Symptom Benefit Working Party Report

Michael Friedlander and Florence Joly

The discussion covered a number of areas

- Update on the Symptom Benefit Trial MF
- Summary of Qol Instruments being used in GCIG Ovarian Cancer studies MF
- Cervix Cancer – review of Qol instruments as well as gaps and needs in survivorship research FJ
- Endometrial Cancer- review of Qol instruments and gaps in survivorship research Jessica McAlpine
- Ovarian Cancer Survivorship Sara Blagden and MF
- Cancer in the elderly- Eric Pujade Lauraine and Gini Fleming

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

Outcomes of Stage 1

Development of an instrument – MOST

4 papers in draft -

1. Symptom Burden and outcomes in patients with platinum resistant/refractory recurrent ovarian cancer - Results of Stage 1 of GCIG Symptom Benefit Study
2. Methods paper describing the development of MOST
3. Hope or Hype – Patients expectations of palliative chemotherapy in platinum resistant ovarian cancer
4. **Qualitative Study-** Attitudes to palliative chemotherapy: the fine line between hope and misunderstanding -"It's not what makes chemo worthwhile, it's what will make chemo unbearable and force me to come off"

Stage 1-outcome

Primary Objective reached-

MOST (**M**easure of **O**varian cancer **S**ymptoms and **T**reatment concerns)

Modification of Patient Data Form

COVERS ALL SYMPTOMS AND ASPECTS OF QOL IDENTIFIED IN STAGE 1

MOST

Measure of **O**varian cancer **S**ymptoms and **T**reatment concerns

Comprises of 35 individual items on a discrete scale of 0-10, where major symptomatic distress is represented by 10.

The first 15 items refer to **disease symptoms (OSI)**

Items 16 and 17 refer to **physical and emotional well-being**
Item 18 is a question referring to **overall well-being**

Items 19-35 deals with **side effects and other concerns**

ANZGOG-0701 Stage 2

- 800 patients
  - MOST, QLQ-C30/Ov28, FACT-O/FOSI
- Assess psychometrics of the MOST
  - Validity, reliability, responsiveness, interpretability
  - determine the minimum clinically important difference (MCID)
- Validate MOST against QLQ-C30/Ov28, FACT-O/FOSI

Recruitment

Stage 2 open> 12 months

Total Recruitment to 30/05/12 = 77

Group	Open	Feasibility/Actual Recruitment to date
ANZGOG	Yes – recruiting	100/49
ICORG	Yes – recruiting	60/13
AGO	Yes – recruiting	100/8
MITO	Yes – recruiting 1/22 sites open	100/5
GINECO	No	100
NSGO	Yes Sweden – recruiting 1/5 sites open	50/2
JGOG GOTIC	No	100
Canada	2 x continuing sites open Other sites still being negotiated	0
UK	No	
USA	No	30 - 40
Total		800

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**

REGISTER

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

Symptom Benefit Group
Chicago, 2012

QoL Trials in Endometrial Cancer

Jessica McAlpine
UBC/BC Cancer Agency

- Improved tools in sexual health?
  - Improve compliance, encompass more
- Use of EM specific tools….EN24, others
- Trials-more, specific subpopulations? Interventions? Survivorship.
- Experts/invitees to Leiden- detailed discussion at the Leiden Endometrial Cancer meeting will focus on Qol and survivorship issues

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SYMPTOM BENEFIT WORKSHOP

Cervix cancer

GCIG

Chicago, Thursday, May 31, 2012

F Joly, MD,PHD

Discussion – Needs

- **Localized disease**
  - Acute/late toxicities: Needs of long-term follow-up +++
  - Others considerations than treatments sequelae (psychosocial impact, ……)
  - More attention to the confounding factors such as age, education, marital status, coping with the disease
- **Advanced disease**
  - PRO : main endpoint : must to be included in all trials
  - With an a-priori QOL Primary endpoint

Discussion – Needs

- **Methods/Statistics**
  - To define an a-priori QOL endpoint and to calculate the power to achieve it
  - To select the right scales according to the main questions in the different situations
  - Do we have the good scales?
  - Prognostic factor =dimension of PWB better than ECOG?
- **Interventional studies**
  - (ex: educational programs) after treatment of localized cervix cancer?

Imperial College London

Ovarian cancer action

OVPSYCH

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

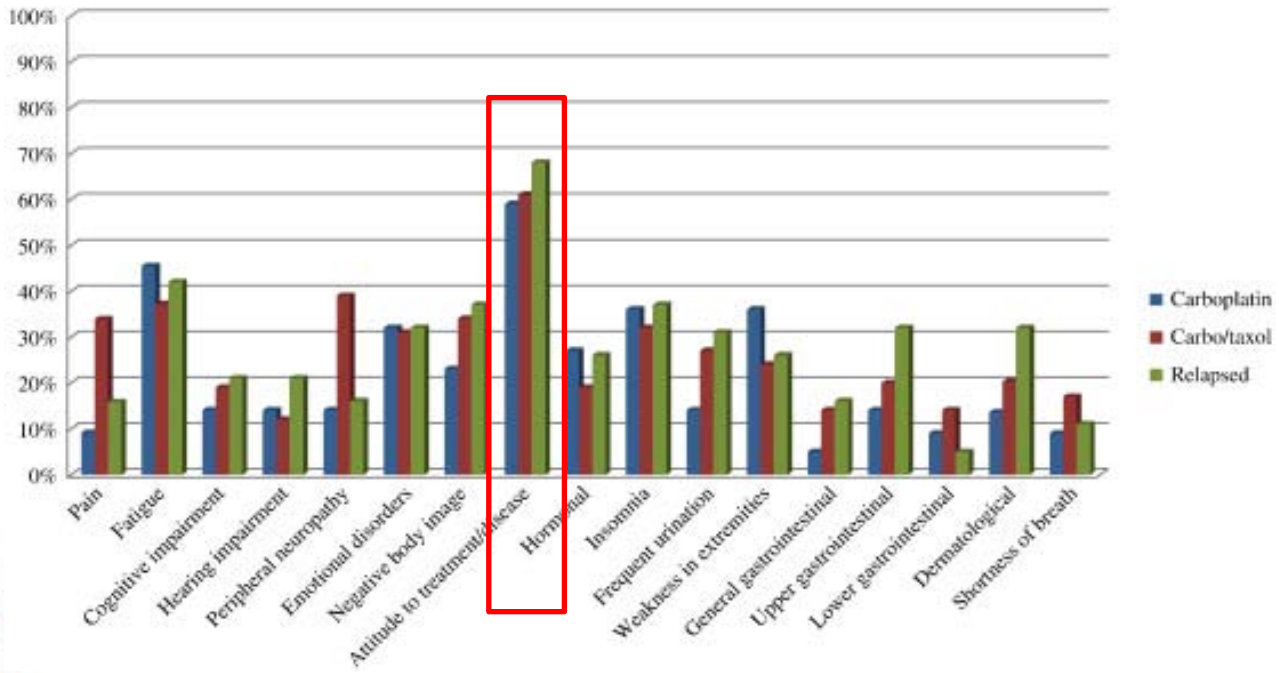
S.Blagden, R.Agarwal, H.Gabra, J.Petrak, P.Alexander, C.Stavraka

Imperial College, London

Imperial College Healthcare Charity

Audit of Survivors in 2010

- Asked 100 ovarian cancer survivors to complete EORTC QLQ-C30 and OV28 questionnaires
- Also included a “Wellbeing thermometer”
- Correlated findings with symptoms reported in clinic notes



Imperial College Healthcare Charity

OVPSYCH - design

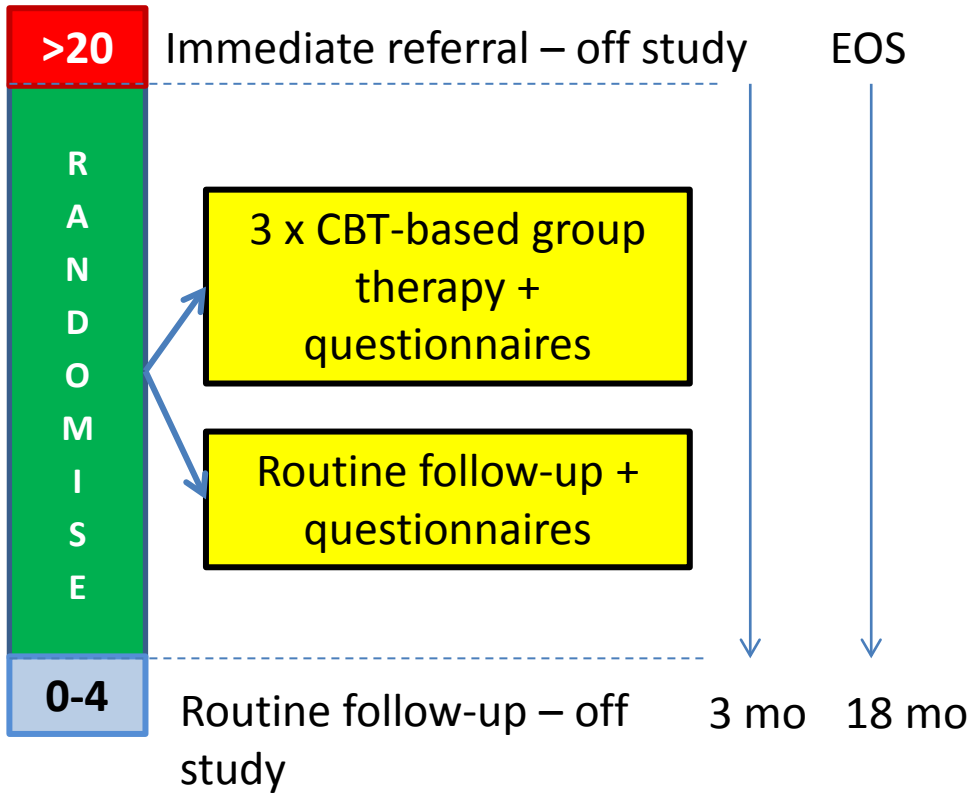
Target population

- >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

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

OPAL

Ovarian cancer prognosis and lifestyle study

Primary aim is to recruit and follow a cohort of >1200 women newly diagnosed with invasive ovarian cancer to:

- Identify whether potentially modifiable aspects of lifestyle after completion of primary treatment are independently associated with patient outcomes.

- Investigate the acceptability of the MOST questionnaire and its ability to (i) detect early symptoms of recurrence and (ii) document the frequency and impact of late-effects of treatment compared to conventional medical records in women with advanced ovarian cancer.

- Identify whether modifiable aspects of lifestyle and/or use of complementary medicines during chemotherapy are independently associated with:
  - prevalence and severity of side-effects during chemotherapy,
  -physical, functional and emotional wellbeing during chemotherapy,
  -chemotherapy completion rates

Cancer in the Elderly

- EWOK study being led by GINECO- presented by Eric Pujade Lauraine – final protocol still being worked on
- GOG study –presented by Gini Flemming

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

Development of a Geriatric Vulnerability Score (GVS)

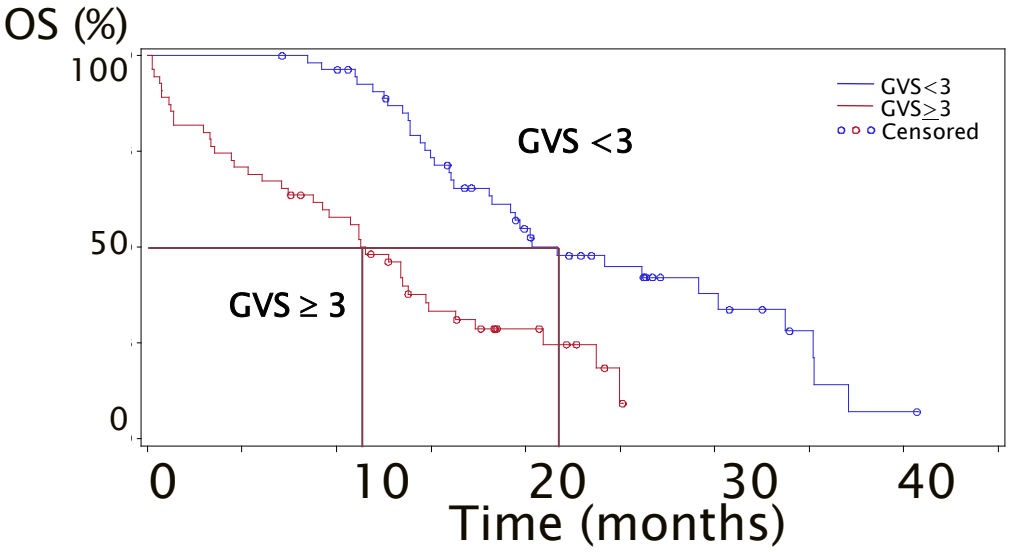
Freyer G. et al. (ASCO 2012 poster #9079)

GVS factors :

- score ADL < 6
- score IADL < 25
- score HADS > 14
- albuminemia < 35g/L
- Lymphopenia < 1G/L

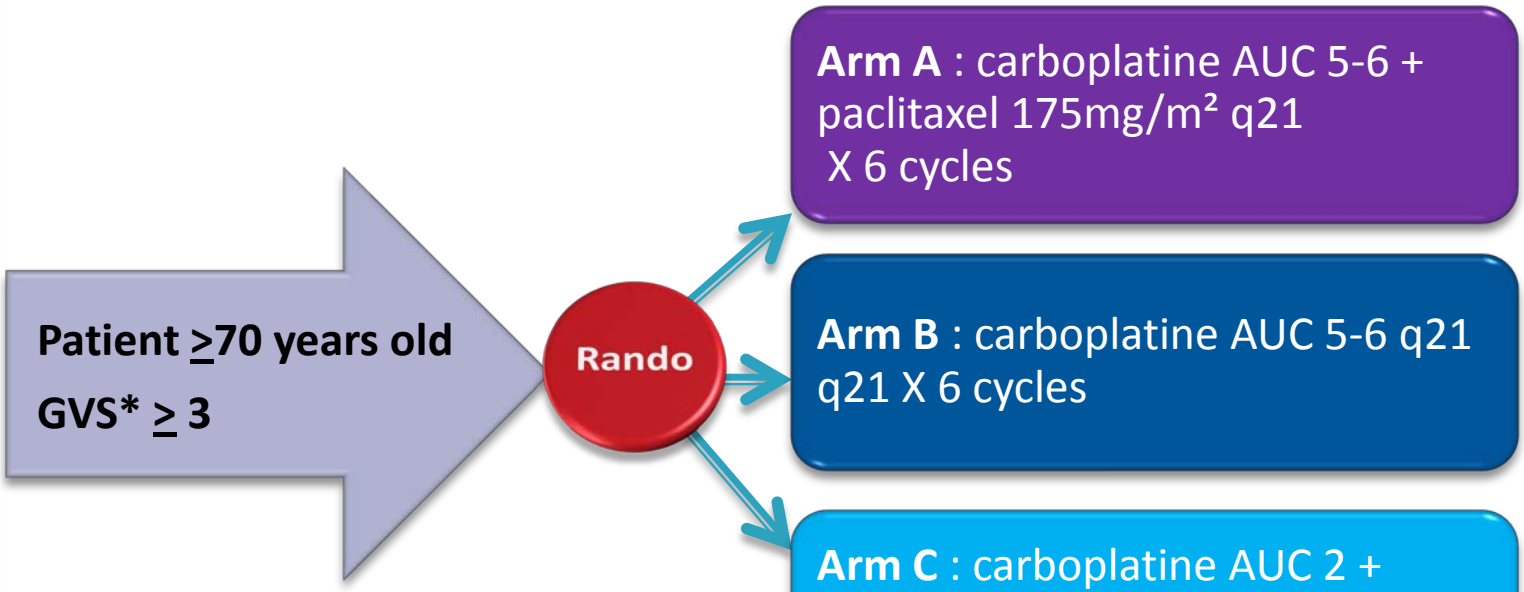
GVS = Σ factors with score above

=>**Patient is Vulnerable if GVS ≥ 3**



ARCAGY - GINECO

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

ARCAGY - GINECO

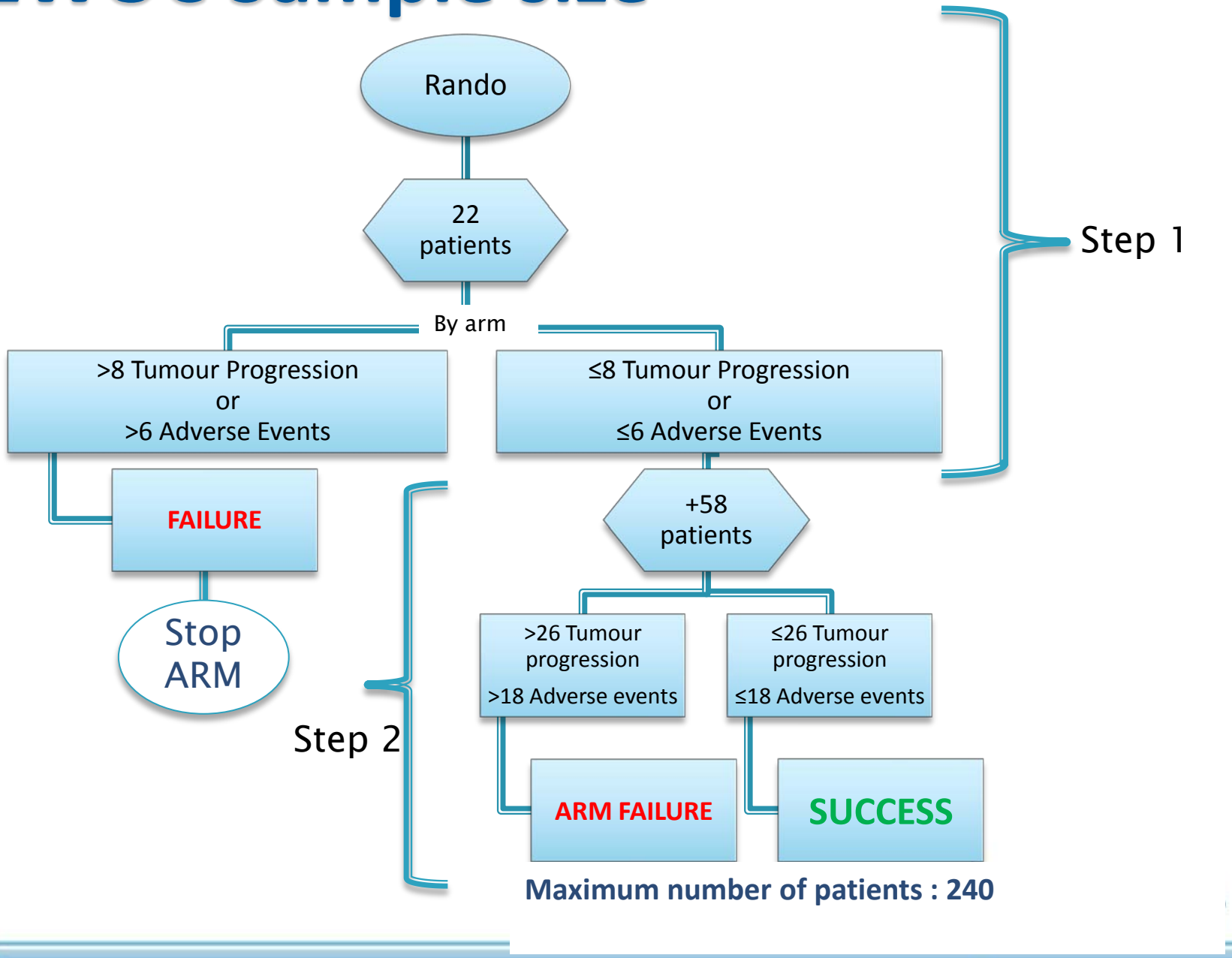
PRIMARY ENDPOINT

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.

ARCAGY - GINECO

EWOC Sample size



PROTOCOL GOG 273

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

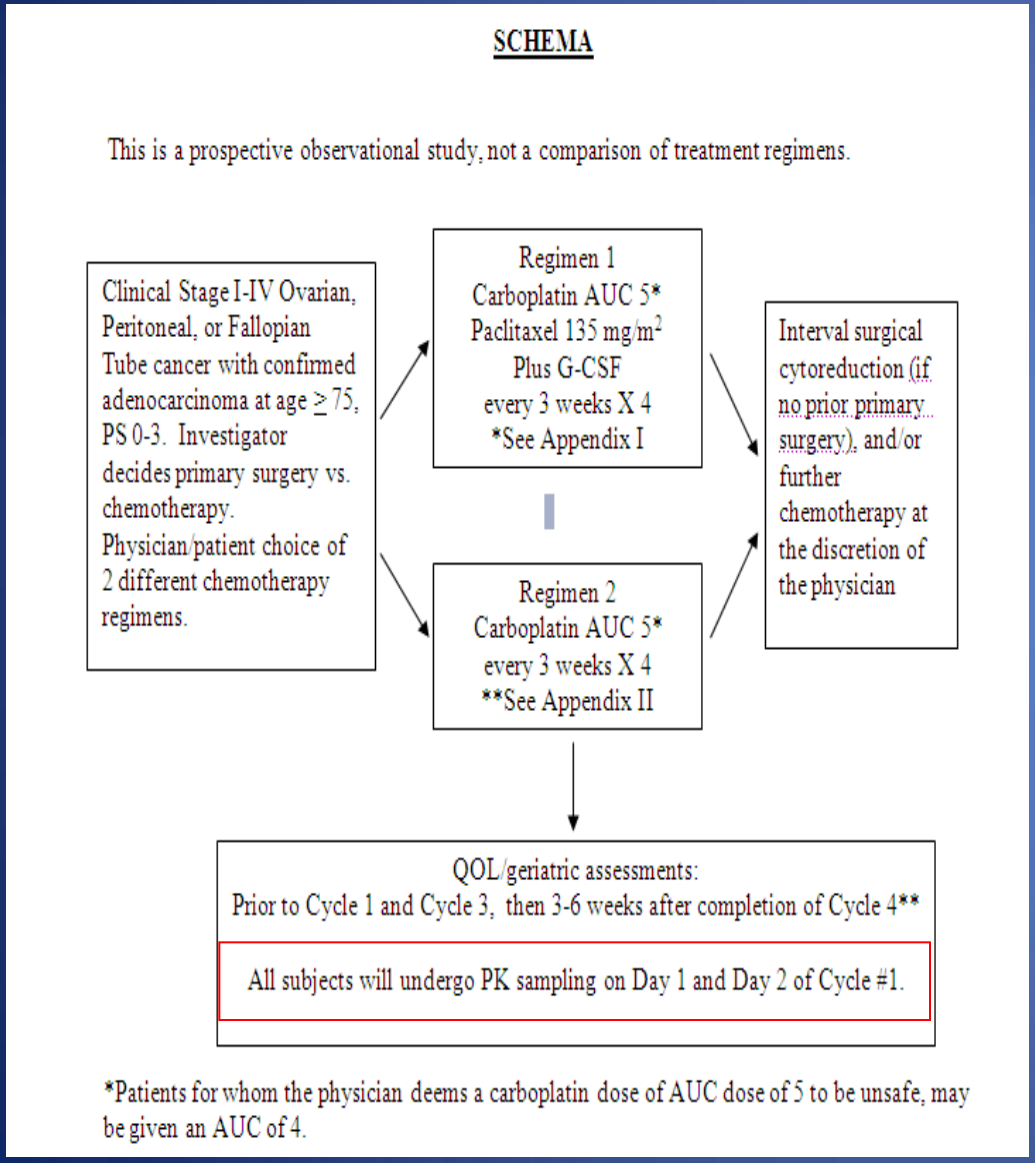
Gini Fleming

for

Vivian von Gruenigen MD, Thomas Herzog MD, Arti Hurria MD, Jan Hendrik Beumer PhD, Anne Heugel RN, Heather Lankes PhD, Helen Huang, MS

GOG Gynecologic Oncology Group

GOG-0273



- PS 0-3
- Patient and physician therapy choices-not randomized
- Prospective geriatric assessment
- Allows neoadjuvant
- PK – time 0, 1 hr, 6 hr, 24 hr
- Targeted accrual is 185

GOG-0273

Primary objectives

- To determine whether score on Instrumental Activities of Daily Living (IADL) at entry is associated with the ability to complete four cycles of chemotherapy without dose reduction or more that 7-day delay
- To estimate by regimen the percentage of patients who are able to complete four cycles of chemotherapy regardless of dose reductions and delays
- To compare actual and calculated carboplatin AUC in this patient population

GOG-0273

Secondary objectives (selected)

- Describe % patients getting neoadjuvant chemotherapy, % getting each regimen, % who eventually get surgery in the chemotherapy group
- Determine association between baseline IADL score and physician choice of regimen
- Explore whether age, baseline scores on functional status, nutritional status, co-morbidity, or QOL assessments correlate with completion of chemotherapy without dose reduction or more than 7 days delay

GOG 273 Assessments

- Charlson co-morbidity scale
- Hearing impairment (OARS)
- Falls in past 6 mos
- BMI, unintentional weight loss past 6 mos
- ADL (subscale of MOS), IADL (subscale of OARS MFAQ), GOG PS, Limitations in Social Activity (MOS)
- FACT/GOG-Ntx 4 subscale
- FACT-O

GOG 273

- Opened 8/15/2011
- Just amended to be on CTSU menu and to allow age > 70 (max 25% of sample size 70-74).
- Current accrual 15; four in last month
- Most common issue cited is PK

Conclusions

- Florence Joly and Jessica McAlpine will now chair the SB working party and Michael Friedlander will stand down
- The focus of the Working Party will now move to other gynaecological cancers and will also address survivorship and cancer in the elderly

Symptom Benefit Working Party

- Endometrial Cancer Qol and Survivorship
- Cervical Cancer Qol / Survivorship/ Endpoints
- Ovarian Cancer Survivorship
- SBS in ovarian cancer- ongoing study
- Cancer in the elderly