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Developing a platform to investigate the heterogeneity of outcomes for patients with ovarian cancer

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ABSTRACT

Background The geographical variation in treatment patterns for patients with ovarian cancer is profound, long-standing and worrying. Although these variations were highlighted in a recent UK registry audit, granular data to provide explanations for these variations have been lacking.

Methods A consortium of six UK centres was generated to curate and submit data for all patients treated at their centre for a 2-year period. Descriptive statistics were combined with Cox regression and Kaplan-Meier analysis to confirm the findings from the national registry audit and identify possible drivers of the heterogeneity previously described.

Results Records for 1117 patients treated in six centres in 2018 and 2019 were collated. Although there were differences in the clinical characteristics of patients between centres, these were not enough to account for the significant variation in survival outcomes between centres (p<0.001). Treatment rates varied between centres with between 30% and 76% of patients receiving combination therapy but in Cox models 'treatment centre' remained a predictor of 1 year survival independent of patient, tumour factors and treatment choice.

Conclusion Variations in outcome seen between UK centres are not related solely to casemix but rather to the approach and ethos of each centre towards advanced ovarian cancer treatment options. Although important, differences in treatment patterns do not completely explain the variations seen and further work is required to understand the drivers of difference seen.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Treatment patterns vary between centres in the UK and this is associated with worrying differences in outcomes.

WHAT THIS STUDY ADDS

⇒ This variation in treatment is not explained by casemix and may therefore be related to the ethos of the centre.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Women with ovarian cancer need better evidence to help them make treatment decisions.

INTRODUCTION

Outcomes for patients with ovarian cancer remain poor with 5-year survival rates of 34.6%.[1] One of the strongest determinants of outcome is the mode of primary treatment.[2] Treatment with a combination of surgery and chemotherapy is associated with best outcomes, although not all patients are suitable for this approach. Guidance is lacking on how to select patients for treatment and consequently practice varies between centres, even within a centralised health service such as the UK. This variation was highlighted in the UK Ovarian Cancer Audit Feasibility Pilot (OCAFP),[1] which showed unacceptable levels of variation in treatment patterns, and overall survival, between Cancer Alliances, the geographical units of administration within England.

OCAFP was a registry study and was thus unable to capture potentially important data, including performance status and comorbidity data. As a result, it is difficult to interpret from OCAFP the underlying reasons for the variations in practice seen. To understand these differences, a dataset is required which includes not only all known prognostic factors but also includes all patients diagnosed in a centre, thus ensuring the correct denominator.[3] Such datasets are not provided by clinical trial datasets which can often be highly selective.

Here, we therefore wanted to assess the feasibility of generating a granular dataset from a consortium of UK centres before using these data to confirm the findings of the OCAFP and start to provide reasons for the variations that are seen in current treatment patterns.

Table 1 Percentage missing data by centre

Variable	Overall	Centre					
	n=794	A, n=84	B, n=94	C, n=202	D, n=207	E, n=83	F, n=124
WHO performance status	9.6	7.1	43	13	0	3.6	0
ACE27	34	89	93	39	0	0	21
CA125	10.1	2.3	22	10.1	3.4	0	8.9
Ethnicity	42	9.5	64	18	11	99	100
Smoking status	35	76	20	28	50	4.8	23
Index of multiple deprivation	2.5	4.8	9.6	3.5	0	0	0
Body Mass Index	27	60	24	29	21	8.4	4
FIGO stage	4.3	7.1	3.2	11	0.5	0	0.8
Histological grade	5.2	19	6.4	2.0	0	13	3.2
Histological diagnosis	12	14	9.6	17	17	7.2	0.8
BRCA mutation present	61	45	54	69	80	41	45

METHODS

Identification of centres

Six UK sites were carefully selected to include large and small centres, and centres from Cancer Alliances with high and low surgical resection rates identified from the OCAFP.[1] The participating centres were selected to reflect the full range of UK practice and included one centre which lies above the 99th centile for resection rates, and one centre lying below the 1st centile, with four centres representing mainstream practice.

A data dictionary was generated to define all clinical variables to be collected. Details of the dictionary have been previously described.[4] Briefly. the data dictionary comprises (1) patient factor data which include demographic, comorbidity using the validated ACE27 system,[5] and germline BRCA status, (2) tumour-related data, including histological type, grade and stage, physiological response data and radiological distribution of disease and (3) treatment-related data including type and outcome of each treatment modality. Deprivation indices were generated from patient postcode using the Indices of Deprivation Score.[6] Three-year follow-up data were also recorded.

Each participating centre was funded to collect data, according to the data dictionary, for all patients registered with a diagnosis of ovarian cancer (ICD56), between 1 January 2018 and 31 December 2019.

Data were transferred to the University of Manchester and stored in a data repository in a pseudonymised fashion. Missing data were managed with median replacement. Data were analysed with Kaplan-Meier, Cox proportional hazard and multivariable Cox models using Rstudios (V.4.2.3).

As part of the data collection process, sites were also asked to complete a resource requirements document, to better understand the time taken to obtain the data at each site. This information was not requested from the one centre, as data collection was complete prior to the commencement of this project.

RESULTS

Data completeness

A total of 1117 patient records were submitted, representing all cases registered with each centre for the 2-year

Table 2 Effort required to collect data

Site*	2018 Cohort			2019 Cohort			
	Time taken to record all data for all patients (hours)	Time taken to complete 10th record (minutes)	Time taken to complete 50th record (minutes)	Time taken to record all data for all patients (hours)	Time taken to complete 10th record (minutes)	Time taken to complete 50th record (minutes)	IT systems required to collect data (n)*
A	46	30	20	38	30	30	2
B	60	60	30	60	60	40	3
C	23.75	20	45	23.5	20	20	7
D	31	18	15	56	17	21	5
E	12.5	13	25	12.5	14	27	5

Times were collected by each centre.
*Site F was not included in the analysis as data had been precollected.

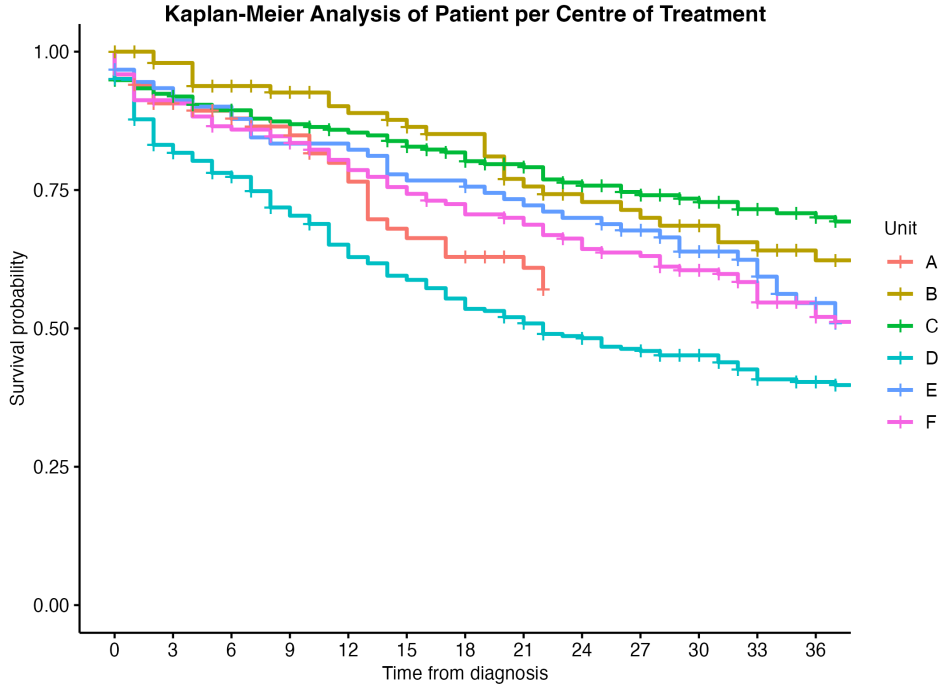

Figure 1 Survival analysis for all FIGO stage 2–4 ovarian cancers, stratified by centre. Follow-up was shorter for patients at one centre resulting in early censoring. Survival differed between the cohorts (p<0.001, log-rank test).

period from 1 January 2018 to 31 December 2019. The numbers registered per centre were 94, 115, 123, 173, 304 and 308, respectively. The numbers per centre varied, as expected, dependent on the varying sizes of the local population.

Performance status, CA125, Deprivation Index, Federation Internation Gynaecology & Obstetrics (FIGO) stage and grade were generally well-recorded and available for analysis. In contrast, while ACE27 (Adult co morbidity evaluation) scores and ethnicity were well recorded in some centres, they were very poorly recorded in others (table 1). Although germline BRCA status was also heterogeneously recorded it should be noted that the study period coincided with the national rollout of germline BRCA testing with centres taking this on at various points during the study period (table 1).

Data collection processes

The resource required to carry out retrospective data collection is rarely calculated. We wanted to generate an estimate of the time and resource required to generate a comprehensive data record, which often requires access to multiple IT systems. Data collectors therefore recorded the time taken to complete each record. Time taken to collect data for each patient varied across centres with a mean score of 27 min per patient, table 2. There was no evidence of time per record decreasing with increasing experience. There was also no correlation between number of patients and time taken to collect data. The number of data systems required to obtain the data (electronic and paper-based) ranged from 2 to 7 in the five centres that submitted resource requirements information (table 2).

Explaining heterogeneity

Median follow-up for the whole cohort was 36 months. However, to explore heterogeneity, we focused on patients with FIGO stage 2–4 disease. Median survival for stage 2–4 patients was 27 months. Kaplan-Meier analysis, stratified by treatment centre, showed marked survival differences between patients in each centre (p<0.001, log-rank test) (figure 1).

Demographics and clinical factors varied between centres. There were marked differences in indices of deprivation between the six centres, with two centres having large proportions of patients with low (1–3) deprivation scores (table 3 and figure 2A).

There were also differences between centres in age, WHO performance status, ACE27 Comorbidity Index,[5] smoking status, ethnicity, Body Mass Index, FIGO stage and histological diagnosis (table 3).

However, most notable was the heterogeneity seen within treatment patterns between the six centres (figure 3). For stage 2–4 disease, the combination of surgery and chemotherapy, which can be delivered with surgery either prior to or during chemotherapy,[7] is considered gold standard treatment for patients with advanced ovarian cancer. Median rates of gold standard treatment in this cohort were 64.2% but ranged from 29.4% in one centre to 75.9% in another. There were similar variations in rates of 'no treatment' (median 12.0%, range 2.1%–31.2%).

Cox proportional hazard modelling showed that the patient and tumour factors that impacted on survival

Table 3 Clinical data for patients with FIGO stage 2–4 ovarian cancer, stratified by centre (A–F)

Variable	Overall, N=794*	A, n=84*	B, n=94*	C, n=202*	D, n=207*	E, n=83*	F, n=124*
Age	68 (17–93)	69 (17–91)	65 (21–89)	68 (21–90)	71 (19–93)	71 (23–93)	62 (19–93)
Not available	23	10	12	0	0	1	0
WHO performance status							
0	358 (45%)	33 (39%)	25 (27%)	107 (53%)	96 (46%)	40 (48%)	57 (46%)
1	199 (25%)	18 (21%)	13 (14%)	51 (25%)	54 (26%)	27 (33%)	36 (29%)
2	94 (12%)	14 (17%)	14 (15%)	8 (4.0%)	33 (16%)	7 (8.4%)	18 (15%)
3	55 (6.9%)	10 (12%)	2 (2.1%)	8 (4.0%)	21 (10%)	4 (4.8%)	10 (8.1%)
4	12 (1.5%)	3 (3.6%)	0 (0%)	1 (0.5%)	3 (1.4%)	2 (2.4%)	3 (2.4%)
Not available	76 (9.6%)	6 (7.1%)	40 (43%)	27 (13%)	0 (0%)	3 (3.6%)	0 (0%)
ACE27							
0	108 (14%)	1 (1.2%)	3 (3.2%)	12 (5.9%)	0 (0%)	44 (53%)	48 (39%)
1	88 (11%)	3 (3.6%)	4 (4.3%)	25 (12%)	0 (0%)	23 (28%)	33 (27%)
2	68 (8.6%)	3 (3.6%)	0 (0%)	32 (16%)	12 (5.8%)	12 (14%)	9 (7.3%)
3	263 (33%)	2 (2.4%)	0 (0%)	54 (27%)	195 (94%)	4 (4.8%)	8 (6.5%)
Not available	267 (34%)	75 (89%)	87 (93%)	79 (39%)	0 (0%)	0 (0%)	26 (21%)
CA125	517 (5–49 031)	366 (14–20 132)	734 (16–12 866)	524 (5–49 031)	477 (6–13 575)	716 (17–11 620)	452 (9–32 305)
Not available	80	19	21	22	7	0	11
Ethnicity							
Asian or Asian British	27 (3.4%)	10 (12%)	7 (7.4%)	7 (3.5%)	3 (1.4%)	0 (0%)	0 (0%)
Black, black British, Caribbean or African	8 (1.0%)	5 (6.0%)	2 (2.1%)	0 (0%)	1 (0.5%)	0 (0%)	0 (0%)
Mixed or multiple ethnic groups	1 (0.1%)	1 (1.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other ethnic group	8 (1.0%)	1 (1.2%)	5 (5.3%)	0 (0%)	2 (1.0%)	0 (0%)	0 (0%)
White	417 (53%)	59 (70%)	20 (21%)	158 (78%)	179 (86%)	1 (1.2%)	0 (0%)
Not available	333 (42%)	8 (9.5%)	60 (64%)	37 (18%)	22 (11%)	82 (99%)	124 (100%)
Smoking status							
Smoker	55 (6.9%)	0 (0%)	4 (4.3%)	15 (7.4%)	18 (8.7%)	6 (7.2%)	12 (9.7%)
Ex-smoker	65 (8.2%)	6 (7.1%)	6 (6.4%)	10 (5.0%)	15 (7.2%)	9 (11%)	19 (15%)
Never smoked	398 (50%)	14 (17%)	65 (69%)	121 (60%)	70 (34%)	64 (77%)	64 (52%)
Not available	276 (35%)	64 (76%)	19 (20%)	56 (28%)	104 (50%)	4 (4.8%)	29 (23%)
Index of multiple deprivation							
1	111 (14%)	22 (26%)	4 (4.3%)	25 (12%)	24 (12%)	1 (1.2%)	35 (28%)
2	85 (11%)	13 (15%)	8 (8.5%)	23 (11%)	25 (12%)	2 (2.4%)	14 (11%)
3	76 (9.6%)	9 (11%)	5 (5.3%)	13 (6.4%)	27 (13%)	9 (11%)	13 (10%)
4	90 (11%)	9 (11%)	9 (9.6%)	28 (14%)	20 (9.7%)	13 (16%)	11 (8.9%)
5	75 (9.4%)	9 (11%)	11 (12%)	11 (5.4%)	15 (7.2%)	13 (16%)	16 (13%)
6	76 (9.6%)	9 (11%)	13 (14%)	16 (7.9%)	19 (9.2%)	9 (11%)	10 (8.1%)
7	81 (10%)	2 (2.4%)	10 (11%)	26 (13%)	23 (11%)	15 (18%)	5 (4.0%)
8	78 (9.8%)	2 (2.4%)	9 (9.6%)	23 (11%)	20 (9.7%)	17 (20%)	7 (5.6%)
9	57 (7.2%)	3 (3.6%)	9 (9.6%)	15 (7.4%)	21 (10%)	2 (2.4%)	7 (5.6%)
10	45 (5.7%)	2 (2.4%)	7 (7.4%)	15 (7.4%)	13 (6.3%)	2 (2.4%)	6 (4.8%)
Not available	20 (2.5%)	4 (4.8%)	9 (9.6%)	7 (3.5%)	0 (0%)	0 (0%)	0 (0%)
Body Mass Index	26.6 (16.0–58.0)	30.0 (19.0–44.0)	25.2 (16.0–50.7)	26.0 (16.0–46.0)	26.0 (16.0–46.0)	26.7 (16.0–58.0)	26.8 (16.4–51.2)
Not available	189	51	23	59	44	7	5
FIGO stage							
2	72 (9.1%)	8 (9.5%)	11 (12%)	16 (7.9%)	11 (5.3%)	10 (12%)	16 (13%)
3	507 (64%)	49 (58%)	51 (54%)	126 (62%)	161 (78%)	46 (55%)	74 (60%)

Continued

Table 3 Continued

Variable	Overall, N=794*	A, n=84*	B, n=94*	C, n=202*	D, n=207*	E, n=83*	F, n=124*
4	181 (23%)	21 (25%)	29 (31%)	37 (18%)	34 (16%)	27 (33%)	33 (27%)
Unstaged	34 (4.3%)	6 (7.1%)	3 (3.2%)	23 (11%)	1 (0.5%)	0 (0%)	1 (0.8%)
Histological grade							
1	59 (7.4%)	4 (4.8%)	3 (3.2%)	20 (9.9%)	12 (5.8%)	10 (12%)	10 (8.1%)
2	11 (1.4%)	1 (1.2%)	7 (7.4%)	0 (0%)	2 (1.0%)	0 (0%)	1 (0.8%)
3	683 (86%)	63 (75%)	78 (83%)	178 (88%)	193 (93%)	62 (75%)	109 (88%)
Not available	41 (5.2%)	16 (19%)	6 (6.4%)	4 (2.0%)	0 (0%)	11 (13%)	4 (3.2%)
Histological diagnosis							
Carcinosarcoma	10 (1.3%)	1 (1.2%)	0 (0%)	2 (1.0%)	0 (0%)	1 (1.2%)	6 (4.8%)
Clear cell	33 (4.2%)	2 (2.4%)	4 (4.3%)	8 (4.0%)	7 (3.4%)	3 (3.6%)	9 (7.3%)
Endometrioid	26 (3.3%)	1 (1.2%)	5 (5.3%)	4 (2.0%)	7 (3.4%)	5 (6.0%)	4 (3.2%)
High grade serous	565 (71%)	62 (74%)	72 (77%)	138 (68%)	144 (70%)	59 (71%)	90 (73%)
Low grade serous	41 (5.2%)	3 (3.6%)	2 (2.1%)	14 (6.9%)	7 (3.4%)	9 (11%)	6 (4.8%)
Mucinous	10 (1.3%)	0 (0%)	0 (0%)	2 (1.0%)	5 (2.4%)	0 (0%)	3 (2.4%)
Germ cell tumour	6 (0.8%)	2 (2.4%)	2 (2.1%)	0 (0%)	0 (0%)	0 (0%)	2 (1.6%)
Sex cord-stromal tumour	5 (0.6%)	1 (1.2%)	0 (0%)	0 (0%)	1 (0.5%)	0 (0%)	3 (2.4%)
Not available	98 (12%)	12 (14%)	9 (9.6%)	34 (17%)	36 (17%)	6 (7.2%)	1 (0.8%)
BRCA mutation present							
Yes	55 (6.9%)	7 (8.3%)	8 (8.5%)	7 (3.5%)	11 (5.3%)	5 (6.0%)	17 (14%)
No	254 (32%)	39 (46%)	35 (37%)	55 (27%)	30 (14%)	44 (53%)	51 (41%)
Not tested	485 (61%)	38 (45%)	51 (54%)	140 (69%)	166 (80%)	34 (41%)	56 (45%)
Treatment received							
Primary debulking surgery and chemotherapy	204 (26%)	28 (33%)	23 (24%)	45 (22%)	28 (14%)	29 (35%)	51 (41%)
Neo-adjuvant chemotherapy and interval debulking surgery	235 (30%)	21 (25%)	43 (46%)	65 (32%)	33 (16%)	34 (41%)	39 (31%)
Chemotherapy only	140 (18%)	18 (21%)	18 (19%)	0 (0%)	80 (39%)	10 (12%)	14 (11%)
Surgery only	68 (9%)	5 (6.0%)	8 (8.5%)	29 (14%)	15 (7.2%)	2 (2.4%)	9 (7.3%)
None	147 (19%)	12 (14%)	2 (2.1%)	63 (31%)	51 (25%)	8 (9.6%)	11 (8.9%)

*Median (Minimum–Maximum); n (%).

included age (HR for death 1.04), performance statue (PS) 3 or 4 (HR 2.06 and 16.5, respectively), FIGO stage 3 or 4 (3.13 and 4.30, respectively) and albumin level (HR 0.97).

When treatment was incorporated into the model, there was no effect of receiving neoadjuvant chemotherapy and interval surgery compared with primary cytoreductive surgery. Unsurprisingly, receiving chemotherapy alone without surgery (HR 3.03) was associated with shorter survival times (HR 4.0).

However, when multivariable Cox models were generated, treatment centre remained a predictor of 1 year survival independent of patient, tumour factors and treatment choice.

DISCUSSION

We have carried out a retrospective, observational study to validate the findings first described in the OCAFP. The latter was a registry-level study and detailed interpretation was limited by lack of data regarding patient demographics. Here, we have carried out a 'bottom-up' study using clinical record data to confirm, and investigate, the findings from the OCAFP.

We have shown that granular datasets can be generated from routinely collected clinical records with acceptable levels of missing data within a centralised cancer care system. We have confirmed that the variations in treatment patterns seen in Cancer Alliances and reported in OCAFP are replicated in data from individual centres.

The variations in age, performance status and particularly deprivation seen between the cohorts in this study highlight the challenges faced by particular centres. These differences are rarely accounted for in commissioning of services but are likely to impact on resource requirements. More concerning are the variations in survival outcomes seen between the centres. These are not fully accounted for by the population and treatment differences between the centres. Given the comprehensive data collection that underpinned this study, it appears that variations in outcome are not fully driven by differences

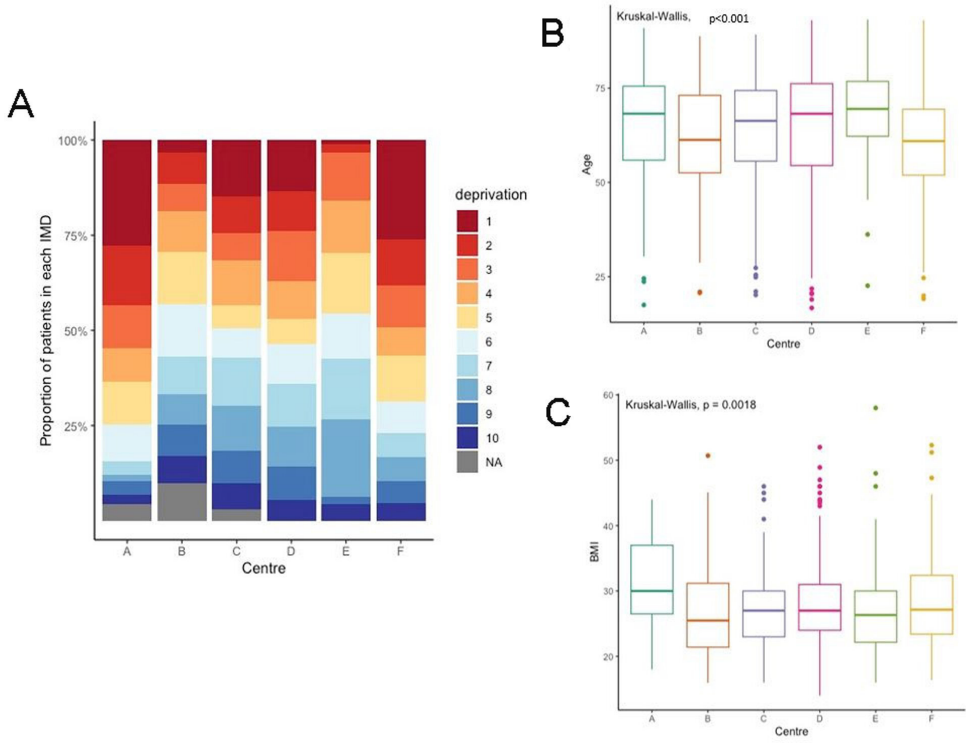

Figure 2 Clinical characteristics of cohort by centre. (A)Index of Multiple Deprivation (IMD) s calculated for each patient using the index of multiple deprivation. Age (b) and BMI (c) also both showed significant differences between centres. BMI, Body Mass Index.

in casemix. Instead, these variations in outcome may be driven by more subtle differences between the centres; potentially including infrastructure, capacity or even an ethos and philosophy about treatment plans and overall treatment approach for patients with advanced ovarian cancer. Indeed, evidence is emerging that there is heterogeneity in the decision-making process for these patients between centres[8] and further work is required to understand these differences.

There has been extensive debate regarding the relative merits of primary versus delayed primary surgery for patients with advanced disease.[9] However, the data presented here clearly indicate that key to survival benefit is the incorporation of surgical resection in the treatment algorithm of advanced ovarian cancer, independently of the timing, that is, upfront or delayed, at interval. Hence, the focus for clinicians should move from discussions about the timing of surgery to increasing the proportion

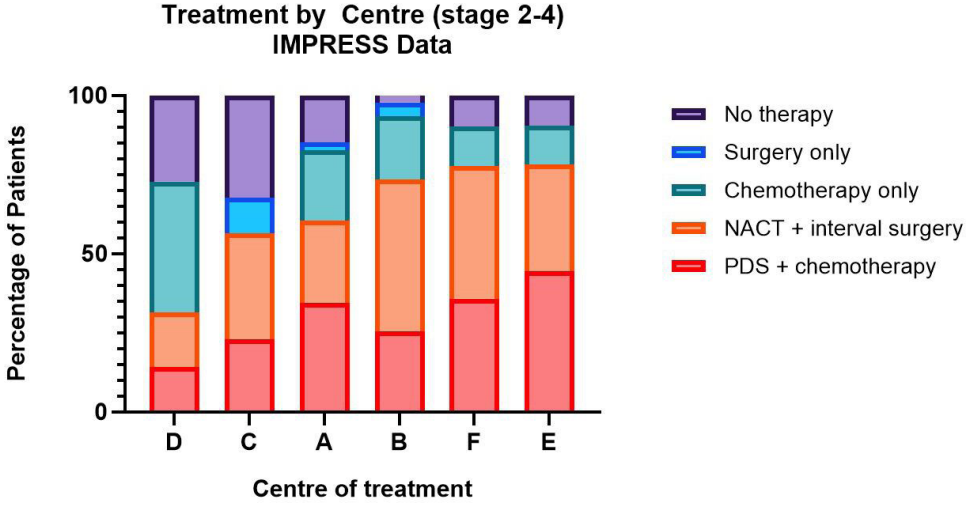

Figure 3 Stacked bar chart showing treatment patterns for patients with advanced ovarian cancer for each centre. Centres are shown in ascending order of 'gold standard' treatment rate, defined as the combination of surgery and chemotherapy (red and orange bars). NACT - Neoadjuvant chemotherapy. PDS - primary debulking surgery

of patients receiving this gold standard treatment,[9] as reducing the inequity surrounding patient's access to surgery could go some away to reducing the heterogeneity outcomes demonstrated here. Empowering patients in the decision-making process, using personalised decision aids as appropriate, may be a useful tool to enable this.

In summary, we have confirmed here the findings that were first outlined in the OCAFP. We have demonstrated that significant heterogeneity exists in treatment patterns, and outcomes, between centres in the UK. This heterogeneity cannot be explained by differences in casemix and further work is now required to understand why this is so, including whether this is related to the ethos and philosophy of the treating team. Perhaps more importantly, work needs to be carried out to show how this may be overcome.

Contributors KB, NW, JM, MM, CF and RE conceived the study. All authors collected and collated data. KB and RE did the analysis. KB and RE wrote the first draft. All authors contributed to editing the first draft.

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Competing interests RE has received honoraria from GSK and AstraZeneca. CF has received honoraria from Roche, GSK, Ethicon, AstraZeneca/MSD and Oncoinvent. No other authors declare any conflicts of interest.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval Ethical approval was granted from the HRA and Health and Care Research Wales for data collection and storage (ref 22/HRA/3264).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data from this study may be shared subject to appropriate ethical approval.

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