

## Expediting market access of ovarian cancer treatments

Systematic review of relevant health state utility values & mapping algorithms

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#HTAiOslo2015

epidemica



## UK ovarian cancer survival

- Survival for FIGO stage III/IV epithelial ovarian cancer (EOC) worse than in Australia, Canada, Sweden, Norway (1)
- 5 yr survival 46.2% (England & Wales)
- 2400 deaths would be avoided in 5 years from diagnosis if survival rate were same as best rates in Europe

(1) Coleman M, Forman D, Bryant H, et al. Cancer survival in Australia, Canada, Denmark, Norway, Sweden and the UK, 2005-2007 (the International Cancer Benchmarking Partnership): an analysis of population-based cancer registry data. *Lancet* 2011; 8:377(9760):99-101



## UK ovarian cancer survival

- Unequal access to treatments cited as potentially playing a role (2)

(2) Maringe, C., S. Walters, J. Butler, M. P. Coleman, N. Hacker, L. Hanna, B. J. Mosgaard, A. Nordin, B. Rosen, G. Engholm, M. L. Gjerstorff, J. Hatcher, T. B. Johannesen, C. E. McGahan, D. Meehan, R. Middleton, E. Tracey, D. Turner, M. A. Richards, B. Rachet and Icbp Module 1 Working Group. "Stage at Diagnosis and Ovarian Cancer Survival: Evidence from the International Cancer Benchmarking Partnership." *Gynecol Oncol* 127, no. 1 (2012): 75-82.



## NICE track record

- Bevacizumab
  - approved by EMA 2005
  - rejected by NICE
  - only available via Cancer Drugs Fund
- Olaparib
  - approved by EMA 16-Dec-2014
  - NICE preliminary decision not to recommend May
  - final decision expected Sept 2015
- Niraparib? EnAd/ColoAd1? Avelumab?



## Question 1

How are we deriving our utilities? How are we measuring HRQoL and could the scales be insensitive to change?



## National Cancer Institute-identified most important symptoms (3)

From core set from across cancer types:

- Anorexia
- Constipation
- Diarrhoea
- Dyspnea
- Fatigue
- Nausea
- Neuropathy
- Pain
- Cognitive problems
- Insomnia

From ovarian cancer-specific symptoms:

- Abdominal pain
- Bloating
- Cramping
- Fear of recurrence/disease progression
- Indigestion
- Sexual dysfunction
- Vomiting
- Weight gain
- Weight loss

(3) Donovan, K. A., H. S. Donovan, D. Cello, M. E. Gaines, R. T. Penson, S. C. Plaxe, V. E. von Gruenigen, D. W. Bruner, B. B. Reeve and L. Wenzel. "Recommended Patient-Reported Core Set of Symptoms and Quality-of-Life Domains to Measure in Ovarian Cancer Treatment Trials." *J Natl Cancer Inst* 106, no. 7 (2014).



## Scales used in phase III trials

QoL	Bevacizumab	Olaparib	Niraparib	AMG 386	Aflibercept	Cediranib	Pazopanib	Rucaparib
AIM 4 symptoms					✓			
EORTC QLQ-C30						✓	✓	
EORTC QLQ-OV28	✓ (AB/GI symptom score)					✓	✓	
EQ-5D		✓	✓	✓			✓	
FACT-Fatigue	✓							
FACT-GOG/NTX4	✓	✓						
FACT-Nausea	✓							
FACT-Ovarian Symptom Index		✓ (NFOSI-18)	✓					✓ (NFOSI-18)
FACT-O		✓		✓				
FACT-O TOI	✓	✓						

<http://clinicaltrials.gov>



## EORTC QLQ-OV28

From core set from across cancer types:

- Anorexia
- Constipation
- Diarrhoea
- Dyspnea
- Fatigue
- Nausea
- Neuropathy
- Pain
- Cognitive problems
- Insomnia

From ovarian cancer-specific symptoms:

- Abdominal pain
- Bloating
- Cramping
- Fear of recurrence/disease progression
- Indigestion
- Sexual dysfunction
- Vomiting
- Weight gain
- Weight loss



## FOSI-8

From core set from across cancer types:

- Anorexia
- Constipation
- Diarrhoea
- Dyspnea
- Fatigue
- Nausea
- Neuropathy
- Pain
- Cognitive problems
- Insomnia

From ovarian cancer-specific symptoms:

- Abdominal pain
- Bloating
- Cramping
- Fear of recurrence/disease progression
- Indigestion
- Sexual dysfunction
- Vomiting
- Weight gain
- Weight loss



## NFOSI-18v2

From core set from across cancer types:

- Anorexia
- Constipation
- Diarrhoea
- Dyspnea
- Fatigue
- Nausea
- Neuropathy
- Pain
- Cognitive problems
- Insomnia

From ovarian cancer-specific symptoms:

- Abdominal pain
- Bloating
- Cramping
- Fear of recurrence/disease progression
- Indigestion
- Sexual dysfunction
- Vomiting
- Weight gain
- Weight loss



## FACT-Ov4

From core set from across cancer types:

- Anorexia
- Constipation
- Diarrhoea
- Dyspnea
- Fatigue
- Nausea
- Neuropathy
- Pain
- Cognitive problems
- Insomnia

From ovarian cancer-specific symptoms:

- Abdominal pain
- Bloating
- Cramping
- Fear of recurrence/disease progression
- Indigestion
- Sexual dysfunction
- Vomiting
- Weight gain
- Weight loss



## Question 2

Do we need a new scale? And validation and mapping algorithm?



## How epidemica is contributing

Conduct an HTA-compliant systematic review of HSUVs & mapping algorithms suitable for ovarian cancer

Consider appropriateness for CEA including degree of NCI-recommended EOC QoL domain coverage & HTA requirements

Dataset will be freely available at [www.epidemica.eu](http://www.epidemica.eu)

Publish in freely accessible manuscript

Update annually



## Methods

- Sources: Embase, Medline, HTA Database, NHS EED, EconLit, PubMed (ahead-of-print), NIHR HTA database, NICE & EQ-5D websites, CEA Registry, HERC database of mapping studies, SCHARRHUD database, reference lists of included publications and of SRs.
- Inclusion: original HSUVs suitable for ovarian or fallopian tube cancer (stage I-IV) or primary peritoneal cancer (stage III-IV) where respondent is a patient or caregiver, or mapping algorithm.
- Exclusion: mixed disease stage; VAS; respondent an expert/HCP or general public.
- Sample size, response, extent & handling of missing data will be used to assess risk of bias.



## Resource availability

- June/July protocol registration with PROSPERO
- July review (comments invited)
- Q3 run systematic review
- Q4 dataset and manuscript



## What will be in the dataset?

- Data extraction:
  - HSUV studies; design, country, health state, respondent, instrument, tariff, HSUV estimate & dispersion measure.
  - Mapping algorithms; country, instruments, tariff, estimation & validation sample descriptions, model type, coefficients, performance, application limits
    - Mapping onto Preference-Based Measures Reporting Standards (MaPS) to be published on EQUATOR website shortly



## Questions

How are we measuring HRQoL in ovarian cancer?

Are we measuring HRQoL accurately enough?

Do we need a new scale on basis of NCI consensus?

Who can do the validation & mapping algorithm work?

Which HTA jurisdictions would you like covered?

Spare some time in July to review protocol?

