ANZGOG Update

Symptom Working Group

Presentation prepared by Michael Friedlander

GCIG Symptom Benefit Study

Baseline quality of life as a predictor of early cessation of chemotherapy and survival in platinum resistant/refractory recurrent ovarian cancer (PRR-ROC)

Felicia Roncolato, Rachel O'Connell, Luke Buizen, Florence Joly, Anne Lanceley, Felix Hilpert, Aikou Okamato, Eriko Aotani, Sandro Pignata, Paul P. Donnellan, Amit M. Oza, Elisabeth Avall-Lundqvist, Jonathan S. Berek, Katrin M. Sjoquist, Kim Gillies, Martin R. Stockler, Madeleine T. King and Michael Friedlander on behalf of GCIG Symptom Benefit group

Session: Gynecologic Cancer
Type: Oral Abstract Session
Time: Sunday June 5, 9:45 AM to 12:45 PM
Location: E450ab

Symptom Benefit Study- Progress

- Taken much longer to analyse than expected
- Analyses of MOST Symptoms completed
- Validation analyses largely completed

Analyses so far have focused on two measures of symptoms:

1. **MOST Ovarian Symptom Index (MOST-OSI), all 15 Symptoms**
2. **MOST Disease-defining symptoms of Ovarian Cancer (MOST-ODDSI), subset of 7 symptoms**

Note: *the acronyms, OSI and ODDSI, are working titles only at this stage, used in the following summary of results.*

MOST Symptoms	MOST-OSI	MOST-ODDSI
abdominal pain, discomfort and/or cramps	✓	✓
abdominal swelling, bloating and/or fullness	✓	✓
poor appetite (or feeling full quickly)	✓	✓
pain (all and anywhere)	✓	✓
trouble eating	✓	✓
shortness of breath	✓	✓
nausea	✓	✓
vomiting	✓	
indigestion	✓	
diarrhoea	✓	
constipation	✓	
bladder problems	✓	
leg swelling	✓	
fatigue (tiredness)	✓	
trouble sleeping	✓	

Methods

To date, we have addressed the following ;

1. internal consistency
2. convergent validity
3. sensitivity to differences between clinically distinct groups
4. relative efficiency in relation to 3.
5. responsiveness to clinically important change over time
6. relative efficiency, in relation to 5.
7. minimally important differences (MID)

of two scales derived from the MOST symptom items:

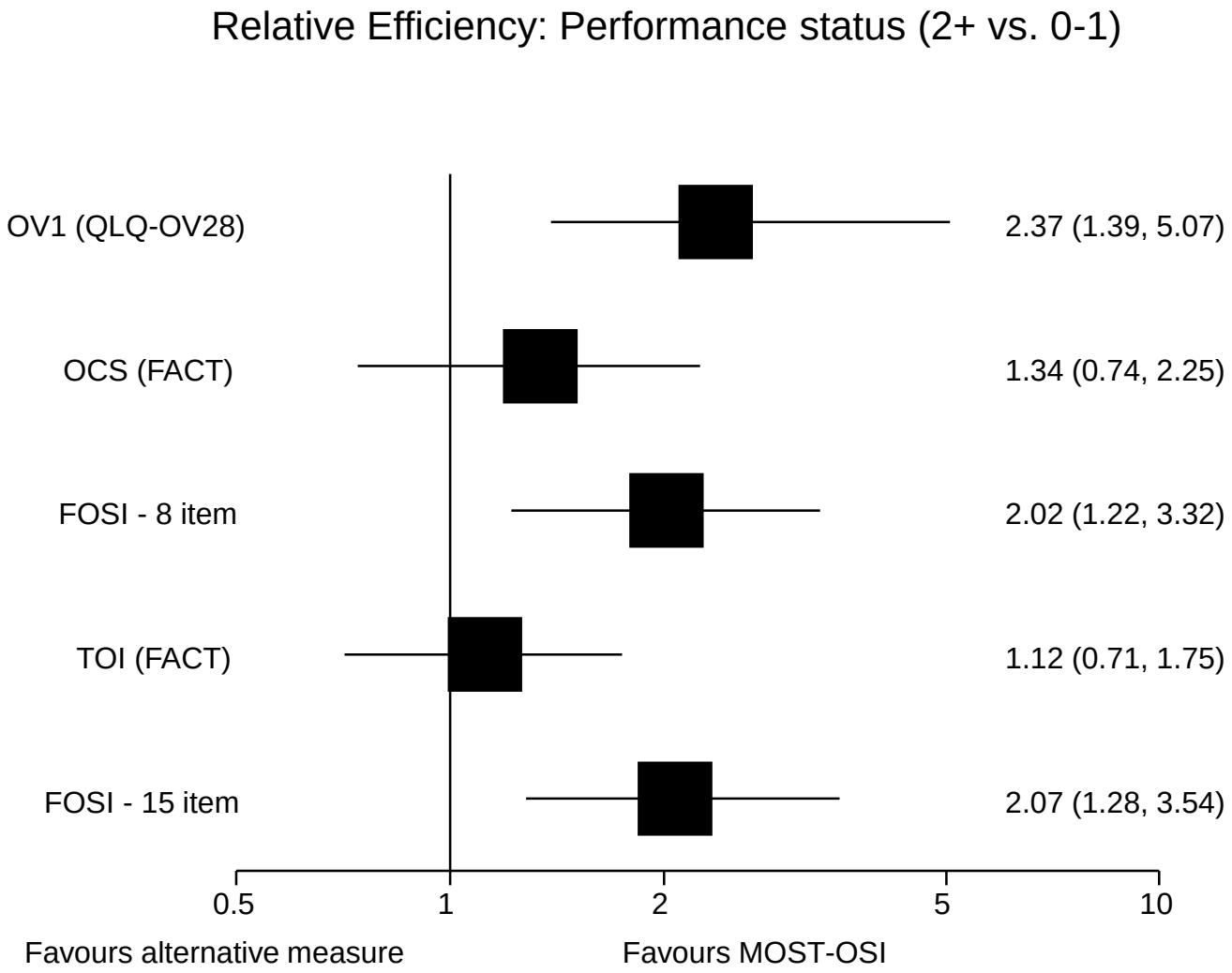
A) MOST Ovarian Symptom Index (MOST-OSI), all 15 symptoms.

B) MOST Disease-defining symptoms of Ovarian Cancer (MOST-ODDSI), a subset of 7 symptoms

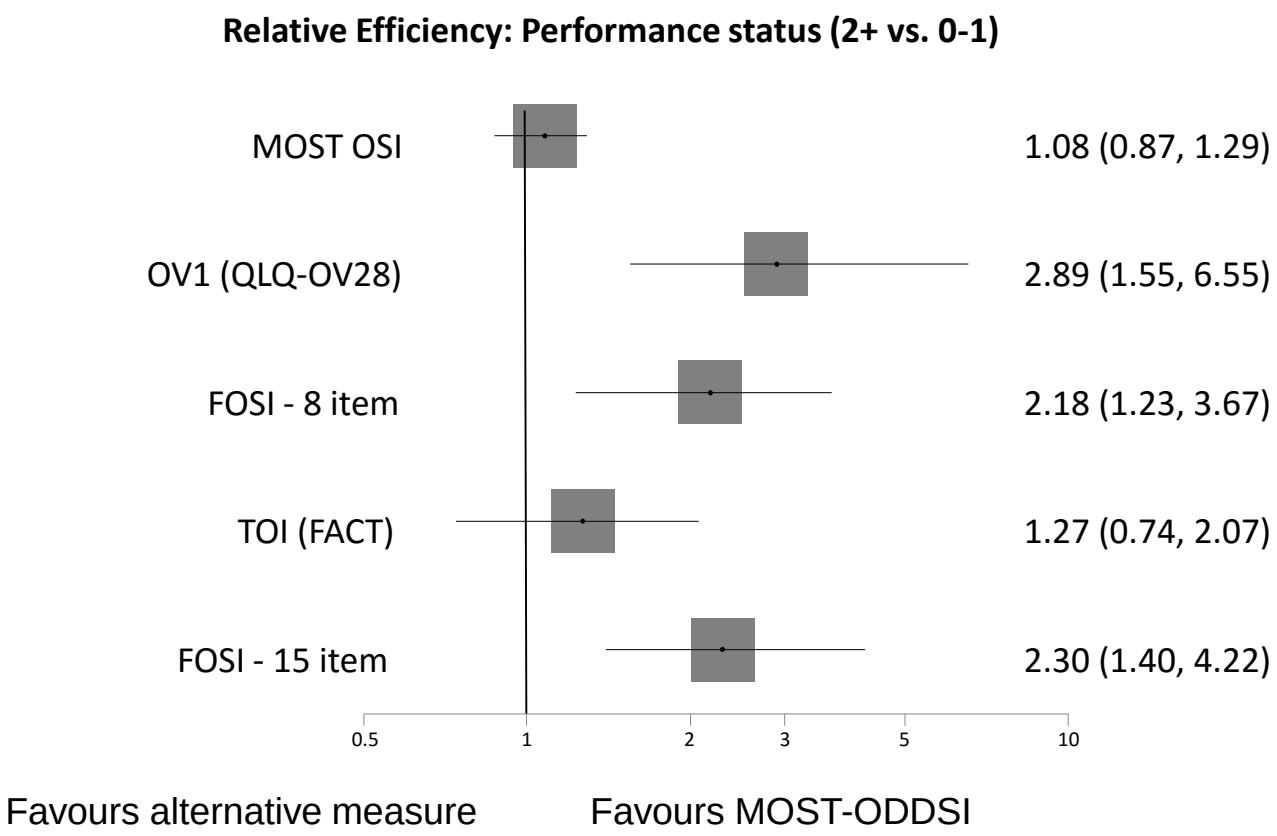
For A) convergent validity and relative efficiency were assessed relative to the scales from the EORTC QLQ-Ov28 and FACT-O that assess symptoms of ovarian cancer, specifically: EORTC Ovarian Cancer abdominal symptoms scale (QLQ-OV28-Abdo); Functional Assessment of Cancer Therapy - Ovarian Additional Concerns Scale (FACT-O OCS) and Trial Outcome Index (FACT-O TOI); FACT-Ovarian Symptom Index (FOSI).

For B) convergent validity and relative efficiency were assessed relative to the above scales and the MOST-OSI.

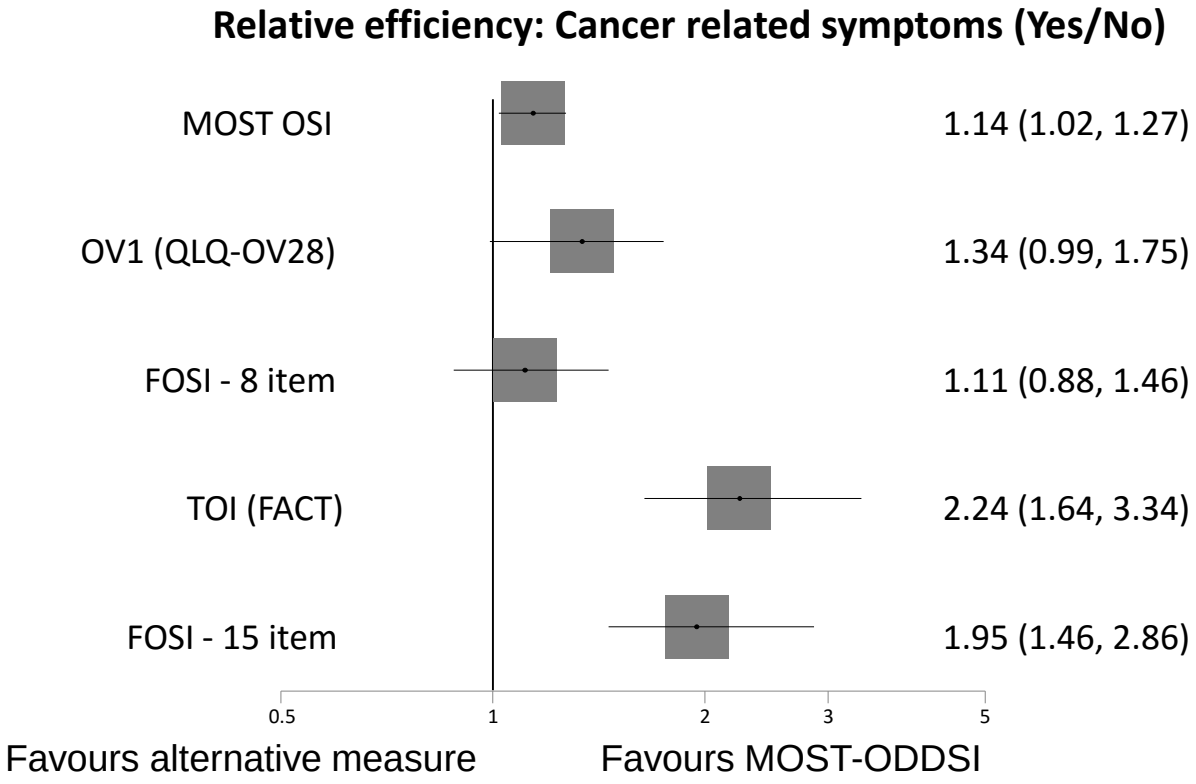
Sensitivity to ECOG PS groups MOST OSI as comparator



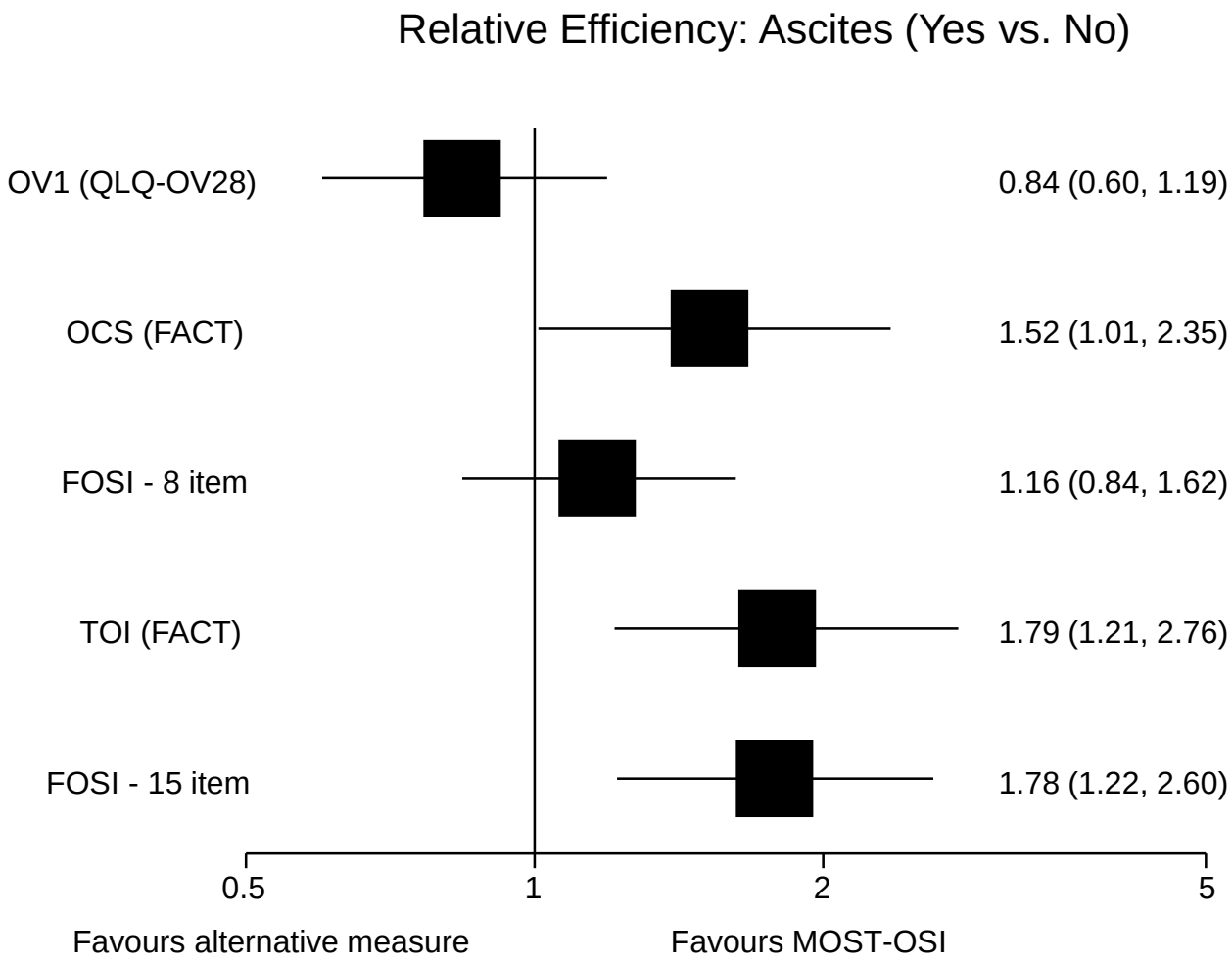
Sensitivity to ECOG PS groups MOST ODDSI as comparator



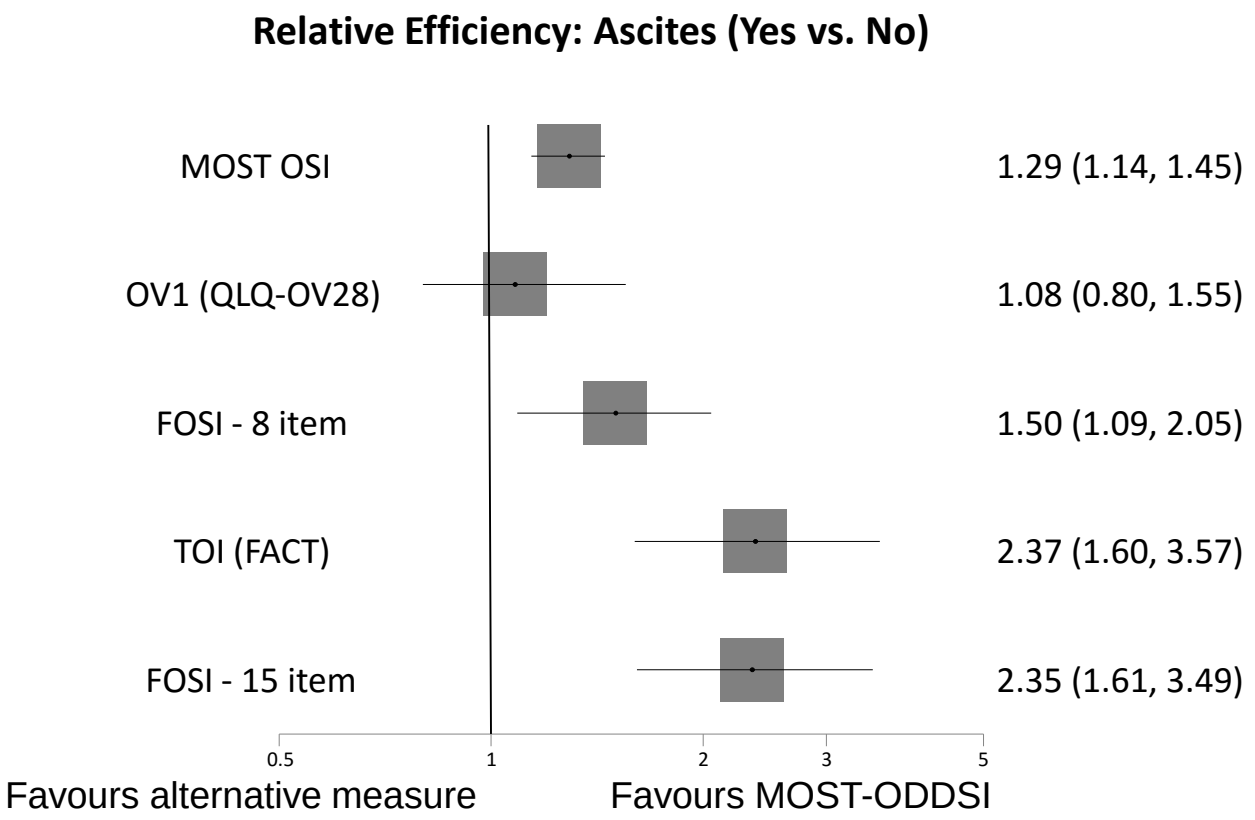
Sensitivity to clinician-rated cancer symptoms MOST ODDSI as comparator



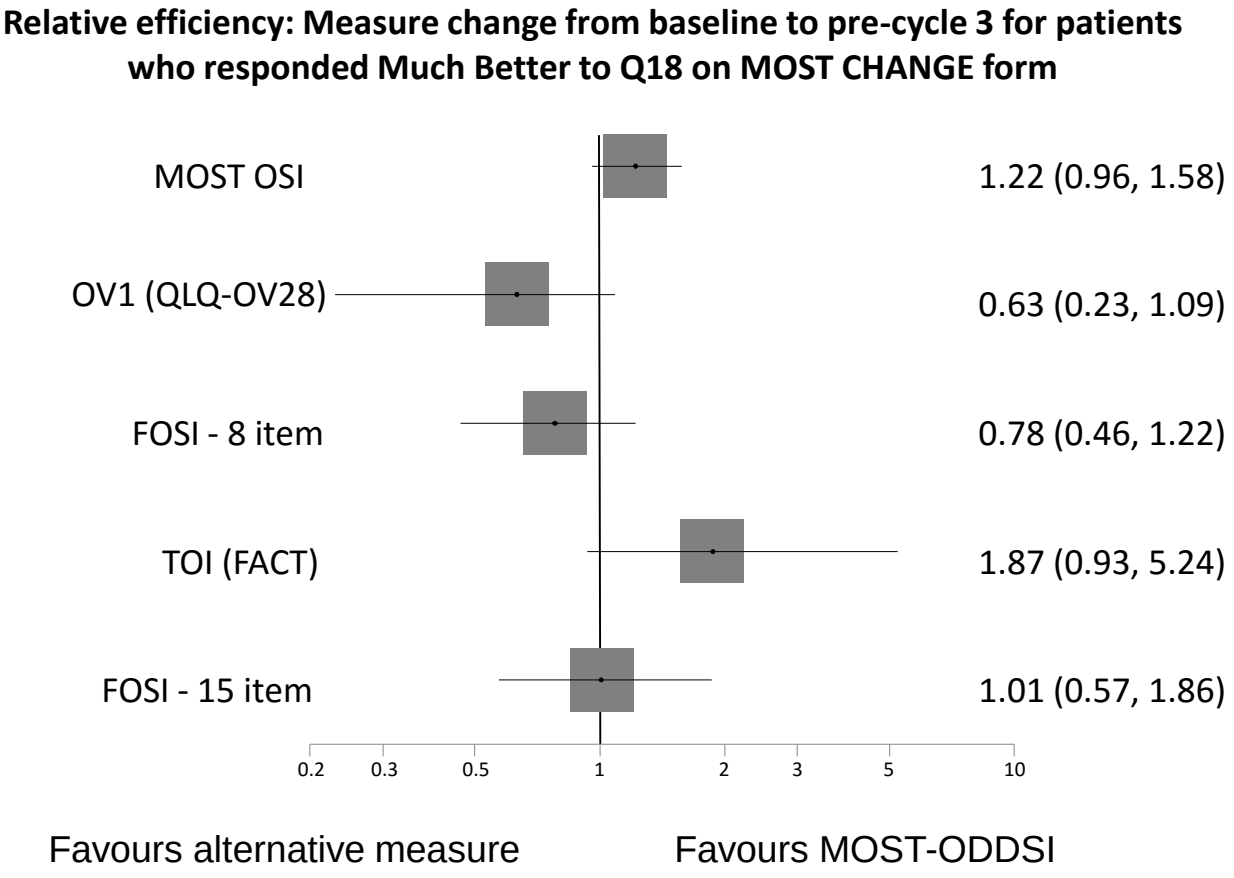
Sensitivity to clinician-rated ascites MOST OSI as comparator



Sensitivity to clinician-rated ascites MOST ODDSI as comparator



Responsiveness to clinically important change MOST ODDSI as comparator



Conclusions

- MOST-OSI / ODDSI were more sensitive than majority of candidate scales, but this differed by clinical grouping.
- MOST- less responsive than some scales- depends on context
- Appears to be fit for purpose
- “Living instrument” that can be modified
- MOST designed to complement HRQOL instruments
- The detailed analyses will help inform choice of PROM’s in clinical trials depending on the context and specific questions being addressed

Tentative titles of papers in preparation (analyses complete):

- Validation of a patient reported outcome measure of ovarian cancer symptoms and treatment related concerns (MOST) with chemotherapy in recurrent ovarian cancer: **Part 1 Clinical validity of symptom measures**

- Validation of a patient reported outcome measure of ovarian cancer symptoms and treatment related concerns (MOST) with chemotherapy in recurrent ovarian cancer: **Part 2 Responsiveness to change and minimally important difference for of symptom measures**

Tentative titles of other papers planned (analyses pending):

- Validation of a patient reported outcome measure of ovarian cancer symptoms and treatment related concerns (MOST) with chemotherapy in recurrent ovarian cancer: ***Measures of treatment related concerns***

- We have not yet decided whether all results for measures of treatment related concerns are best presented together in a third paper, or presented in two cohesive groups, as for the symptom measures above i.e ***Part 3 Clinical validity and Part 4 Responsiveness to change and minimally important difference.(To be decided)***

MOST User guide

In addition to scientific papers reporting the detailed methods and results of validation analyses, we will also prepare a User Guide.

This will include:

- instructions for scoring multi-item scales (such as symptom indexes)
- approaches to defining and analyzing endpoints based on data from the MOST
- approaches to presenting and reporting results from the MOST
- how to interpret results from the MOST, including the minimally important difference (MID).

Looking forward

When will MOST validation publications be ready for GICG review?

- Part 1 – July 2016
- Part 2 – Sept 2016
- User Guide – Dec 2016

When will MOST be ready for use in trials?

- March 2017 – when User Guide agreed

- These three papers will provide validation of the MOST in the clinical context of measuring symptom benefit with chemotherapy in recurrent ovarian cancer.
- Further validation studies are planned for other contexts, including post chemotherapy follow up- MOST-OPAL

MOST-OPAL

Primary objectives: To

1.investigate the utility of the MOST (OSI /ODDSI) to detect early symptoms of recurrence during follow up and

2. document the frequency, grade and trajectory over time of adverse-effects of treatment reported by women after completion of first line chemotherapy.

871 patients recruited to date – recruitment closed November 2015

Months post-diagnosis										
T=0 Diagnosis	T~3 Mid-chemo	T~6 Post-chemo	T~9	T~12	T~15,18, 21	T~24	T~27, 30, 33	T~36	T~39, 42, 45	T~48
OPAL Q	OPAL Q	OPAL Q	OPAL Q	OPAL Q	-	OPAL Q	-	OPAL Q	-	OPAL Q
-	-	MOST	MOST	MOST	MOST	MOST	MOST	MOST	MOST	MOST

MOST administered every 3 months after completion of chemotherapy for 2 years

OvQuest

- **Internet-based cross-sectional self-report questionnaire**
- **Eligibility: >18, ovarian cancer diagnosed at least 6 months ago, received chemo**
- **Content:**
  - Self-reported demographics, cancer, treatment and follow-up care
  - HRQOL - FACT-O
  - Symptoms - FACT-GOG-NTX, SPHERE, ISI,
  - Physical activity - IPAQ-SF
  - Supportive care needs - SCNS-SF34
  - Free text comments

AUSTRALIA NEW ZEALAND GYNAECOLOGICAL ONCOLOGY GROUP

OvQuest

Ovarian cancer survivorship survey

Living after the diagnosis and treatment of ovarian cancer

UNSW

Approval number HC13316

Participant selection and purpose of study

You are invited to take part in a study supported by the Australia New Zealand Gynaecological Oncology Group (ANZGOG) and Ovarian Cancer Australia, to better understand the concerns and challenges faced by women who have been treated for ovarian cancer.

AUSTRALIA NEW ZEALAND GYNAECOLOGICAL ONCOLOGY GROUP

OvQuest

YOUR ELIGIBILITY FOR THIS STUDY

The following questions are to confirm that you are eligible to participate in this study.

Please confirm that the following statements are true:

- [ ] I am 18 years of age or older
- [ ] I was first diagnosed with ovarian cancer at least 6 months ago
- [ ] I have received treatment with chemotherapy

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Completed:

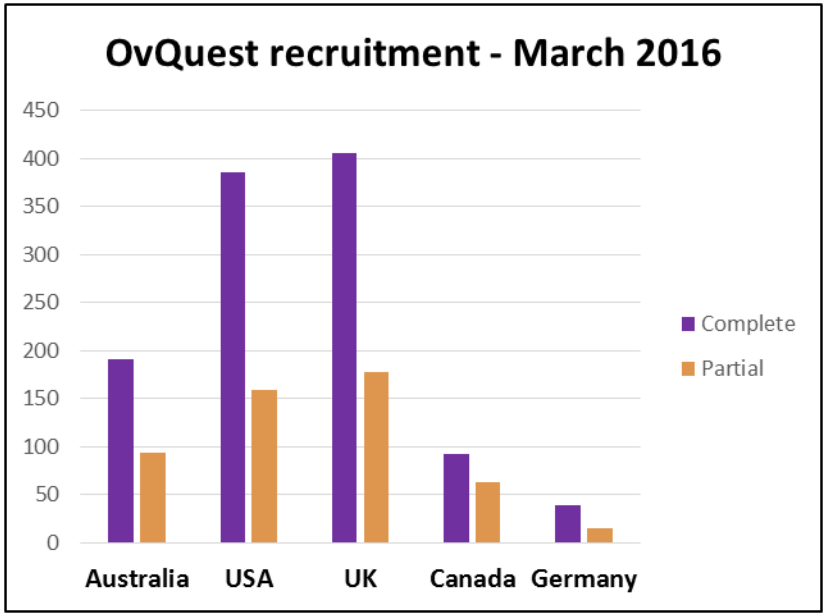
Ovarian Cancer Australia

Progress

Closed in Australia, USA, UK, Canada
Germany closing mid-2016

Recruitment:

1114 completed surveys
534 partial



- Australian data presented ANZGOG and IGCS 2014
- International data - oral presentation ESGO 2015

  Obesity, physical inactivity and symptoms after ovarian cancer treatment

Future plans

Final analyses following closure in Germany

Adaptation for endometrial cancer **– *EmQuest***

Understudied population
International collaboration from outset
Survey reviewed by consumers, translated into French
Challenges with analogous consumer groups for distribution