Symptom Benefit Working group
F Joly and J McAlpine

- **Ovarian Cancer:**

- **Symptom Benefit study** for M Friedlander

- **Elderly**

  EWOC study E Pujade-Lauraine
  GOG 273 for G Fleming

- **Survivorship**

  Ovpsych S Blagden

  Others

- **Endometrial Cancer:**

- **Update of the EM QOL brainstorming** - session - Dec. 1, 2012 in Leiden

- Current studies and Future Directions

- **Cervix Cancer**

- Current studies and Future Directions

Symptom Benefit Study

Update and current status

Michael Friedlander on behalf of all
GCIG Symptom Benefit Study
Investigators

GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

PoCoG

ANZGOG
www.anzgog.org.au

ANZGOG-0701 Stage 2

- Validation of the MOST
- 800 patients expected
- Validate MOST against QLQ-C30/Ov28, FACT-O/FOSI

Schema – Stage 2

Target Population

- **Informed consent**
- **≥18yrs**
- **Platinum Resistant/Refractory***
- **ECOG 0-3**
- **Life expectancy > 3 months**
- **Able to commence treatment within 2wks of registration**
- **Able to complete questionnaires independently**

→

R E G I S T E R

→

Data Collection

- **Baseline**
- **Each treatment cycle**
- **One month post completion of treatment or until disease progression**

* Amendment to include patients receiving 3rd line or greater lines of treatment - including potentially platinum sensitive

Current accrual status

GROUP	NO. OF SITES	ACCRUAL
ANZGOG	24	76
CANADA	2 (1 to open)	16
AGO	11	24
ICORG	8	32
MITO	1 (3 to open)	12
NSGO	5 (1 to open)	8
TOTAL	**51**	**168**

Current status

The following groups should be open to recruitment by Q1 2013

- Canada (PMH) (additional sites)
- CoGI
- Japan
- GINECO (Q4 2012)
- UK

Two manuscripts submitted for publication:

- Symptom Burden and outcomes of patients with platinum resistant/refractory recurrent ovarian cancer - Results of Stage 1 of GCIG Symptom Benefit Study. ML Friedlander, MR Stockler, R O'Connell, M Voysey, AM Oza, K Gillies, HS Donovan, J Martyn, K Sjoquist, P Butow and MT King. *Submitted to The Oncologist*

- Hope, symptoms and quality of life in women having chemotherapy for platinum resistant/refractory recurrent ovarian cancer - the GCIG Symptom Benefit Study. KM Sjoquist , ML Friedlander, RL O'Connell, M Voysey, MT King , MR Stockler, AM Oza, K Gillies, J Martyn and P Butow. *Submitted to Journal of Clinical Oncology*

Elderly Trials

- Ewoc
- GOG 273

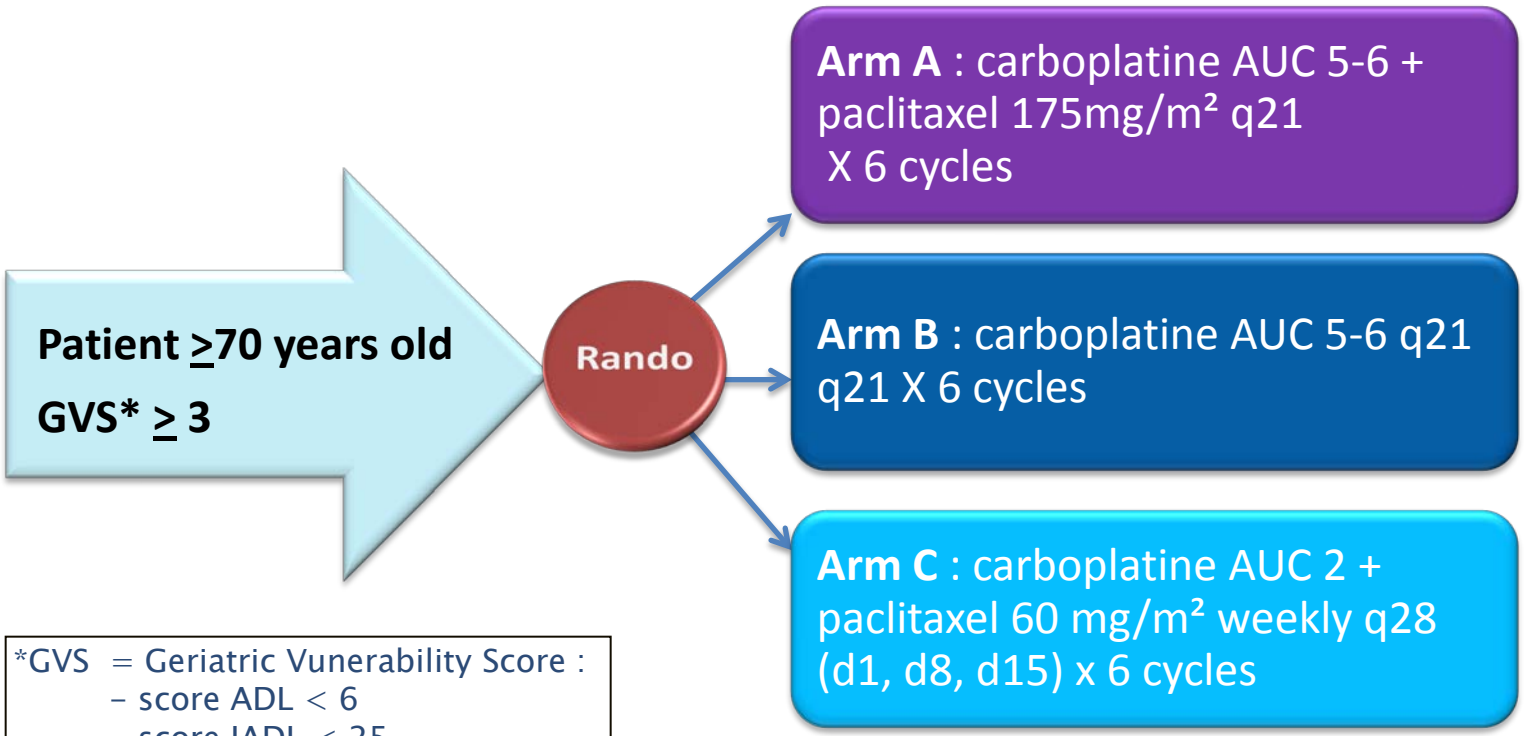
EWOC

Elderly **W**omen **O**varian **C**ancer

Multicenter, randomized trial of carboplatin +/- paclitaxel in vulnerable elderly patients with stage IIB-IV advanced ovarian cancer

Eric Pujade Lauraine

EWOC DESIGN of Chemotherapy in Advanced OC
(stage IIB-IV Elderly Vulnerable Pts)



*GVS = Geriatric Vunerability Score :
- score ADL < 6
- score IADL < 25
- score HADS > 14
- albuminemia < 35g/L
- Lymphopenia < 1G/L

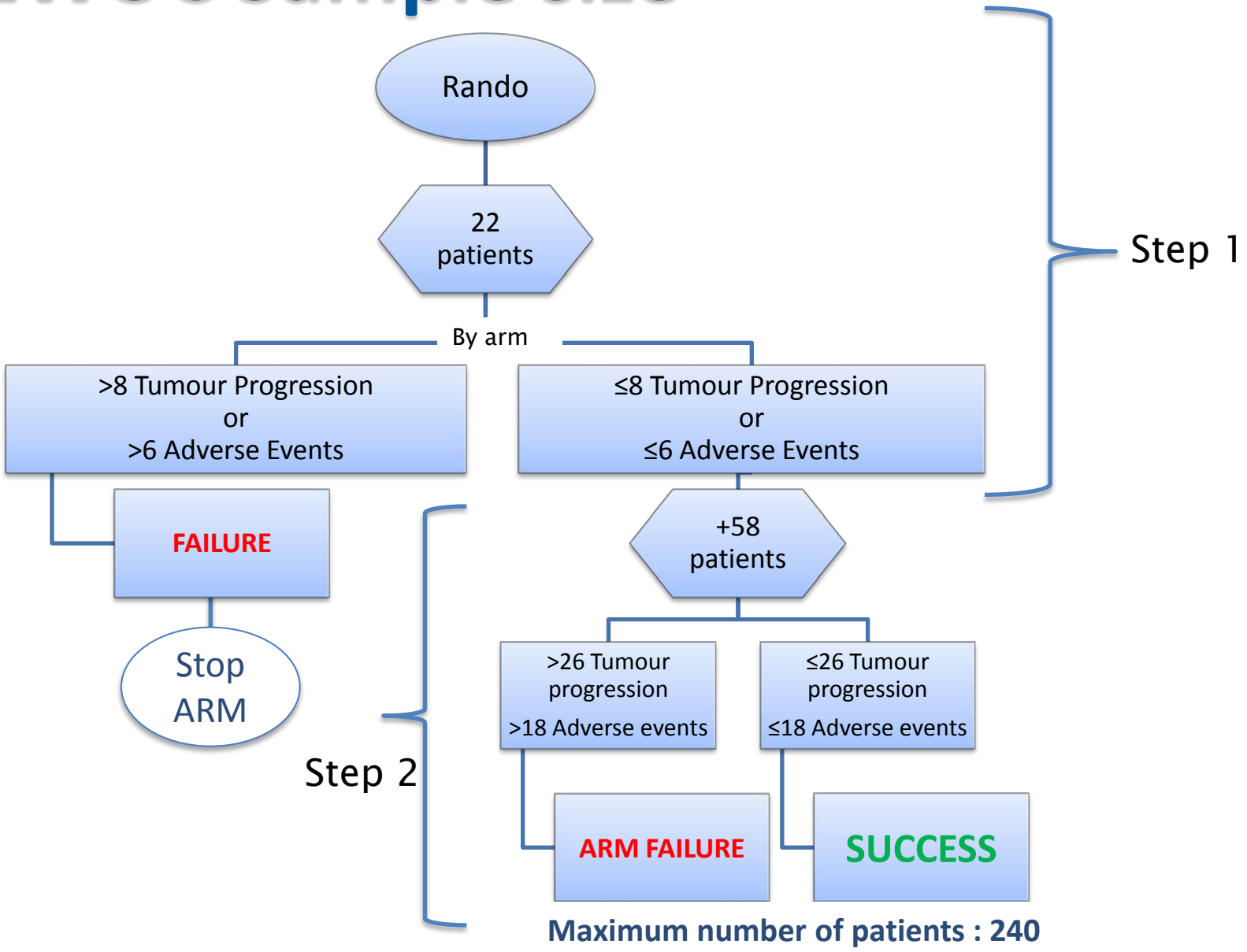
GVS = Σ factors with vulnerable score

PRIMARY ENDPOINT

To compare the rate of success to deliver 6 chemotherapy courses without PD at 6 months or unacceptable toxicity *of 3 different regimens in vulnerable elderly patients

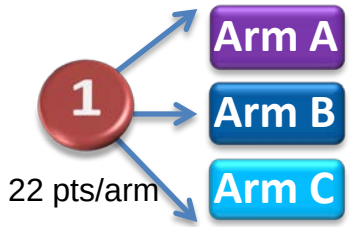
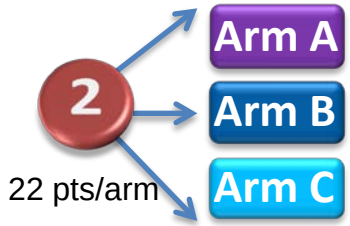
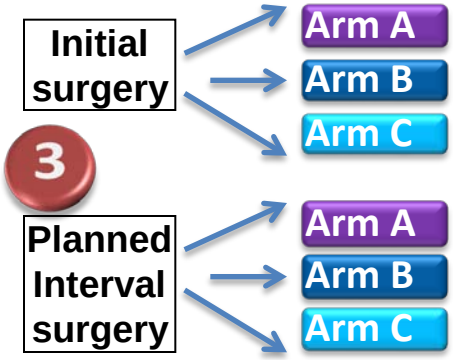
* Unacceptable Toxicity = is defined as a major adverse event related to chemotherapy or treatment procedures leading either to early treatment stopping, to an unplanned hospital admission or to death.

EWOC Sample size



Question : what is your best option?

Pts are stratified according to initial or planned interval debulking surgery

Option	Time of feasibility evaluation	interim analysis	interpretation
	6 months	Pts with initial or planned IDS are mixed in each arm (stratified)	▪ Heterogeneity of pts treatment and characteristics ▪ simple; real life
	4 cycles IDS is performed after the 4th cycle)	Pts with initial or planned IDS are mixed in each arm (stratified)	▪ Heterogeneity of pts characteristics ▪ chemo only is evaluated (but may be felt too early)
	6 months	Separate analysis in each surgical stratum (possibility of mixing if results are coherent in each stratum)	▪ Homogeneity of pts treatment and characteristics ▪ risk of doubling the initial maximum pts target number

ACCRUAL TO PROTOCOL GOG 273

Chemotherapy Toxicity in Elderly Women with Ovarian , Primary Peritoneal or Fallopian Tube Cancer

Gini Fleming

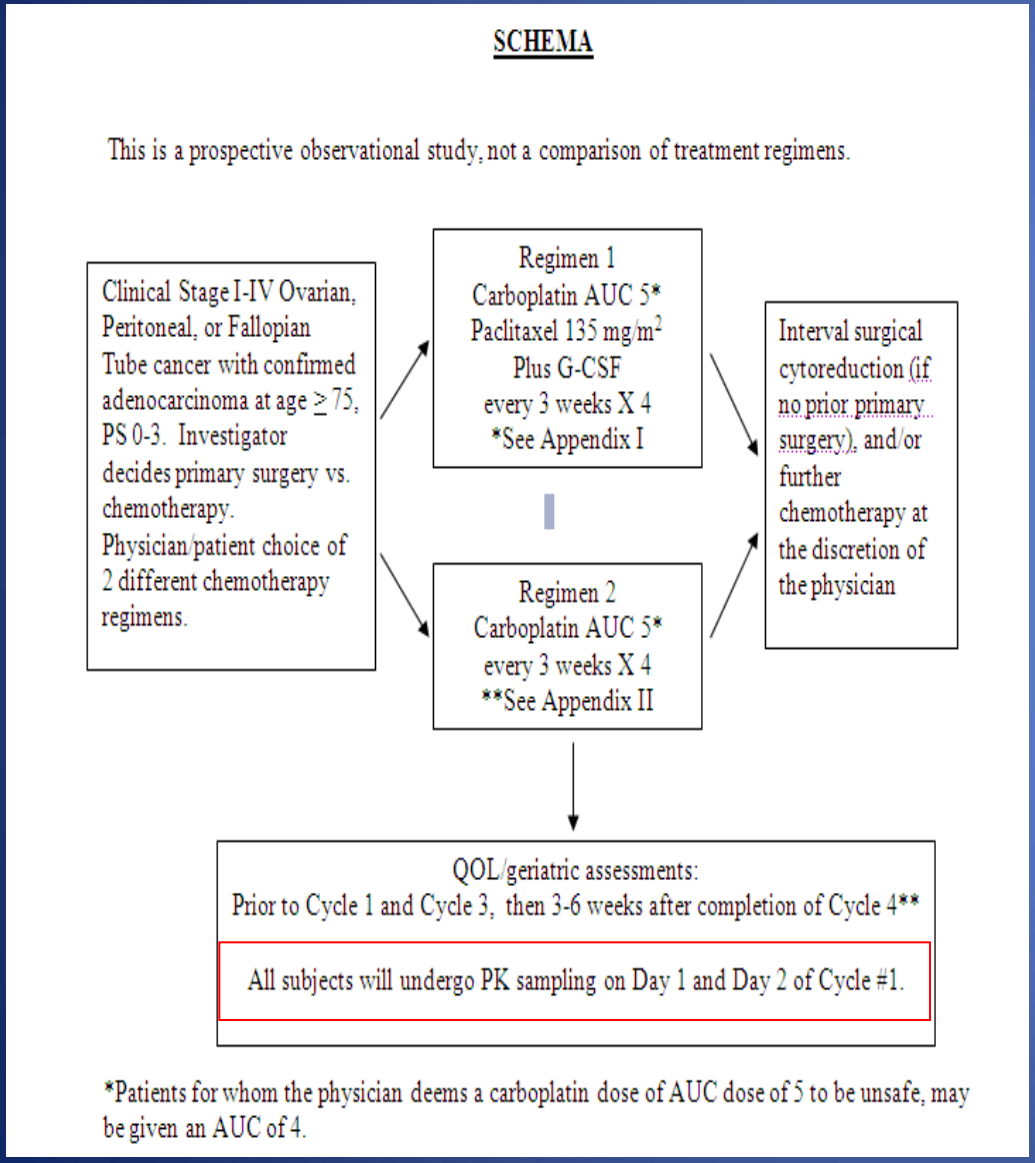
Chair GOG Working Group on Elderly

StudyChair

Vivian E. von Gruenigen, MD

GOG Gynecologic Oncology Group

GOG-0273



- Liberal eligibility criteria
- Patient and physician therapy choices-not randomized
- Prospective geriatric assessment
- Allows neoadjuvant chemotherapy
- PK – time 0, 1 hr after, 6 hrs after, 24 hrs
- Targeted accrual is 185

GOG-0273

The primary objectives

- Determine if Instrumental Activities of Daily Living (IADL) at entry is associated with the ability to complete chemotherapy
  - Sequential Pros (patient-related outcomes)
- Estimate by regimen the % pts who are able to complete chemotherapy w & w/o dose reductions or delays and
- Compare actual and calculated Carboplatin AUC

GOG 273

- Accrual Goal n=185
- Open Aug 15, 2011
- First pt on Dec 2011
- 1-2 pts/month accrued first 4 months
  - Survey sent to all GOG PIs re: accrual issues
  - Amended to allow pts age ≥ 70 (instead of 75)
  - Clarified flexibility in scans and dosing
  - Slide set for posting on SGO
- Current accrual 81

Imperial College London

Ovarian cancer action

OVPSYCH

Randomised controlled trial to evaluate the impact of psychological support on ovarian cancer survivors

Imperial College London and Maggie's Centres in UK

Imperial College Healthcare Charity

maggie's cancer caring centres

OVPSYCH - design

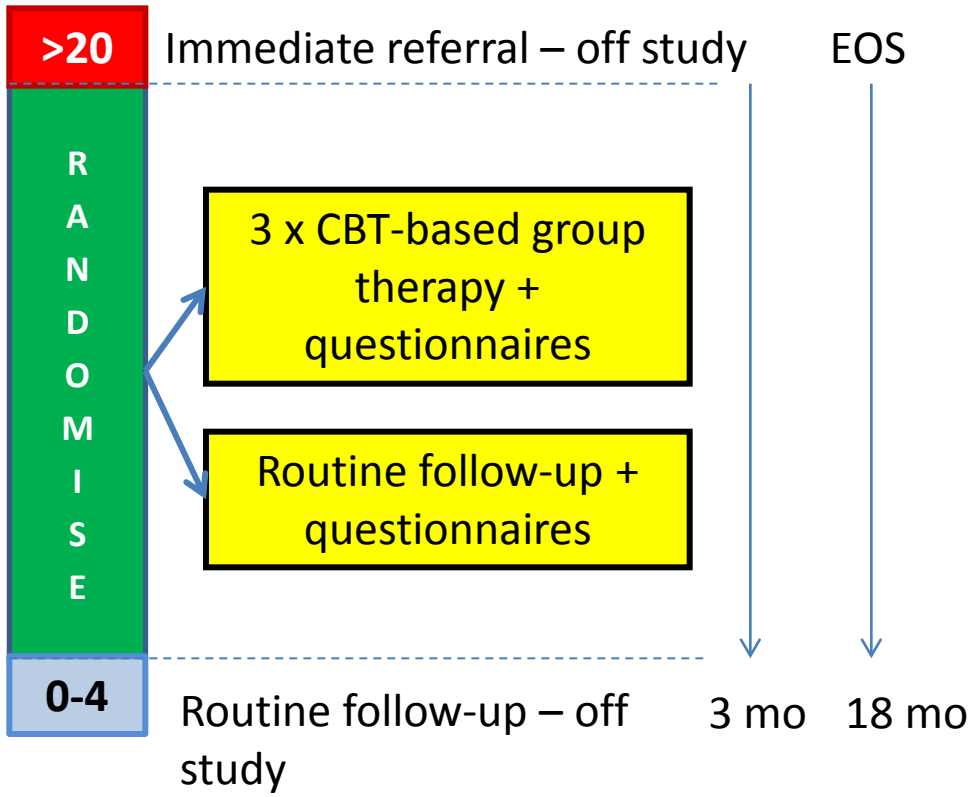
Target population

- >18 years
- Chemotherapy for primary or relapsed ovarian (fallopian tube or primary peritoneal) cancer <6 weeks previously
- Not on anti-depressants or receiving counselling

REGISTER

- **PHQ-9**
- GAD-7
- QLQ-C30
- QLQ-28

PHQ-9 score



Imperial College Healthcare Charity

OVPSYCH - endpoints

Primary Endpoint

•Change in PHQ score at 3 months compared to baseline in CBT vs non-CBT arms

Requires 126 patients, 63 in each arm

Secondary Endpoints

• Change in PHQ-9 at 6,12,15,18 months

• Change in other scores at 3,6,12,15,18 months

• Subgroup analyses

32 consented
9 randomised
2 drawn psychological intervention arm

Imperial College Healthcare Charity

maggie's cancer caring centres

EM QOL Brainstorming

Symptom Benefit Working Group: Endometrial cancer brainstorming session

Speakers: Eva Greimel, Remy Nout

- **Tools: general and specific, process of development, strengths and weaknesses**
- **QOL studies in endometrial ca**

Symptom Benefit Working Group: Endometrial cancer brainstorming session

GOAL 1 → **Consideration of QOL components in endometrial cancer trials***

- Use a validated tool
- Define the purpose/research question QOL tool being utilized for
  - Consider an a-priori PRO/QOL hypothesis (according to the trial)
- Consider how results will be presented: subscales, single items, both

*Must be a reason TO include QOL or explanation of why NOT to include

Symptom Benefit Working Group: Endometrial cancer brainstorming session

GOAL 1 → continued…

- Core: EORTC EN24 or FACT-En
- Secondary: study specific

e.g., neurotoxicity, body image, sexual health:

Symptom Benefit Working Group: Endometrial cancer brainstorming session

GOAL 2→ Unmet needs/deficiencies in QOL studies in EM cancer

- Very little is known on how treatment of specific populations of EM cancer patients (e.g. elderly) varies per institution/country/tumor group
- Symptoms in advanced stage group?
- Long term/survivorship issues for high risk group?
- Current tools do not fully address patient needs (vs. symptoms)
- From previous trials
  - QOL measures but remain unpublished, or not well highlighted
- Patient preferences have not been assessed

Symptom Benefit Working Group: Endometrial cancer brainstorming session

GOAL 3: →2 papers?

I. Up-to-date of EM QOL Prior studies

II. Didactic: tools, purpose/statements

Symptom Benefit Working Group: Endometrial cancer brainstorming session

NEXT: Short term*

I.Trial group contact/communication: QOL data in EM cancer past trials

II.Manuscript drafts

III.Survey : Treatments of specific group of patients (elderly) according to countries, groups and institutions)

*I. <2 months, II/III. Circulated 2 months prior to GCIG/ASCO with email comments/feedback and final decisions and revisions in Chicago

Symptom Benefit Working Group: Endometrial cancer brainstorming session

NEXT: Intermediate-Long term

I. Establish patient preferences study

II. Identifying survivorship issues for high risk endometrial cancers

III. Identifying predominant symptoms of advanced endometrial cancers (e.g., as in symptom benefit study)

IV. Intervention trials (symptoms post treatment)

Conclusions

- The focus of the Working Party will now move to other gynaecological cancers and will also address **survivorship** and cancer in the **elderly**
- **Recommendations** for the GCIG for Symptom-benefit evaluation in EM Cancer

Back-up

ADVOCATE

ADVANCED OVARIAN CANCER: CARE AND TREATMENT EXPERIENCES

Valerie Jenkins & Lesley Fallowfield
University of Sussex

ANZ GOG AUSTRALIA NEW ZEALAND GYNAECOLOGICAL ONCOLOGY GROUP

Follow up and Survivorship

Prospective study *to*

1. Evaluate the MOST questionnaire to detect symptoms of recurrence in patients in follow up after 1st line chemotherapy for advanced ovarian cancer *and to*

2. Document the Patient reported- incidence, severity and duration of adverse effects after completion of treatment

OPAL
Ovarian cancer prognosis and lifestyle study