of Interventional Oncology Services in the United Kingdom

| | |
|---------------------------------|--|
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1 **Cross-sectional Study of the Provision of Interventional Oncology Services in the United**
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50 50 **Contributorship Statement**

51 51 Dr Jim Zhong (JZ) was also involved with designing the initial study concept, initial literature
52 52 search, designing the survey and questionnaire layout, all data collection and analysis, writing up
53 53 the manuscript and revising the manuscript in discussion with other authors. He has prepared the
54 54 manuscript for publication.

55 55 Dr Peter Atiiga (P A) was also involved with designing the survey and questionnaire layout, the
56 56 data collection and revising the manuscript in discussion with other authors.

1
2 57 Dr Des J Alcorn (DJA) was also involved with finalizing the initial study concept, reviewing and
3
4 58 approving the survey and questionnaire layout, reviewing the data and analysis and approving the
5
6 59 manuscript for publication in discussion with the other authors.

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8 60 Dr David Kay (DK) was also involved with finalizing the initial study concept, reviewing and
9
10 61 approving the survey and questionnaire layout, reviewing the data and analysis and approving the
11
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14 63 Dr Rowland Illing (RI) was also involved with finalizing the initial study concept, reviewing and
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16 64 approving the survey and questionnaire layout, reviewing the data and analysis and approving the
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18 65 manuscript for publication in discussion with the other authors.

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20 66 Dr David Breen (DB) was also involved with finalizing the initial study concept, reviewing and
21
22 67 approving the survey and questionnaire layout, reviewing the data and analysis and approving the
23
24 68 manuscript for publication in discussion with the other authors.

25
26 69 Dr Nicholas Railton (N R) was also involved with finalizing the initial study concept, reviewing and
27
28 70 approving the survey and questionnaire layout, reviewing the data and analysis and approving the
29
30 71 manuscript for publication in discussion with the other authors.

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32 72 Dr Ian J McCafferty (IJM) was also involved with finalizing the initial study concept, reviewing and
33
34 73 approving the survey and questionnaire layout, reviewing the data and analysis and approving the
35
36 74 manuscript for publication in discussion with the other authors.

37
38 75 Dr Philip J Haslam (PJH) was also involved with finalizing the initial study concept, reviewing and
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40 76 approving the survey and questionnaire layout, reviewing the data and analysis and approving the
41
42 77 manuscript for publication in discussion with the other authors.

43
44 78 Dr Tze Min Wah (TMW) was also involved with designing the initial study concept, approving the
45
46 79 survey and questionnaire layout, reviewing the results and analysis, and revising the manuscript in
47
48 80 discussion with other authors and approving the manuscript for publication in discussion with the
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50 81 other authors.

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56
57 84 study.

1
2 85 **Abstract**

3
4 86 **Objective:**

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6 87 To map out the current provision of interventional oncology (IO) services in the United Kingdom.
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10 89 **Design:**

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12 90 Cross-sectional multi-centre study.
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16 92 **Setting:**

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18 93 All National Health Service (NHS) Trusts in England and Scottish, Welsh and Northern Ireland
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20 94 health boards.
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24 96 **Participants:**

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26 97 Interventional Radiology departments in all NHS trusts/ health boards in the United Kingdom.
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30 99 **Results**

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32 100 A total of 179 NHS trusts/health boards were contacted. We received a 100% response rate. Only
33
34 101 19 (11%) institutions had an interventional oncology lead. 144 trusts (80%) provided IO services or
35
36 102 had a formal pathway of referral in place for patients to a recipient trust. 21 trusts (12%) had plans
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38 103 to provide an IO service or formal referral pathway in the next 12 months only. 14 trusts (8%) did
39
40 104 not have a pathway of referral and no plans to implement one.

41
42 105 70 trusts (39%) offered supportive and disease-modifying procedures. 1 trust had a formal referral
43
44 106 pathway for supportive procedures. 73 trusts (41%) provided only supportive procedures
45
46 107 (diagnostic or therapeutic). Of these, 43 (59%) had a referral pathway for disease-modifying IO
47
48 108 procedures, either from a regional cancer network or through interventional radiology networks and
49
50 109 30 trusts (41%) did not have a referral pathway for disease-modifying procedures.
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53 110

54
55 111 **Conclusion**
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2 112 The provision of IO services in the UK is promising however collaborative networks are necessary
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4 113 to ensure disease-modifying IO procedures are made accessible to all patients and to facilitate
5
6 114 larger registry data for research with commissioning of new services.
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9
10 116 **Article Summary**

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12 117 **Strengths and limitations of this study**

- 13
14 118 • This is the first study to investigate the provision of Interventional Oncology (IO) Services in the
15
16 119 UK.
17
18 120 • The sample size is large and covers all acute trusts and health boards in the UK.
19
20 121 • Cross-sectional study design allowed for multiple variables to be studied
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22 122 • Data was self-reported therefore at risk of incompleteness.
23
24 123 • Limitations include those inherent to survey/ questionnaire format, including subjective bias.
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32 127 **We have read and understood BMJ policy on declaration of interests and declare that we**

33
34 128 **have no competing interests**
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2 129 **Introduction**

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4 130 More than 1-in-3 people will develop cancer in their lifetime[1]. Since the NHS Cancer Plan in
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6 131 2000, the Department of Health has strived to improve diagnosis and treatment[1]. As part of the
7
8 132 NHS Cancer Plan to deliver world-class cancer services, there is a drive to achieve better
9
10 133 outcomes by ensuring all patients have access to the best treatments available[2]. Wide variation
11
12 134 remains in performance across the country with major differences in access to cancer services[1].

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14 135

15
16 136 Interventional oncology (IO) the use of image guided techniques to diagnose and treat cancer
17
18 137 patients is fast becoming the fourth pillar of oncological care alongside medical, surgical and
19
20 138 radiation oncology; The Royal College of Radiologists have set out best practice guidance for the
21
22 139 incorporation of interventional oncology into all cancer services nationally[3].

23
24 140 Supportive and symptomatic procedures were defined as those providing relief from tumour-
25
26 141 related symptoms but not modifying the underlying malignant disease process and include
27
28 142 diagnostic tests such as image guided biopsy which 'support' the provision of definitive
29
30 143 treatment[3]. These may be palliative procedures such as image guided drainage or stent
31
32 144 insertion. Disease modifying procedures were defined as those where the intent is to modify
33
34 145 malignant progression and/or modify the prognosis and include image-guided ablation, trans-
35
36 146 arterial chemoembolisation (TACE) and selective internal radiation therapy (SIRT).

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38 147

39
40 148 There remains a significant shortage of interventional radiologists, who are the primary contributors
41
42 149 towards IO, with almost half of services in England unable to provide a local or networked out of
43
44 150 hours access to Interventional Radiology (IR)[4]. Undoubtedly this shortfall will have consequences
45
46 151 on the provision of elective IO services in the UK and potentially affect patient care through
47
48 152 limitations to access.

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52 154 The current provision of Interventional Oncology services throughout the UK is unknown, therefore
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54 155 NHS commissioners are unable to realistically factor IO into national cancer pathways as evident
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56 156 in a previous Department of Health publication[1] which did not acknowledge IO as a treatment
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58 157 option for patients.
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2 158
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4 159 The primary objective of this cross sectional study was to map out the current provision of
5
6 160 interventional oncology services in the UK. We also sought to uncover formal patient referral
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8 161 pathways, the types of IO procedures offered and any limitations to providing IO. Ultimately, we
9
10 162 aim to develop IO networks and improve access to these treatments for cancer patients.

11 163
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13
14 164 The survey was designed and undertaken in collaboration with the Interventional Oncology United
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16 165 Kingdom (IOUK) group, a specialist interest group of the British Society of Interventional Radiology
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18 166 (BSIR).

19
20 167

21 168 **Method**

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24 169 No research ethics committee approval was required for this data-gathering project. No patient
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26 170 identifiable data was captured.

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30 172 This cross-sectional study involved all acute NHS Foundation Trusts in England[5] and all health
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32 173 boards in Scotland, Wales and Northern Ireland which were contacted by email with the survey
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34 174 (see supplementary material). This was followed by a telephone follow-up of all hospital radiology
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36 175 departments that did not complete the survey within 2 weeks of the first email being sent out.
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38 176 Telephone follow-up was conducted by a single radiologist (JZ). The survey could be completed by
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40 177 any of the following: The head of department of radiology/ interventional radiology, any consultant
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42 178 radiologist (diagnostic or interventional) or superintendent radiographer who has insight into the
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44 179 local provision of services.

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47
48 181 The surveys key points were:

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50 182
- 51 183 • Are IO procedures offered in the trust?
 - 52 184 • If so, are these supportive treatments only or both supportive and disease-modifying?
 - 53 185 • We asked about the types of procedures undertaken
 - 54 186 • If no IO procedures are offered, is there an agreed formal pathway to another recipient trust?
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2 187 • If there was no agreed pathway, was there a plan to provide IO or a pathway in the next 12
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4 188 months?
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6 189 • What barriers are there to setting up an IO service?
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10 191 The full survey can be found in the online supplementary file.
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14 193 Following the initial survey we followed up all trusts/ health boards which only offered supportive
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16 194 treatments to see if there were formal referral pathways for disease-modifying procedures.
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18 195 A formal referral pathway was defined as an existing mechanism of referral through a multi-
19
20 196 disciplinary team responsible for the patient, usually through a pre-existing local oncology or
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22 197 radiology network.
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25 26 199 **Results**

27
28 200 A total of 179 NHS trusts or health boards were contacted throughout the United Kingdom. We
29
30 201 received 100% response rate. The responses came from consultant interventional and diagnostic
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32 202 radiologists and superintendent radiographers who had insight into the local provision of services.
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34 203 143 trusts (80%) had an IR department in their trust. All trusts with an IR department offered IO
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36 204 procedures. Only 19 (11%) institutions had an interventional oncology lead.

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38 205 144 trusts (80%) provided IO services or had a formal pathway of referral in place for patients to a
39
40 206 recipient trust (Figure 1 and 2), of which 137 trusts (77%) stated what types of IO services they
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42 207 offered. 21 trusts (12%) had plans to provide an IO service or formal referral pathway in the next
43
44 208 12 months only. 14 trusts (8%) did not have a pathway of referral and no plans to implement one.

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46 209 70 trusts (39%) offered both supportive and disease-modifying procedures (Figure 3). 1 trust had a
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48 210 formal referral pathway for supportive procedures. 73 trusts (41%) provided only supportive
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50 211 procedures (diagnostic or therapeutic).
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55 213 The number of trusts providing each supportive/ symptomatic IO procedure and disease-modifying
56
57 214 procedure are shown in table 1 and table 2. The 7 trusts that gave no details to which IO
58
59 215 procedures were offered were excluded when calculating the percentages
60

1 216 129 trusts out of 179 (72%) offered therapeutic IO procedures after excluding trusts, which only
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3
4 217 offered diagnostic image guided biopsy. Figure 4 and 5 show the maps of the trusts providing each
5
6 218 type of disease-modifying procedure.

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9
10 220 For England only, a total of 153 NHS Foundation trusts in England were contacted. 127 (83%)
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12 221 trusts provided IO services or had a formal pathway of referral to another agreed recipient trust for
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14 222 IO procedures (Figure 1). Out of the 26 that did not have a formal referral pathway, 21 (14%) trusts
15
16 223 had plans to provide an IO service or formal referral pathway for patients to have IO at another
17
18 224 trust within the next 12 months. 5 (3%) trusts did not have a pathway and had no plans of providing
19
20 225 IO or a referral pathway in the next 12 months (Figure 1). 57 out of 127 (45%) trusts providing IO
21
22 226 offered both supportive and disease modifying procedures (Figure 3). 70 out of 127 (55%)
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24 227 provided only supportive procedures.

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26 228

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28 229 For Scotland, 10 out of 14 health boards provided IO or had a formal pathway of referral to a
29
30 230 specialist hospital in another health board (Glasgow or Edinburgh). Of these, 8 health boards
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32 231 provided both supportive and disease-modifying IO whilst 2 provided only supportive IO. 4 health
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34 232 boards (29%) did not provide IO and did not have plans to provide a pathway in the next 12
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36 233 months.

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40 235 For Wales, 6 out of 7 health boards (86%) provided IO or had a referral pathway in place. 4 Welsh
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42 236 health boards (57%) provided both types of IO, one health board provided only supportive IO and
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44 237 one had a formal referral pathway. One Welsh health board did not offer IO or have a referral
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46 238 pathway implemented in the next 12 months.

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48 239 Only 1 out of 5 health boards in Northern Ireland (Belfast Health and Social Care Trust) provided
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50 240 IO (both types). 4 health boards did not have plans to offer IO or have a referral pathway
51
52 241 implemented in the next 12 months.

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56 243 Out of the 70 English NHS trusts and 3 Scottish/ Welsh Health Boards, which provided only
57
58 244 supportive IO, 43 trusts (59%) had a referral pathway to another hospital/ trust for disease-

1
2 245 modifying IO procedures. This was from a local regional cancer network referral initiated following
3
4 246 a formal discussion at the multi-disciplinary team meeting or through interventional radiology
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6 247 networks. 30 trusts (41%) did not have a referral pathway for disease-modifying procedures.
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10 249 The most common barriers to providing disease-modifying IO were insufficient funding, lack of
11
12 250 staff, lack of support from other non-radiology clinicians, having a pathway already in place and
13
14 251 problems with recruitment into IR.

15 252

16 253 **Discussion**

17
18 254 Overall, the provision of IO in the UK is unevenly spread.. Based on the Royal College of
19
20 255 Radiologists definition of 'supportive' IO[1], this encompasses many routine procedures that can be
21
22 256 carried out by diagnostic radiologists which is reflected in the excellent availability of these
23
24 257 procedures throughout the UK. Beyond basic image-guided drainage procedures, the provision of
25
26 258 specialist vascular, gastro-intestinal or biliary 'symptomatic' intervention is less routinely available
27
28 259 apart from in the larger tertiary centers which were also providing disease-modifying IO. This
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30 260 highlights important areas to target nationally for radiology and IO training.
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35 263 Given the vital role of IR in the management of critically ill patients, the comprehensive provision of
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37 264 supportive IO in most parts of the UK reflects the drive to train more radiologists with basic
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39 265 interventional skills, which are also transferrable to IO[6]. Only 1 trust without an IR department
40
41 266 offered IO. We were unable to capture if most of the IO procedures were done by the IR
42
43 267 department or not, with institutions occasionally splitting non-vascular (e.g. ablation) and vascular
44
45 268 interventions (e.g. transarterial chemoembolization - TACE) between the diagnostic radiologists
46
47 269 and the interventional radiologists who also have to cover the on-call service for non-oncology
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49 270 related emergency procedures such as trauma, bleeding or aortic syndromes. A major recruitment
50
51 271 drive currently is the provision of on-call IR services and given the overlap between IO and IR
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53 272 training, emergency IR provision is therefore linked with the provision of IO services not only for
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55 273 maintaining the availability of supportive services in small district hospitals but also for the
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60 273 provision of disease-modifying IO in specialist centres. Additional need for interventional

1
2 274 radiographers and nursing cover for IO services should not be overlooked either to allow a new IO
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4 275 service to be introduced.
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8 277 We acknowledge that disease-modifying treatments form a smaller proportion of IO workload and
9
10 278 centralization of this is happening as part of the current NHS model for cancer services[7]. One
11
12 279 argument for this model in the context of IO is to ensure that more complex IO procedures are
13
14 280 undertaken by those who carry out a sufficient number of cases to maintain competency however
15
16 281 this should not preclude suitable patients from being referred due to their geographic location.
17
18 282 There are NHS trusts/ boards, most noticeably in rural Scotland and Northern Ireland where
19
20 283 access to disease-modifying IO services appears limited and linking up with neighboring hospitals
21
22 284 to set up formal referral pathways should be considered. What also remains unclear is what the
23
24 285 current demand for IO services are generally but particularly in these rural regions, as we have no
25
26 286 data to suggest current arrangements are sub-optimal. It would not be necessary or appropriate for
27
28 287 all providers to liaise with IO services, and these should be facilitated through regional cancer
29
30 288 networks with more integrated pathways of care[7]. Currently there appears to be 136 out of 153
31
32 289 acute NHS trusts in England, which are listed to offer acute oncology services[8]. Further work is
33
34 290 required to elucidate whether there is any discrepancy in the regional demand and supply of
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36 291 disease-modifying IO.
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38 292
39
40 293 The perceived barriers to starting up elective disease-modifying services stemmed from shortfalls
41
42 294 in funding, staffing and support from other specialties. With tertiary centres undertaking much
43
44 295 higher volumes of disease modifying IO procedures, some smaller district general hospitals felt
45
46 296 unsupported in starting up their own service, from financial considerations when purchasing the
47
48 297 equipment to garnering support from allied specialties such as surgery and oncology. This is an
49
50 298 important point as it highlights the need for greater awareness of the role of the interventional
51
52 299 radiologist in oncology care and we must strive to work even closer with oncologists given the new
53
54 300 evidence suggesting the added value of combination therapies and incorporation of IO procedures
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56 301 into European cancer guidelines[9]. However, with the current model of centralizing cancer
57
58 302 services, these barriers would only be an issue if cancer centers were unable to provide IO. To
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1
2 303 improve patient selection for complex IO procedures, interventional radiologists should have a
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4 304 regular role in multi-disciplinary team meetings. With only 19 institutions (11%) currently having a
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6 305 formal IO lead clinician, there is a role for dispersed leadership to achieve structural change in
7
8 306 established cancer networks.

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10 307

11 308 Local expertise and facilities help determine the IO that is offered. An example is the provision of
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13 309 disease-modifying IO for the liver, which is centred around the national liver transplant units[10].

14 310 Clearly image-guided tumour ablation, TACE and SIRT are effective therapies than can be used
15
16 311 solely or in combination with chemotherapy or surgery to improve the outcome of such patients.

17
18 312 [11 12]. Participation in MDT discussions will also allow interventional radiologists and radiologists

19
20 313 familiar with IO Techniques to educate other clinicians on the role of IO in the management of

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22 314 patients and contribute towards improvement and restructuring of services. This will also open

23
24 315 opportunities to undertake collaborative research that will be higher impact and wider reaching to

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26 316 the oncology community.

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29
30 318 The recurrent issue of lack of staffing within IR remains a barrier. Despite the promising provision

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32 319 of supportive IO, most departments are struggling to cope with the demand for basic vascular,

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34 320 urological and biliary procedures, necessary to provide a sustainable out of hours service, without

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36 321 compounding this with additional workload and need for additional training for disease-modifying

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38 322 IO.

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42 324 Changes to the delivery of healthcare throughout the UK demands that IO treatments can

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44 325 demonstrate not only a therapeutic benefit but also cost-effectiveness. For units with a referral

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46 326 pathway for disease-modifying IO, there was a common theme that this set-up was more cost

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48 327 effective than starting a service from scratch. Without knowledge of the actual demand for these IO

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50 328 procedures, there is no answer to this currently, and clinical investigators must incorporate

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52 329 measures of cost-effectiveness and patient-reported outcomes into large-scale studies to provide

53
54 330 more robust evidence[13]. Even if these IO treatments can be shown to be equally effective

55
56 331 compared with the current standard of care but with significantly less morbidity, then it will allow

1
2 332 the specialty to develop further, however current studies have not offered definitive
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4 333 conclusions[14]. Building upon the knowledge of these IO networks will allow better registry data
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6 334 that can be used to derive larger cohorts for future trials and also commissioning of new services.
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9
10 336 The limitations of the present study include those inherent in the survey/ questionnaire format such
11
12 337 as the subjective element depending on whether a superintendent radiographer or consultant
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14 338 radiologist responded given their underlying experience and knowledge of their radiology services
15
16 339 which could impact on the detail of their survey answers. The strengths of the survey include 100%
17
18 340 response rate from 179 acute NHS trusts/ health boards which allowed a comprehensive map of
19
20 341 both supportive and disease-modifying IO procedures offered in the UK that will help direct
21
22 342 radiology/IO training, future planning of new IO services and allow for more integrated cancer
23
24 343 pathways.
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26 344

27 28 345 **Conclusion**

29
30 346 The provision of IO services in the UK is promising however collaboration and networking is
31
32 347 necessary to ensure disease-modifying IO procedures are made accessible to all patients
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34 348 throughout the UK and to facilitate improved registry data collection for research and
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36 349 commissioning or funding of new services.
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5 354 All authors have completed the ICMJE uniform disclosure form at
6
7 355 www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted
8
9 356 work; no financial relationships with any organisations that might have an interest in the submitted
10
11 357 work in the previous three years; no other relationships or activities that could appear to have
12
13 358 influenced the submitted work

14 359

15
16 360 Transparency declaration: I affirm that the manuscript is an honest, accurate, and transparent
17
18 361 account of the study being reported; that no important aspects of the study have been omitted; and
19
20 362 that any discrepancies from the study as planned (and, if relevant, registered) have been
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22 363 explained.

23 364

24 365 Data sharing: no additional data available.

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2 408 **Figure Legends:**

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4 409 **Figure 1:** UK Map showing the overall provision of interventional oncology (IO) services
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6 410 throughout the UK.

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8 411 **Figure 2:** Middle pie chart (A) displaying total number/percentage of trusts which offer IO or have a
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10 412 referral pathway, number which plan to set up IO service or referral pathway in the next 12 months
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12 413 (All English trusts) and those without any plans to set up a IO service pathway. The top (B) and
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14 414 bottom (C) pie charts display the breakdown of healthcare trusts/ health boards by country.

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16 415 **Figure 3:** UK Map showing what types of IO procedures (supportive and/ or disease modifying
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18 416 procedures) are undertaken in each NHS trust/ health board.

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20 417 **Figure 4:** UK Map showing the provision of ablation services: (A) Renal ablation (B) Liver ablation
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22 418 (C) Bone ablation and (D) Lung ablation.

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24 419 **Figure 5:** UK Map showing the provision of (A) Trans-arterial chemoembolization (TACE) and (B)
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26 420 Selective internal radiation therapy (SIRT).

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426 **Table Legends**

427 **Table 1:** Type of supportive/ symptomatic IO procedure and number of trusts that offer each and
 428 percentage of total number of trusts that provided information on the types of procedure offered
 429 (n=137). 7 out of 144 who offered IO did not include what procedures were offered and were
 430 excluded from calculations.

| Type of supportive/ symptomatic IO procedure | Number of trusts | Percentage of total (%) |
|---|------------------|-------------------------|
| Image-guided biopsy | 137 | 100 |
| Nephrostomy | 129 | 94 |
| Image-guided drainage | 128 | 93 |
| Central venous catheter | 125 | 91 |
| Ureteric stenting | 124 | 91 |
| Biliary drainage and stenting | 118 | 86 |
| Vena caval filtration | 88 | 64 |
| Gastrointestinal stenting | 87 | 64 |
| Percutaneous Trans-hepatic Cholangiography (PTC) | 84 | 61 |
| Enteral tube placement e.g. Radiologically Inserted Gastrostomy (RIG) | 81 | 59 |
| Vena caval stenting | 79 | 58 |
| Ascitic diversion | 39 | 28 |
| Vertebroplasty | 6 | 4 |
| Isolated perfusion chemotherapy | 5 | 4 |

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432 **Table 2:** Type of disease-modifying IO procedures and number of trusts that offer each and
 433 percentage of total number of trusts (n=179).

| Type of disease-modifying IO procedure | Number of trusts | Percentage (%) |
|---|------------------|----------------|
| Trans-arterial chemoembolization (TACE) | 40 | 22 |
| Liver ablation | 39 | 22 |
| Kidney ablation | 39 | 22 |
| Lung ablation | 28 | 16 |
| Bone ablation | 18 | 10 |
| Selective Internal Radiation Therapy (SIRT) | 17 | 9 |
| Prostate ablation | 2 | 1 |

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Figure 1: UK Map showing the overall provision of interventional oncology (IO) services throughout the UK.

94x127mm (300 x 300 DPI)

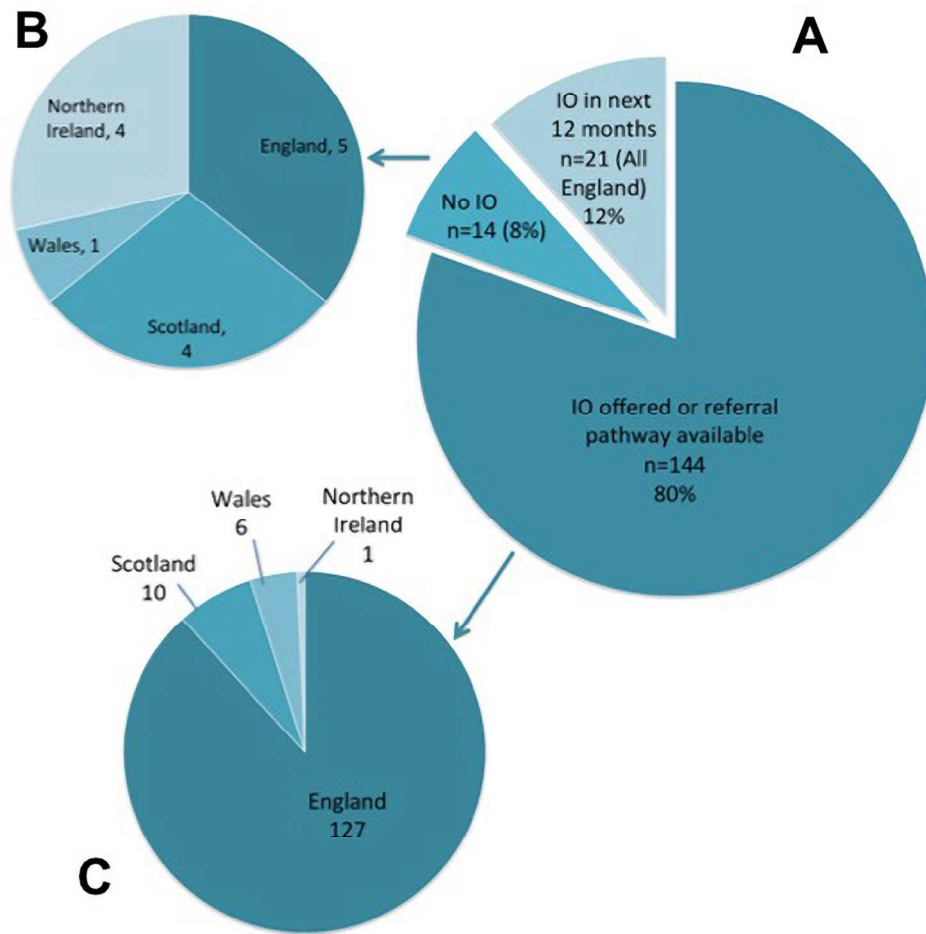


Figure 2: Middle pie chart (A) displaying total number/percentage of trusts which offer IO or have a referral pathway, number which plan to set up IO service or referral pathway in the next 12 months (All English trusts) and those without any plans to set up a IO service pathway. The top (B) and bottom (C) pie charts display the breakdown of healthcare trusts/ health boards by country.

196x187mm (300 x 300 DPI)



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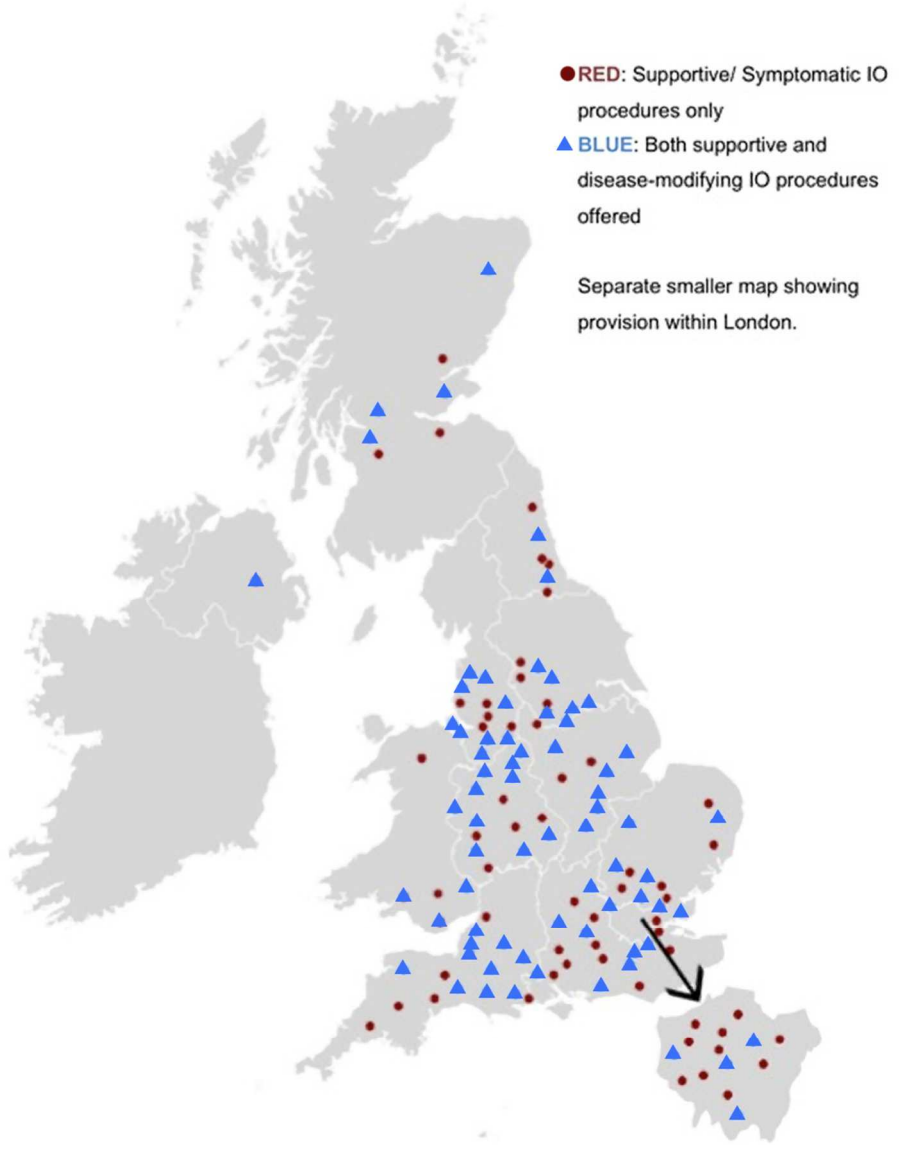


Figure 3: UK Map showing what types of IO procedures (supportive and/ or disease modifying procedures) are undertaken in each NHS trust/ health board.

118x157mm (300 x 300 DPI)

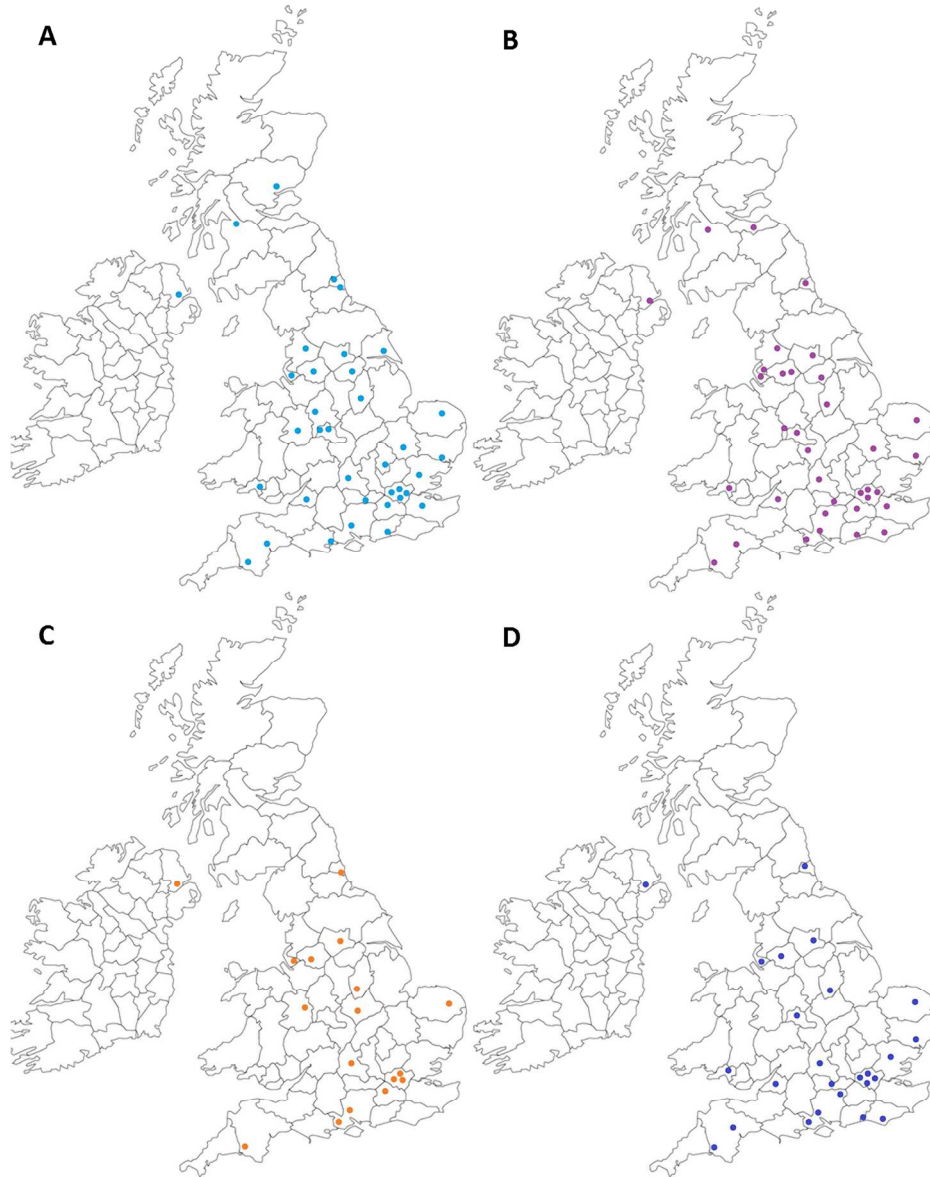


Figure 4: UK Map showing the provision of ablation services: (A) Renal ablation (B) Liver ablation (C) Bone ablation and (D) Lung ablation.

230x299mm (300 x 300 DPI)

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Figure 5: UK Map showing the provision of (A) Trans-arterial chemoembolization (TACE) and (B) Selective internal radiation therapy (SIRT).

259x169mm (300 x 300 DPI)

view only

Cross-sectional Study of the Provision of Interventional Oncology Services in the United Kingdom

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

| | Item No | Recommendation | Page in Manuscript |
|------------------------------|---------|---|--------------------|
| Title and abstract | 1 | (a) Indicate the study's design with a commonly used term in the title or the abstract | 1 |
| | | (b) Provide in the abstract an informative and balanced summary of what was done and what was found | 4 |
| Introduction | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 6 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 6 |
| Methods | | | |
| Study design | 4 | Present key elements of study design early in the paper | 7 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 7 |
| Participants | 6 | (a) Give the eligibility criteria, and the sources and methods of selection of participants | 7 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 7 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 7 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 13 |
| Study size | 10 | Explain how the study size was arrived at | 7 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 7 |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding | 7 |
| | | (b) Describe any methods used to examine subgroups and interactions | 7 |
| | | (c) Explain how missing data were addressed | 7 |
| | | (d) If applicable, describe analytical methods taking account of sampling strategy | n/a |
| | | (e) Describe any sensitivity analyses | n/a |
| Results | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 8 |
| | | (b) Give reasons for non-participation at each stage | n/a |
| | | (c) Consider use of a flow diagram | n/a |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 8 |

| | | | |
|--------------------------|-----|--|-------|
| | | (b) Indicate number of participants with missing data for each variable of interest | n/a |
| Outcome data | 15* | Report numbers of outcome events or summary measures | 8-10 |
| Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | n/a |
| | | (b) Report category boundaries when continuous variables were categorized | 8-10 |
| | | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | n/a |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | 9-10 |
| Discussion | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 10-13 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 12-13 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 10-13 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 11-13 |
| Other information | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 3 |

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.