

# Symptom Benefit Working Party

Co Chairs

Michael Friedlander and Florence Joly

# Agenda

- Presentation of the findings of Stage 1 SBS- and brief discussion of Stage 2
- Focus of the WP will now be to address the “gaps” identified at the 4<sup>th</sup> OCCC with respect to Cancer in the Elderly as well as Survivorship

# Stage 1-To Determine:

- The symptoms and aspects of HRQL that are rated as most severe, troublesome and important by patients with platinum resistant ovarian cancer.
- The optimal items and questionnaires for measuring these improvements.

## Timing of filling out Questionnaires

<b>QoL Instrument</b>	<b>Baseline (within 2 weeks before first cycle)</b>	<b>Before every subsequent cycle of treatment q3 – 4 weekly</b>	<b>4 weeks after starting 4th cycle of treatment or after end of treatment</b>
<b>SRQ</b>	X	X	X
<b>FACT-O</b>	X	X	X
<b>QLQ-C30 + Ov-28</b>	X	X	X
<b>Pt DATA Form</b>	X	X	X
<b>Expected &amp; perceived benefit</b>	X	X	X
<b>HADS</b>	X		X
<b>Herth Hope Index</b>	X		X

# Reasons for Starting Chemotherapy

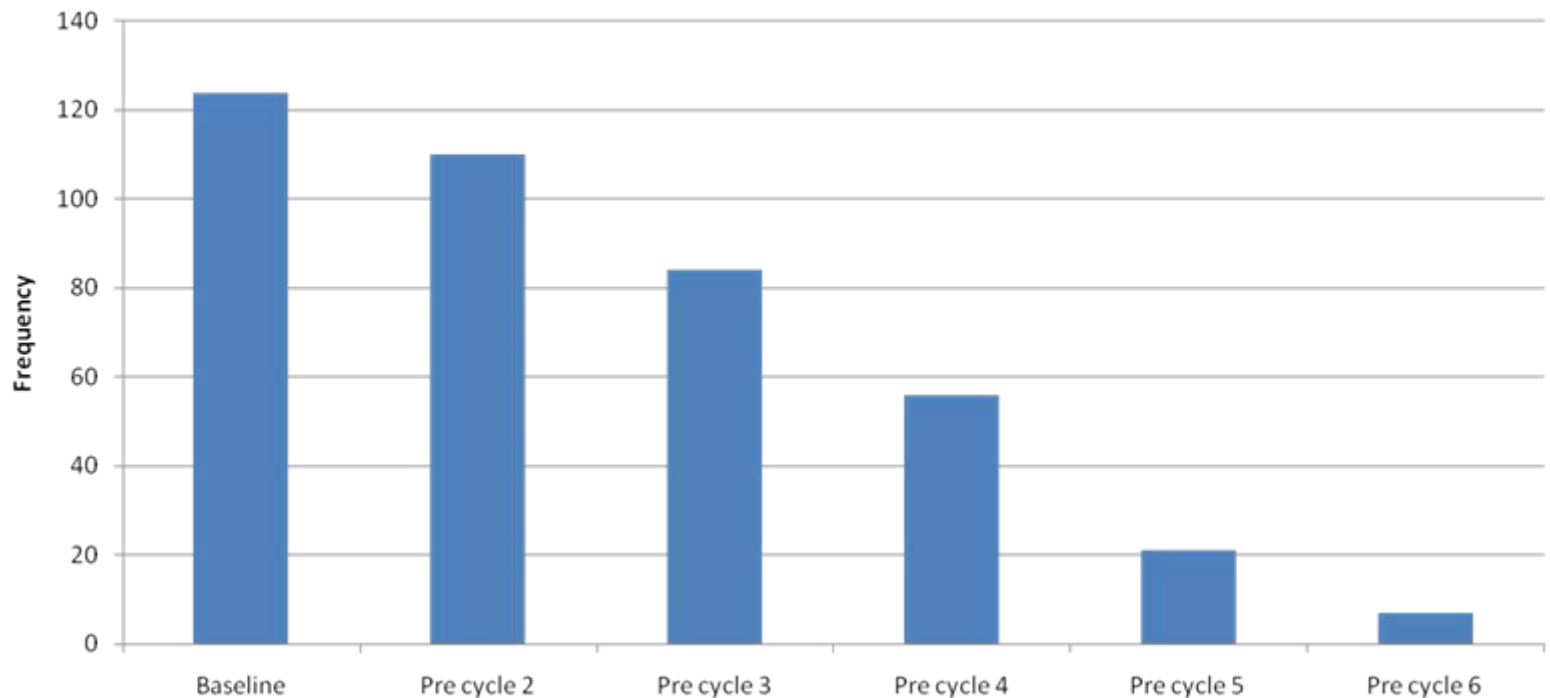
REASONS FOR CHEMOTHERAPY	Patients (N=124)
Symptom control	92( 76%)
Rising CA125 only	2(2%)
Radiological evidence only	2(2%)
Rising CA125 + radiological evidence only	26(22%)

# Patients “3 most noticed symptoms” and clinician rated ‘Adverse Event’s at baseline

CAUSE	SYMPTOM	% Patients reported	% AE reported by clinician
BOTH TREATMENT & DISEASE	FATIGUE	<b>42%</b>	53%
PREDOMINANTLY DISEASE RELATED	PAIN (ABDOMINAL/ UNSPECIFIED)	<b>48%</b>	25%
	ABDOMINAL PROB/BLOATING	<b>31%</b>	<b>13%</b>
	NAUSEA/VOMITING	<b>22%</b>	22%
	BOWEL PROBLEMS	<b>21%</b>	26%
	SHORTNESS OF BREATH	<b>11%</b>	<b>2%</b>
	APPETITE LOSS	<b>10%</b>	19%
PREDOMINANTLY EMOTIONAL	SLEEP DISTURBANCE	<b>24%</b>	<b>4%</b>
	DEPRESSION/MOOD PROBLEMS	<b>18%</b>	<b>4%</b>

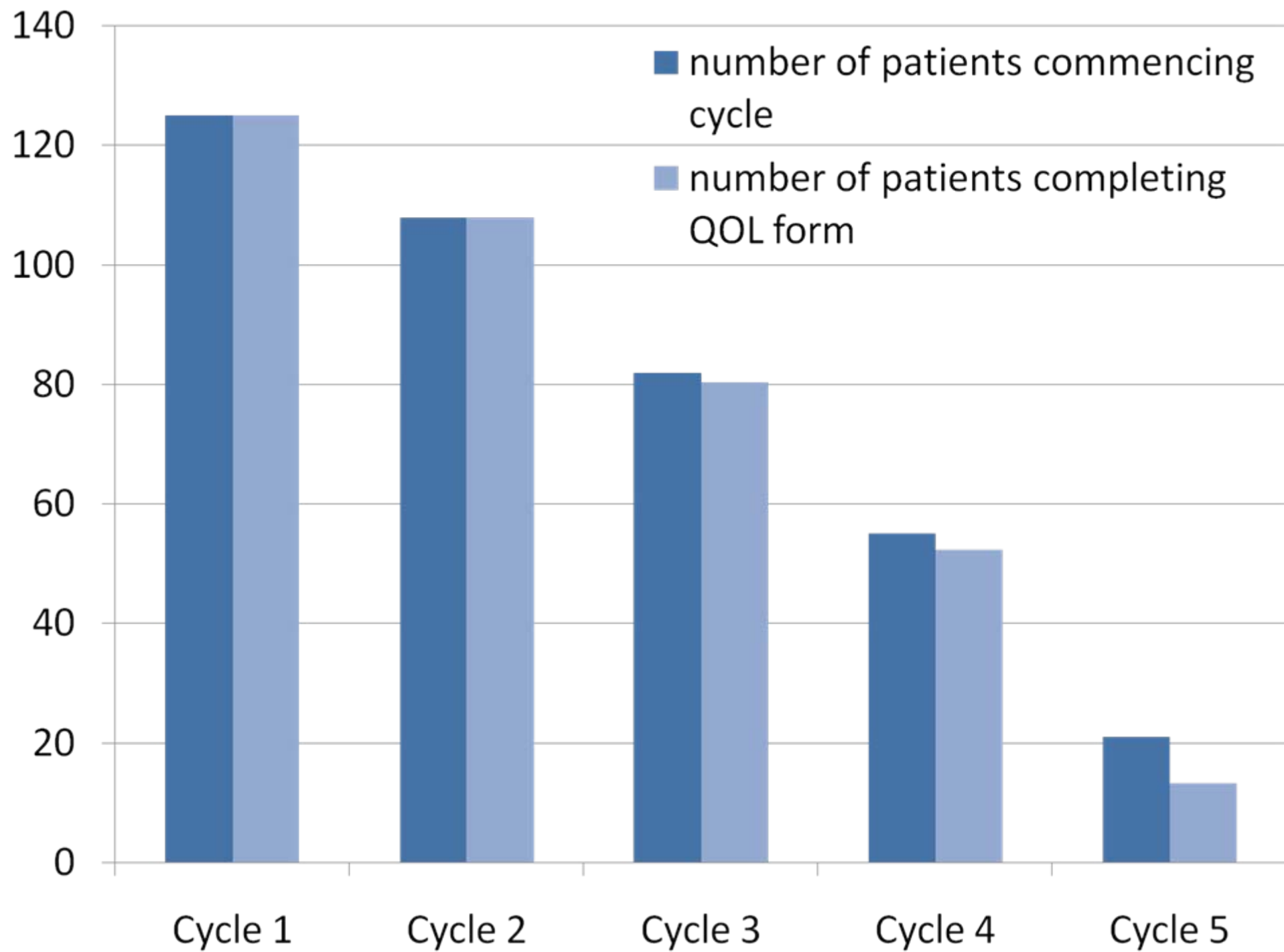
# Chemotherapy over time

Number of patients proceeding with treatment by visit

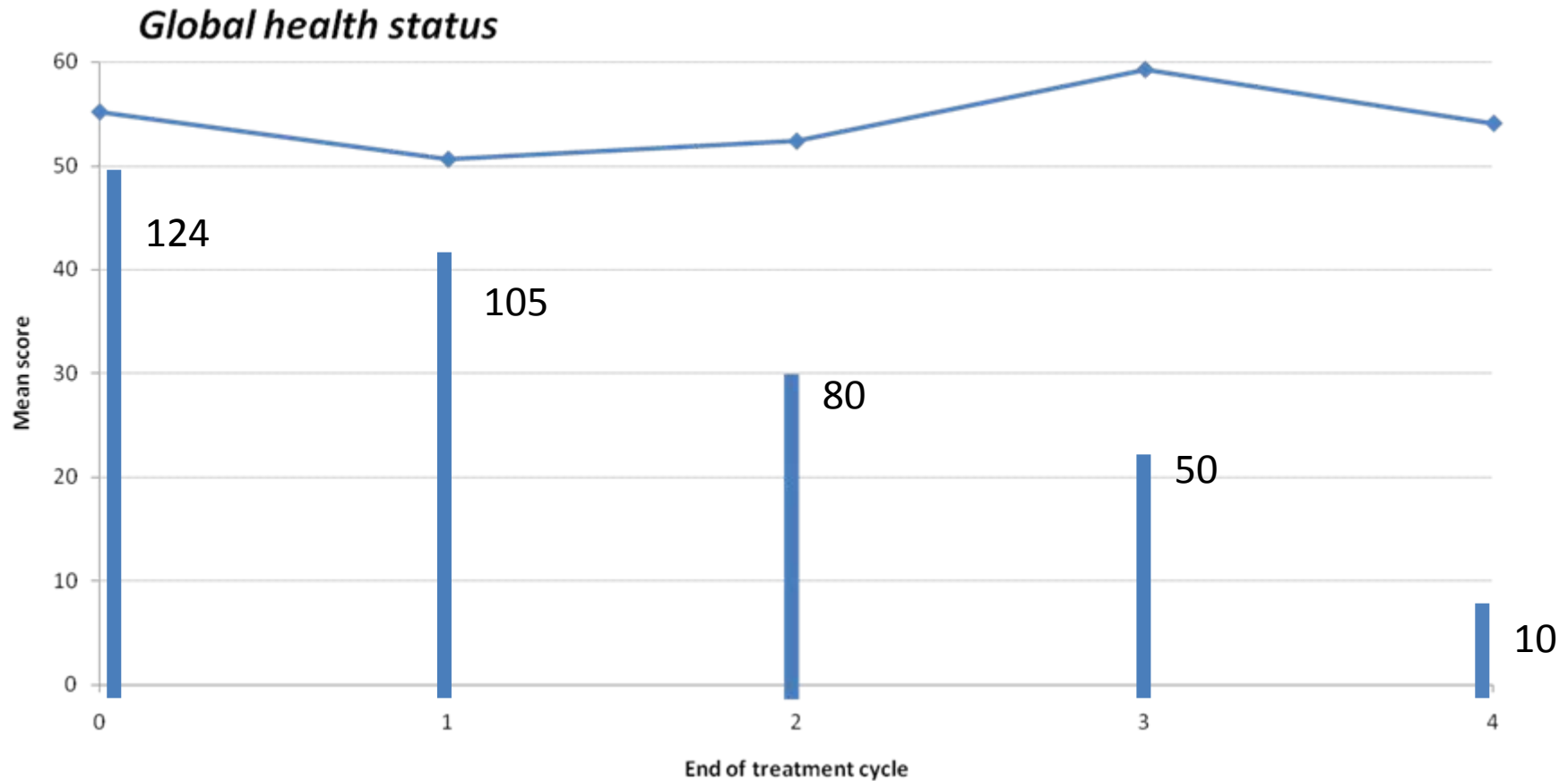


## Clinician Reported Grade 3 /4 Adverse Events and Patient Reported Side Effects > 7+ Patient Data Form

Symptoms/ adverse event	BOTH YES	Clinician YES Patient NO	Clinician NO Patient YES	BOTH NO
NAUSEA		3( 2.6%)	<b>25 (21.6%)</b>	88 ( 75.9%)
VOMITING	3 (2.6%)	2(1.7%)	<b>13 (11.2%)</b>	98 (84%)
DIARRHOEA	1(0.9%)	2(1.7%)	<b>18(15.5%)</b>	95(81.9%)
CONSTIPATION		3(2.6%)	<b>26(22.4%)</b>	87(75%)
ANOREXIA	2(1.7%)	5(4.3%)	<b>57(49.1%)</b>	52(44.8%)
FATIGUE	10(8.6%)	2(1.7%)	<b>51(44.0%)</b>	53(45.7%)
PARASTHESIA	1(0.9%)	1(0.9%)	<b>14(12.1%)</b>	100(86.2%)

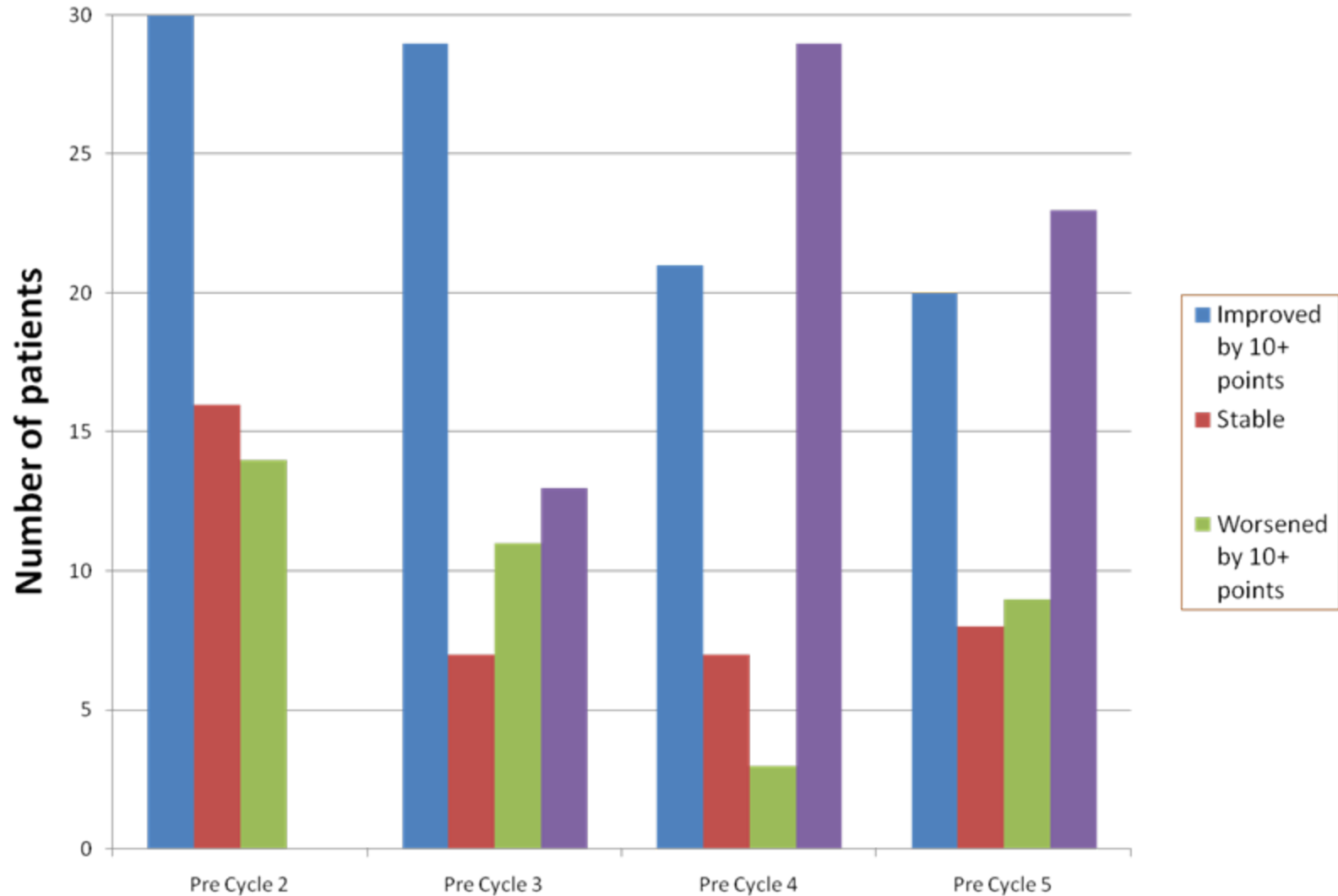


# Was there an improvement in QoL EORTC Global Health Status



**Patient coming off therapy over time**

**Change from Baseline in patients with significant abdominal/gastrointestinal symptoms at baseline  
(EORTC Abdominal/GI domain score >30)**



# Schema – Stage 2

## Target Population

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

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## Data Collection

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

# Ovarian Cancer in the Elderly

## Penny Webb- (unselected population)

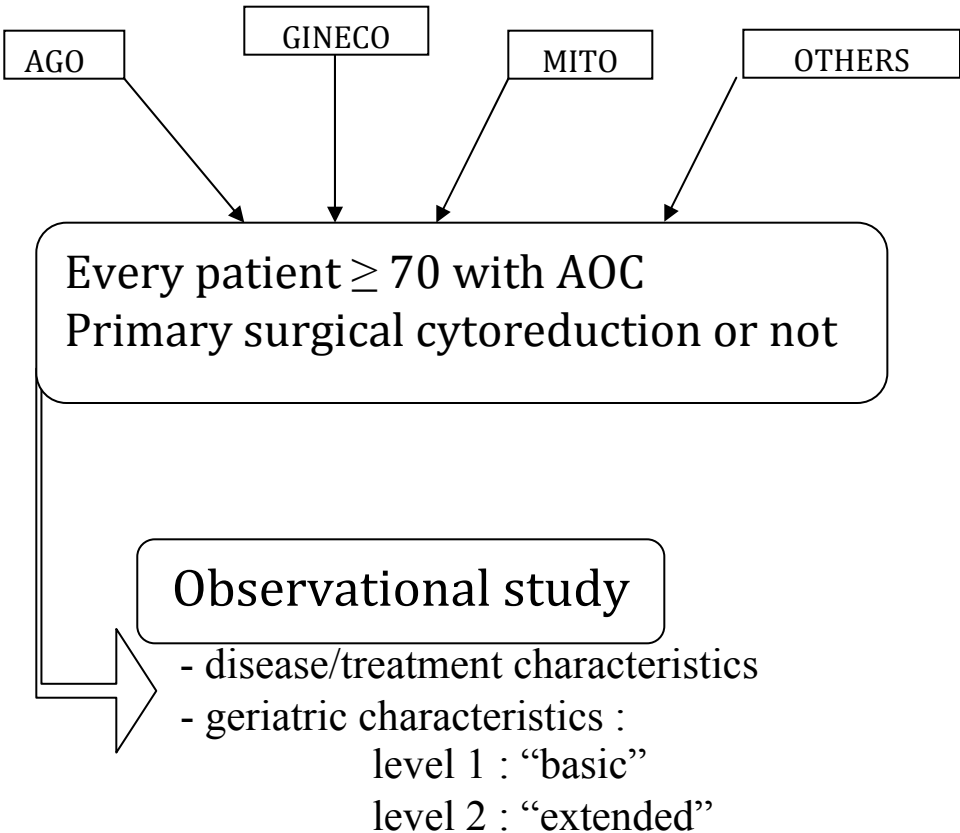
- Australian Patterns of Care study women with Invasive OC
- Women > age 70
  - 80% adjuvant
  - 20% neoadjuvant
  - 60% single agent Carboplatin
  - 30% Carbo-taxol

Most had treatment modifications

**EWOC (Elderly Women Ovarian Cancer) Trial :**  
**International prospective clinical trial of carboplatin +/-**  
**paclitaxel for vulnerable elderly ovarian cancer patients.**

A collaboration between the GINECO (Groupe d'Investigateurs Nationaux pour l'Etude des Cancers de l'Ovaire et du sein) and the GCI (Gynaecologic Collaborative International Group)

# Observational study



## Geriatric

### *Level 1 basic*

ADL/IADL  
VES13  
Albuminemia  
Lymphocytes  
Depression  
Comorbidities

### *Level 2 extended*

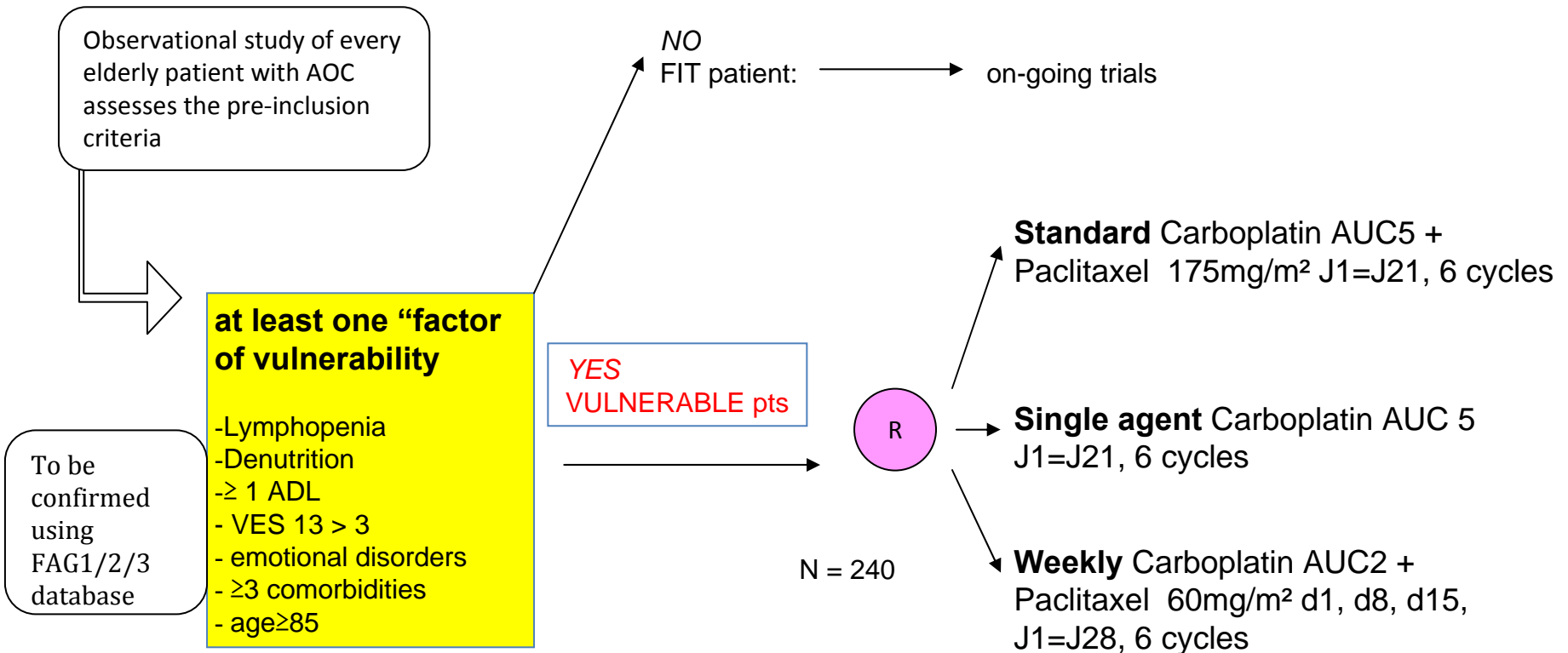
HADS  
MNA<sub>d</sub>  
Falls in the 6 months  
others?

## Follow up

Treatment ?  
Cycles? Delay? Dose  
reduction?  
Gr3-4 toxicities  
PFS; OS  
study participation

# EWOC (Elderly Women Ovarian Cancer) Trial : International prospective clinical trial of carboplatin +/- paclitaxel for vulnerable ovarian cancer patients.

A collaboration between the GINECO (Groupe d'Investigateurs Nationaux pour l'Etude des Cancers de l'Ovaire et du sein) and GCIG (Gynaecologic Collaborative International Group)



2-step-design with safety analysis after 22 pts in each arm  
(stopping criteria are the following: tumor progression  $\geq 8$ , excess toxicity  $\geq 6$ .)

# Plans

- Committee to be chaired by Florence Joly to develop the GINECO proposal and potentially modify it based on input from other groups e.g. Sehouli et al
- Committee to address survivorship issues

Will meet by TC/email regularly with aim of having near final draft protocol to discuss and present in June 2012