Quay West Resort, Bunker Bay
Tuesday 23rd – Saturday 28th March

The Australian Society of Gynaecologic Oncologists

CONFERENCE PROGRAM
ABSTRACT BOOKLET

"Looking Back – Moving Forward"

ASGO

ASGO 2010
25th Annual Scientific Meeting

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The Australian Society of
Gynaecologic Oncologists
25th Annual Scientific Meeting

ASGO 2010 Program

Tuesday 23rd March	
6:00pm – 9:00pm	Welcome reception at the Sheraton Hotel
Wednesday 24th March	
7:30am – 10:00am	**FELLOWS BREAKFAST PRESENTATION**
10:10am	Coaches depart Sheraton
1:40pm – 3:40pm	Wise Winery Lunch
4:00pm	Arrive Bunker Bay
6:00pm – 9:00pm	Welcome BBQ/Opening of Trade Exhibition and Sponsor Presentations • 6:30pm - 7:30pm-'Body Painting' Scientific Session – led by **Prof Paul McMenamin** • Sponsors Presentations:7:30pm-8:30pm
Thursday 25th March	
7:30am – 8:00am	Trade Exhibition Open
8:00am – 10:00am	**TRAINING IN GYNAECOLOGIC ONCOLOGY 2010** Chair: Robert Rome *A personal view* **– *Don Marsden (20min)*** *Anatomical training in Gyn Oncology* **– *Ian Hammond & Paul McMenamin (20 min)*** *Is research an important part of CGO training* **– *Alison Brand (10 min)*** *Training from the trainees perspective* **– *Tom Walsh (15 Min)*** *Do we need a CGO examination* **– *Jonathan Carter (15 min)*** *Discussion and closing remarks* **(*40 min*)**
10:00am – 10:30am	Morning Tea and Trade Exhibition
10:30am – 12:00pm	**CERVICAL CARCINOMA** Chair: Chris Dalrymple **STAGING:- the laparoscope, the magnet and the isotope** *Laparoscopic staging* **- *Penny Blomfield (15 min)*** *MRI Staging* **– *Kailash Narayan (15 min)*** *PET Staging* **– *Andy Garrett (15 min)*** *Discussion and closing remarks* **(*45 min*)**
12:00pm – 1:00pm	**OCCUPATIONAL WELLBEING IN THE GYN ONCOLOGIST** Chair – Yee Leung Keepad Survey Live in Real Time *Discussion* *Doctor's health 2010* **– *Geoff Riley***

1:00pm – 1:45pm	Lunch and Trade Exhibition
2:00pm – 4:00pm	ASGOlympics afternoon team building activity for delegates, spouses and sponsors
6:00pm – 10:30pm	Dinner at Clairault Winery Sponsored by genzyme

FRIDAY 26th March 2010

7.45am – 8:00am	Trade Exhibition Open
8.00am – 8.30am	**Fellows Presentations (continued from Wednesday)**
8:30am – 10:30am	**TUMOUR BOARD – Ian Hammond and Yee Leung**
10:30am – 11:00am	Morning Tea and Trade Exhibition
11:00am – 1:00 pm	**FOLLOW UP OF GYNAE CANCERS** Chair: Jonathan Carter *ASGO current practice FU Gynae Cancer* ***– Rhonda Farrell (15 min)*** *Overview FU Gynae Cancers* ***– Rob Rome (25 min)*** *Evidence base for FU Ovarian Cancer* ***– NBOCC (20 min)*** *To image or not to image: that is the question!* ***– Martin Buck (20 min)*** *Discussion – Moving toward National consensus* - ***led by Rhonda Farrell (40 min)***
1:00pm – 1:45pm	Lunch and Trade Exhibition
2:00pm – 5:00pm	Afternoon sports Golf, Tennis Or Wine Tasting tour
5:00pm – 6:00pm	Wine Tasting at Bunker Bay
7:00pm – 11:00pm	Dinner at Bunker Bay

SATURDAY 27th March 2010

8:00am – 10:00am	**ENDOMETRIAL CARCINOMA:** **CONTROVERSIES IN MANAGEMENT** Chair – Alex Crandon *ASGO Survey on current practice* ***– Yee Leung (10 min)*** *"Laparoscopic Approach to Carcinoma of the Endometrium: First Results on short-term outcomes and Quality of Life" –* ***Andreas Obermair/ Monika Janda(15 min)*** *Current status of surgical staging –* ***Marcelo Nascimento (20 min)*** *Current status of radiation therapy* ***– Robyn Cheuk & Serena Sia (20 min)*** *Current status of chemotherapy* ***– Andrew Dean (15 min)*** *Discussion and Closing Remarks* ***(40 min)***
10:00am – 10:30am	Morning Tea and Trade Exhibition
10:30am – 11:30am	**SURGEONS CORNER** Chair – Tom Jobling Surgical approaches to the upper abdomen – **Paul Moroz (30 min)** Endoscopic approaches to the retroperitoneum – **David Sofield (30 min)**

11:30am – 1:30pm	**OVARIAN CARCINOMA: RADICAL DEBULKING SURGERY** Chair: A J McCartney ASGO survey on current and future practice – **Stuart Salfinger (15 min)** QCGC experience in radical debulking surgery – **Jim Nicklin (20 min)** Evidence for radical upper abdominal debulking – **NBOCC (20 min)** A surgeons view: Pseudomyxoma Peritoneii – **Paul Moroz (20 min)** The Heidleberg view – **Simon Hyde (15 min)** Discussion and Closing Remarks **(30 min)**
1:15pm – 1:45pm	Lunch and Trade Exhibition
1:45pm – 2:45pm	**ASGO AGM (60 min)**
2:45pm – 4:00pm	Coastal walk departs from reception Day spa treatments or free afternoon
6:30pm – 11:00pm	Vasse Felix Black Tie Dinner
SUNDAY 28th March 2010	
8.30 am	1st Transfer departs for Perth Airport
10.10 am	2nd Transfer departs for Perth Airport

Welcome:

Dr Stuart Salfinger, Chair of the 2010 ASGO organizing committee is pleased to welcome members and guests to Bunker Bay.

Organising Committee:

Dr Stuart Salfinger – Chair Organising Committee
Prof. Ian Hammond
Prof. Tony McCartney
Dr Yee Leung

Secretariat:

The registration desk will be open throughout the conference to answer any questions you may have.

Wednesday 24th March	4pm – 6.30pm
Thursday 25th March	7.30am – 1.45pm
Friday 26th March	7.45am – 1.45pm
Saturday 27th March	8.00am – 2.45pm

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Continuing professional Development Program:

This meeting has been approved as a RANZCOG Approved O&G Meeting. Eligible Fellows of this College will earn CPD points for attendance as follows:
Full Attendance: 19 Points
Attendance 24 March: 4 Points Attendance 25 March: 5 Points
Attendance 26 March: 5 Points Attendance 27 March: 6 Points
Certificates are to be collected from the registration desk.

SOCIAL PROGRAM:

WEDNESDAY 24th March	
1:40pm – 3:40pm	Wise Winery Lunch Dress: Smart Casual
6:00pm – 9:00pm	Welcome BBQ/Opening of Trade Exhibition and Sponsor Presentations Location: Grassed area beneath the swimming pool Children welcome to attend Dress: Smart Casual
THURSDAY 25th March	
2:00pm – 4:30pm	ASGOlympics afternoon team building activity for delegates and sponsors Delegates, spouses and families to meet at the beach Dress: Team T-shirt and shorts
6:00pm – 10:30pm	Coach departs from reception at 6.00pm sharp. The first coach will return at 10.15pm and the second at 10.40pm. Don't forget to wear your Genzyme beret, as this is your entry ticket Dress: Beret, French or smart casual NB. This is an adults only dinner Clairault Winery Dinner**– Sponsored by** genzyme
FRIDAY 26th March	
1.15pm – 6.15pm	Golf Dunsborough Lakes Golf Club – Coach departs reception 1.15pm
2.00pm – 4.30pm	Tennis Bunker Bay Resort
2.00pm – 5.00pm	Wine Tasting Tour Cullen Wines, Saracen Estates and Brookland Valley Wineries
5:00pm – 6:00pm	Wine Tasting at Bunker Bay
7:00pm – 11:00pm	Dinner at Bunker Bay Resort Dress: Smart casual
SATURDAY 27th March	
2.45pm – 4.00pm	Coastal Walk departs from reception. Day Spa treatments or free afternoon
7:00pm – 1:00pm	Coach departs from reception at 6.30pm sharp. The first coach will return at 10.50pm and the second at 11.10pm Entry is by ticket only, which you will receive at registration Dress: Black Tie Vasse Felix Dinner

TRANSFERS:

SUNDAY 28th March	
Depart 8.30am and arrive 12.30pm	Bunker Bay to Domestic and International Terminal
Depart 10.10am and arrive 2.15pm	Bunker Bay to Domestic Airport

Session:	**Wednesday 24th March** **7:30 am – 10:00am**
Topic:	**Fellows Presentations**

Dr Vivek Arora

Discharge on Postop Day 2 after Major Gynaecological Surgery. Is it Possible?

Fast Track (FT) programs have been developed and refined in many specialties with documented improved patient outcomes and reduced length of stay (LOS).

The aim of the audit was to provide additional data and information on patients who were able to be discharge on or before day 2 (early discharge).

During the 2-year study period 172 patients underwent a laparotomy for a variety of indications. Thirty-two (19%) patients overall were able to be discharged on day 2, 7 (10%) during the first year of the study and 25 (25%) during the second year of the study. The average age of patients discharged on postop day 2 was significantly lower (P=0.005) than those discharged after day 2. The majority of patients had benign pathology, have ovarian tumours, transverse incisions performed, shorter surgery, successfully complete early oral feeding, were able to tolerated COX inhibitors and had a lower perioperative net Hb change. There were no adverse RANZCOG Quality Indicators reported. There were no re-admissions to hospital in the early discharge group.

Conclusions
With increased clinical experience with FT, up to 25% patients undergoing laparotomy on a FT program, can be safely discharged on day 2 without an increase in the readmission rate or morbidity

Notes:_____

Dr Michael Bunting

The role of routine hysterectomy in the surgical management of ovarian cancer.

Current national and international guidelines for the surgical management of ovarian cancer recommend routine hysterectomy.

Optimal surgery for advanced ovarian cancer includes removal of all macroscopic tumour from the abdominal and pelvic cavity, including removal of both ovaries and fallopian tubes and usually an omentectomy. Both the Australian Cancer Network Clinical Practice Guidelines and the NCCN Practice Guidelines in Oncology 2010 recommend that initial surgery should include total abdominal hysterectomy as part of initial surgical staging.

In this study we analyze the last five years of data from women who underwent surgery for the management of ovarian cancer at the Hunter Centre for Gynaecological Cancer. We have critically evaluated the scientific rationale for hysterectomy in ovarian cancer cytoreductive surgery and propose a systematic approach to consider patients who may be better served by uterine conservation.

Notes:_____

Dr Naven Chetty

Ovarian Pathology Diagnosed Via Echocardiogram

First described by Stewart et al. (1939), carcinoid tumours of the ovary are rare.

Approximately 150 cases of primary ovarian carcinoids in patients ranging from 21 to 79 years of age have been Reported (Talerman 1984). Ovarian carcinoid tumours account for 0.3% of carcinoid tumours, but are associated with one third of carcinoid syndrome, as venous drainage by-passes the liver (Somak, Shramana et al. 2008).

We would like to present a case of an ovarian carcinoid tumour that was diagnosed after the patient presented with the classic cardiac features of carcinoid syndrome.

As a result of the carcinoid syndrome she suffered severe right-sided cardiac dysfunction- requiring valvular replacement. However this could not be achieved until the primary tumour was removed.

As a result symptoms were controlled with Octreotide and a laparotomy was performed under intra-operative trans-oesophageal echocardiogram monitoring. Therefore we provide a literature review, descried mode of diagnosis, features of carcinoid syndrome and resulting management.

Notes:_____

Dr Paul Cohen

Ovarian granulosa cell tumours (GCTs) are a specific subtype of malignant ovarian neoplasm and account for 5% of all ovarian cancers. GCTs are rare tumours which most commonly present in the early post-menopausal period.

They are often hormonally active and may present with features of oestrogen excess such as post-menopsausal vaginal bleeding. There is limited literature regarding their optimum management, molecular profiling and treatment strategies. Currently women with ovarian GCTs receive similar treatment as those with epithelial ovarian cancer, but given the unique biology of granulosa cells, GCTs are likely to behave differently to the more common epithelial ovarian tumours. Alternative GCT-specific treatments and prognostic markers are needed if outcomes are to be improved.

The aim of this research project was to characterise the role of oestrogen receptor ß (ERß) in ovarian granulosa cell tumours in order to determine its potential as a GCT-specific prognostic marker and treatment target. Specific objectives were: first to investigate the hypothesis that ERß inhibits cell proliferation in the ovarian GCT-derived cell lines COV434 and KGN-T and second, to determine what genes and gene pathways are uniquely expressed in both juvenile and adult granulosa cell tumours compared to other ovarian cancers.

ERß has been identified as a potential tumour suppressor in many human malignancies, and its effect on proliferation in two GCT-derived cell lines was studied with the aid of an ERß-specific agonist, diarylpropionitrile, and by silencing expression of ERß using small interfering RNAs.

Ethical approval was obtained for a national multicentre prospective study to collect human GCT tissue for genetic analysis. The first GCT samples were collected and gene expression profiling was performed by microarray analysis.

Preliminary results suggest that ERß appears to be antiproliferative in the GCT-derived cell lines and loss of ERß

Notes:_____

Dr Viola Heinzelmann-Schwarz

Anti-glycan antibody detection of non-mucinous epithelial ovarian cancers using printed glycan array

Altered glycosylation is associated with oncogenic transformation producing tumor-associated carbohydrate antigens. We investigated anti-glycan antibodies in the diagnosis of ovarian cancer using a printed glycan-array containing 211 glycans.

Serum samples were collected from healthy controls (n=24) and non-mucinous ovarian cancer patients (n=33) following written informed consent. Bound anti-glycan antibodies were detected via a biotin-streptavidin fluorescence system. Data were pre-processed and analyzed by univariate feature selection as well as multivariate hypothesis testing using Matlab and R.

High reproducibility in measuring antibodies were found and binary classifiers revealed 24 glycans which significantly discriminated ovarian cancer from healthy controls, including P1 (Gala1-4Galß1-4GlcNAcß; $p<0.001$). Higher sensitivity and specificity than CA125 was achieved by a panel of multivariate selected and linear combined anti-glycan antibody signals (83.3% and 84.8%, respectively).

These findings indicate that glyco-arrays have a high potential for the development of a new generation of biomarkers for ovarian cancer.

Notes:_____

Dr Julie Lamont

Audit: Correlation of MRI, Frozen Section and Final Histological Diagnosis in Ovarian Pathology

Intraoperative histological assessment of ovarian pathology by frozen section is a mainstay in the management of ovarian masses, and plays a vital role in the decision to complete surgical staging. Despite its benefits it can often prolong operative time and place further demands on often already busy laboratory resources.

MRI imaging has been shown to have high sensitivity and specificity in the diagnosis of ovarian pathology. As MRI is readily accessible for assessment of pelvic masses at Royal Women's Hospital Melbourne, it is routinely performed as part of preoperative planning to provide a radiologic opinion as to the likelihood of malignancy.

This audit assesses the correlation of preoperative MRI, frozen section and final histological diagnosis in ovarian masses at RWH Melbourne over the year of 2009; and aims to address the question of whether MRI diagnosis could replace frozen section without compromising treatment.

Notes:_____

Dr Ganendra Raj Mohan

Positron Emission Tomography and Granulosa Cell Tumor Recurrence: A Report of 2 Cases

Two case reports of women with recurrent granulosa cell tumors identified initially by increasing levels of inhibin. As part of their investigation to assess the extent of the recurrence, an abdominopelvic computed tomography and a positron emission tomography scans were performed. Interestingly, the recurrent tumors were identified on the abdominopelvic computed tomography but not on the positron emission tomography scan. These recurrences were confirmed at surgery, and the histopathologic findings were identical to the original lesion.

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Dr Premala Paramanathan

Colorectal carcinoma – should women be offered prophylactic oophorectomy at the time of surgery?

Background:
The published literature on prophylactic oophorectomy during surgery for colorectal carcinoma has been conflicting. Some data suggest a 3-4% incidence of ovarian metastasis from colorectal adenocarcinoma.

Methods :
Data was obtained from the National Cancer Registry Ireland (NCRI). These were cases reported from 1994 to October 2009.

Results :
12,752 women were diagnosed with colorectal carcinoma in Ireland during the study period. The incidence of ovarian metastasis was 1.3% (N=162), with 0.8% (N=108) having ovarian metastasis diagnosed at the time of primary surgery and 0.5% (N=68) being diagnosed some time after their primary surgery. 16 women (0.1%) were diagnosed with primary colorectal carcinoma and primary ovarian carcinoma at the same time and 35 women (0.3%) were diagnosed with primary ovarian carcinoma at a later stage. Our data suggests that 0.8% of women (N=103) could have benefited from prophylactic oophorectomy during the study period.

Conclusion:
Prophylactic oophorectomy removes the risk of metachronous metastasis and primary ovarian carcinoma.

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Mr Amit Patel

Ultra-radical Procedures and Morbidity in Gynaecological Oncology Surgery: The Need for Clinical Governance Processes

Objectives:
1. To determine the peri-operative morbidity outcomes of major abdominal procedures by surgeon and radicality of procedure.

2. To determine if clinical governance processes improves clinical outcomes.

Methods:
Pre-defined and prospectively collected peri-operative complications of 632 laparotomies during two time periods (March 2008–April 2009 and May 2009–August 2009) at the NGOC were analysed. 133 (21%) were classed as ultra-radical based on upper abdominal, visceral, gastric/infra-gastric and/or intestinal surgery.

Conclusions:
Clinical governance processes reduces morbidity associated with major abdominal procedures. More detailed data on comparison with non-ultra-radical procedures (n=499) and morbidity by primary surgeon will be presented at the meeting.

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Dr Jegajeeva Rao

Gynaecological Oncology Training – Perspective of an Overseas Fellow in Australia

The RANZCOG has an internationally reputed training scheme in Gynaecological Oncology; available to overseas trainees via the CORT (Certificate of Recognised Training) scheme. It provides full formal training up to maximum of 3 years.

The pathway differs to that of Australian trainees leading to CGO because research component is not required and attempting final CGO examination disallowed. This scheme is not centrally administered by the RANZCOG and the prospective trainee makes own arrangements through an identified centre/supervisor.

Registration with RANZCOG subspecialty committee to get the training prospectively approved leading to CORT (GO) upon satisfactory completion is essential. Other requirements prior to commencement are evidence of English language competence, medical board registration, appropriate visa and own funding. This scheme is very beneficial to any overseas subspecialty trainee particularly from developing and underdeveloped countries. It also provides a good platform for international linkages, future collaborations and more global role for the RANZCOG.

Notes:_____

Dr Kym Reid

Correlation of Preoperative Combined Positron Emission Tomography/ Computed Tomography with Surgical and Histopathological Findings for Patients with Endometrial Cancer

Currently women diagnosed with endometrial cancer undergo preoperative assessment with imaging such as Computed Tomography (CT). The use of Combined Positron Emission Tomography (PET) and CT with fluoro-2-deoxyglucose (FDG) is becoming more commonplace as a tool for assessment of various malignancies with respect to detection of metastases and recurrence. However, there appears to be limited evidence as to whether combined PET/CT is useful for the assessment of preoperative patients with endometrial cancer.

The aim of this prospective pilot study of 30 patients with endometrial cancer is to assess whether PET/CT has a place in the preoperative assessment of women with endometrial cancer. Of particular interest is whether PET/CT will be able to delineate the primary endometrial cancer, and whether PET/CT imaging will be able to predict the presence or absence of distant metastases. A secondary aim is to determine whether the degree of FDG uptake correlates with the histopathological cell type

Notes:_____

Dr Jason Tan

Applying FIGO 2009 Staging for Carcinoma of Vulva on Patients Previously Staged with FIGO 1988 Staging System

In 2009, FIGO revised the staging system for vulva cancer. As addressed by Neville Hacker, the previous staging system:
Similar survivals stage 1 and 2
Large survival range stage 3
Number and morphology of positive nodes not considered.

Our study compares the 1988 FIGO staging system to that of 2009, and assess whether the above concerns with the previous system has been addressed.

Vulva cancer patients between 1988 to present was obtained from the QCGC (Queensland Centre for Gynaecological Cancers, Australia) . Out of 435 patients, 394 were eligible for analysis after exclusion of melanoma histology, incomplete data and those incompletely staged. Chart and pathology review conducted and appropriately restaged. Data was analysed using Kaplan-Meier method, and survival was compared.

Further results and discussion will be presented.

Notes:_____

Dr Amy Tang

Serum CA125 in Ovarian Tumours of Low Malignant Potential (LMP)

Background: Borderline ovarian tumours account for about 15% of all epithelial ovarian cancers. Recurrence rate ranges from 5-20% and survival is very good with 95% at 10 years from surgery. The role of CA125 in ovarian LMP tumours is not as well established as that in epithelial ovarian cancers. The number of patients studied was small and very limited conclusions could be drawn.

Objectives:We hypothesize that CA125 is a prognostic factor for recurrence of ovarian LMP tumours. The purpose of this study is to determine the distribution and the association of preoperative CA125 with tumour stage and histological cell types. The association between CA125 levels, clinical and histopathological features and tumour recurrence will also be studied.

Methods (including type of data collected): This is a multicentre retrospective study. A feasibility questionnaire was sent to identify the gynaecological oncology centres with a complete database on ovarian LMP tumours and CA125. Patients diagnosed with ovarian LMP tumours between Aug 1985 and Jan 2008 were identified. Information including demographics, histology and stage, preoperative CA125 level, treatment and relapse details as well as follow up and survival data was collected and analysed.

Results:Over 800 patients with ovarian LMP tumours were eligible and included for analysis. The data was collected from various gynaecological oncology centres in Australia, Hong Kong and Holland. CA125 is more likely to be elevated in serous tumours and advanced stage disease.

Conclusions:
Ca125 has a role in patients with ovarian LMP tumours. It is associated with serous cell type and can also predict more advanced stage disease. The ability for CA125 to predict recurrence is still doubtful. More data will be collected from a few more centres to achieve a total of 1000 patients before final conclusion can be made.

Notes:_____

Session:	**Thursday 25th March 2010** **TRAINING IN GYNAECOLOGIC ONCOLOGY 2010** **8.00am – 10.00am**
Session Chair:	**Robert Rome**
Topic & Presenters:	A Personal View **– Don Marsden** Anatomical training in Gyn Oncology **– Ian Hammond & Paul McMenamin** Is research an important part of CGO training **– Alison Brand** Training from the trainees perspective **– Tom Walsh** Do we need a CGO examination **– Jonathan Carter**

Presenter: Don Marsden

A Personal View

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Presenter: Ian Hammond & Paul McMenamin

Anatomical Training in Gyn Oncology

In recent years many observers have noted that anatomical education no longer dominates the early undergraduate medical curriculum and cadaveric dissection as a means of learning topographical anatomy is becoming increasingly rare in many countries including the UK and Australia. In postgraduate surgical/obstetric and gynaecological curricula, a practical anatomical training is not considered essential. Most learning is gained from books and operative exposure. Radical gynaecologic cancer surgery requires extensive anatomical knowledge including: pelvic organs, vasculature, gastrointestinal-urological tracts, and the major abdominal vessels. The trend towards ultraradical cytoreductive surgery requires knowledge of the critical anatomy in the upper abdomen including the diaphragm, liver, pancreas and spleen.

Trainees and subspecialists in gynaecologic oncology recognise the need for more formalised training in surgically relevant anatomy. The challenge to mentors is to provide relevant teaching.

A range of learning opportunities is available and will be determined by the trainee, training institution and academic environment. Whilst basic anatomical knowledge can be readily acquired from textbooks, anatomical charts, computer generated 3-D programs and internet-based materials, surgical anatomical training obtained in the operating room is the mainstay of postgraduate educational experience. Surgical trainers must take the opportunity to reinforce surgical anatomical learning at every operation. Useful training may be gained by examination of relevant prosected cadaver specimens, formal cadaveric dissection and operating on fresh frozen cadavers (see www.acworkshop.com) which provide a realistic surgical simulation. Formal assessment of anatomical learning should be encouraged. This presentation details a “utopian” anatomical curriculum and assessment relevant to gynaecologic oncology training.

Notes:

Presenter: Alison Brand

Is research an important part of CGO training?

Notes:

Injury, Int. J. Care Injured (2006) **37**, 583—594

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REVIEW

Designing, conducting and reporting clinical research. A step by step approach

Beate P. Hanson *

AO Clinical Investigation and Documentation (AOCID), Clavadelerstrasse, CH-7270 Davos Platz, Switzerland

Accepted 21 June 2005

KEYWORDS
Clinical research;
Specific aims;
Study protocol;
Study methods;
Publication

Summary There are five major steps that one must navigate successfully to take a study idea and turn it into a publication that may have an impact on clinical practice. These steps include developing the study question(s), developing the study plan, implementing the study plan, reporting the results and submitting the manuscript(s) for publication.

This review takes each of these steps and expands on its important components. More detail is given for steps one, two and five.

Furthermore, the review is augmented with tables and checklists that may serve as tools in the planning and execution of a clinical study. Though it does not address every detail for each of the steps discussed, readers of all experience levels should find it a useful tool in the planning, execution and reporting of their next clinical study.

Contents

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0020-1383/$ — see front matter © 2005 Elsevier Ltd. All rights reserved.
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Introduction

Being careful is what designing and conducting research is all about; taking care in articulating the study question, in choosing the correct study design and in ensuring that data are carefully extracted, recorded, managed and analysed. In short, those who conduct research must be careful when they imply that what is found in their study is the truth in the surgical universe.

The purpose of this review is to help both clinicians and researchers to develop an overall plan for their future clinical research, by discussing the following five important steps:

(1) developing the study question(s);
(2) developing the study plan;
(3) implementing the study plan;
(4) reporting the results;
(5) submitting manuscript(s) for publication.

The focus of the review will be on steps one, two and five. Details of steps three and four will be reserved for another publication.

Step 1: developing the study question

Developing a study question that is destined for success is based on three important phases: (a) defining the study question(s); (b) refining the study question(s); (c) converting the study question(s) into a specific aim(s).

Defining the study question

The first phase in defining a study question is to take an initial idea and narrow it down to an answerable, or testable, question. In determining whether your initial research question is answerable, you must ask yourself, ''Is my research idea do-able the way that I'm currently proposing it?'' In order to make progress, this question must be answered honestly before getting started. This is best facilitated by bouncing ideas off mentors and colleagues, through brainstorming and group discussions, before settling on a preliminary question that you can refine further.

Refining the study question

Once a study idea has been defined, it needs to be refined into an answerable study question. There are four main factors to consider that will help you refine your study question further. A simple way to help you to frame a clinical question is to use the acronym PICO (patients, intervention, comparison and outcome). It is a good idea to put your idea on paper using the PICO method (Table 1).

Table 1 Example of PICO method for an orthopaedic trauma study question

Patients	What patient group?	Young active adults ages 18—40 years old. Tibial pilon fractures (AO 43-A1, 43-B2.2, 43-C3)
Intervention or procedure	What surgical procedure or implant?	Plate osteosynthesis
Comparison	What treatment is being compared?	External fixation
Outcomes	In what outcomes are you interested?	Length of hospital stay Time to weight bearing Complications Functional and quality-of-life outcomes

Table 2 Important issues to consider when refining your study question

Consideration	Ways to address it	Ways to improve it
Is this study novel?	Conduct a literature search of your topic in PUBMED and other literature resources, such as the AO's OTD and Evidence Summaries in the Knowledge Portal. Look at *Conference Proceedings* to see what has been done but not yet published	Modify the study question to include some novel aspect. Do something better than it has been done before (e.g. study design, more patients, better control, longer and more complete follow-up)
Does my team of collaborators have adequate expertise to carry out this research?	Schedule meetings with study collaborators during the early stages of refining your study question to identify potential gaps in knowledge or skills	Seek outside consulting
What are your objectives? Is the scope of this study manageable?	Write down and discuss your specific aims with study collaborators	Modify the aims, retain those that are most significant
Can I enrol enough willing, consenting participants meeting my inclusion criteria to make meaningful inferences?	Determine the likely number of patients you will see in a given time period at your hospital or facility. Critically review results of previous studies for participation rates and prevalence of outcomes and treatments of interest. Do a power analysis to determine necessary number of subjects	Broaden inclusion criteria, length of enrolment and number of investigative sites to increase sample size
Do I have the time to see this study from start to finish?	Draft a timeline	Consider an alternative study design
Do I have enough financial support to address this study question adequately?	Draft a budget plan	Apply for funding
Is this study ethical?	Discuss with your collaborators and Human Subjects Division. Submit an application to the human subjects review board at your institution	Modify the study question or study design

Once you have put your idea on paper, you can then consider the novelty, feasibility and ethics of the study question, early in the stages of development, to ensure that the project will succeed. Some of the important steps in accomplishing this include conducting a detailed literature search, creating a team of collaborators, writing a draft of your specific aims, doing some initial sample size calculations, drafting a timeline, applying for funding and determining when you will submit an application to the IRB (Table 2).

Converting your study question(s) into a specific aim(s)

The most valuable of the above-mentioned steps, which ultimately will drive your study plan, are the *specific aims* of your study. The aims of a study

Table 3 Example of specific aims for a randomized controlled trial comparing the Locked Compression Plate (LCP) to standard plates in the treatment of tibial pilon fractures[a]

	Specific aim
Primary aim	
1	To compare the incidence of deep infections
2	To compare functional outcomes
Secondary aim	
1	To compare the incidence of ankle osteoarthritis
2	To compare bony union by measuring Incidence of delayed union Incidence of malunion

[a] Typically, specific aims have more detail than what is presented in the table to include how one would measure the outcome and the time frame of interest.

Table 4 Checklist for study outline

Specific aim(s)	√
Background and significance	√
Expected outcomes	√
Time frame	√
Methods and brief research plan	√
Study design	
Subject inclusion and exclusion criteria	
Demographic, predictor and outcome variables	
Statistical issues (hypotheses, sample size and basic analysis plan)	
Participants	√
Resources and budget	√
Research site	√

should be specific and hypothesis-driven. It is common for a study to have between two and four specific aims that are components of an overarching research question. It is common to have one or two primary questions that you would like to answer and another one or two secondary questions you would be interested in exploring. Those questions that are of primary interest are commonly considered *primary aims*. The rest of your protocol is centred on your primary aims, including your sample size calculations and data analysis. It will be necessary that you have adequate power (e.g. a large enough sample size) to answer the primary aims. On the other hand, you do not necessarily need to power your study to answer your *secondary aims*. Therefore, it is recommended that questions that are of secondary interest, or may require a sample size that you cannot obtain, should be secondary aims. These specific aims will provide the cornerstone for developing your study plan. Table 3 is an example of how you might craft a set of specific aims.

Step 2: developing the study plan

Once the specific aims have been established, you can begin to develop your study plan. The study plan

Table 5 Outline for a study protocol

Section	Purpose
1. Specific aim(s)	What aims will the study address?
2. Background and significance	What is known about the subject and why are these aims important?
3. Methods	
Study design	What study design will best answer the question given the various limitations?
Subjects	Who are the subjects that are to be included?
Selection criteria	How will the subjects be selected and recruited?
Sampling	
Intervention	What is the treatment or intervention?
Patient enrolment and data collection	How will patients be recruited and enrolled? How will data be collected?
Measurements	What measurements will be made?
Predictor variables	What instruments or techniques will be used to measure them?
Potential confounding variables	Are these valid, reliable and responsive?
Outcome variables	
Quality control and data management	How will the data be input and managed?
Compliance	How will compliance and follow-up be ensured?
Follow-up	
4. Statistical issues	
Sample size	How large will the study need to be?
What analysis will I do?	How will the data be analysed (descriptive and analytical statistics)?
5. Timetables and organization	What is the timeframe for starting and finishing the clinical trial?
6. Ethical considerations	
Safety, privacy and confidentiality	How will safety, privacy and confidentiality be handled?
Informed consent/institutional review	

is best developed in the following two stages: (a) study outline and (b) study protocol. The purpose of the *study outline* is to provide a framework for the basic elements of the proposed study, and should be one to two pages in length. Furthermore, the study outline can serve as a short proposal for your idea, that you might share with colleagues, potential co-investigators, funding sources, etc., before developing the study protocol. When applying for funding through a governmental organization, the outline is typically called a letter of intent (LOI). The basic components for this outline are listed in Table 4.

The *study protocol* is an extended version of the outline and should contain as much detail as possible (Table 5). This protocol provides the main framework for the study justification and operations. It will be submitted to the Institutional Review Board (IRB) and any sponsor, or future funding organizations, if applicable. A well thought out protocol is a recipe for success. Time spent 'working out the kinks' and creating a detailed written plan will make for an efficient and successful research study. The following sections discuss important aspects of your study plan that will ultimately end up in your study protocol.

Study design

The age of evidence-based medicine has arrived. Now more than ever, you need to think about the study design before committing time to research that you will ultimately want to publish. Choosing an appropriate study design is critical to your ability to address the specific aims of your study (Fig. 1).

There are two main categories of comparative study designs: *experimental* (i.e. randomized controlled trial) and *observational* (i.e. cohort and case—control). *Descriptive* designs, such as case-series, are also informative in certain situations, but have significant limitations when attempting to determine treatment superiority. In the hierarchy of study designs, the RCT provides the strongest evidence for safety and effectiveness (Fig. 2).

Randomized controlled trials

Randomized controlled trials are characterized by:

- Random assignment of intervention, or treatment, in which a group of patients are randomly assigned either to an experimental group to receive a treatment such as surgery, or to a control group (the control group might receive nothing, placebo or an active alternative).
- Minimizing confounding variables (known and unknown). A confounding variable is both associated with the exposure of interest (e.g. treatment) and is a risk factor (or prognostic factor) for the outcome.
- Offering the most solid basis for an inference of cause and effect, compared with the results obtained from any other study design.

When employing randomization, it is important to keep treatment group assignments unpredictable

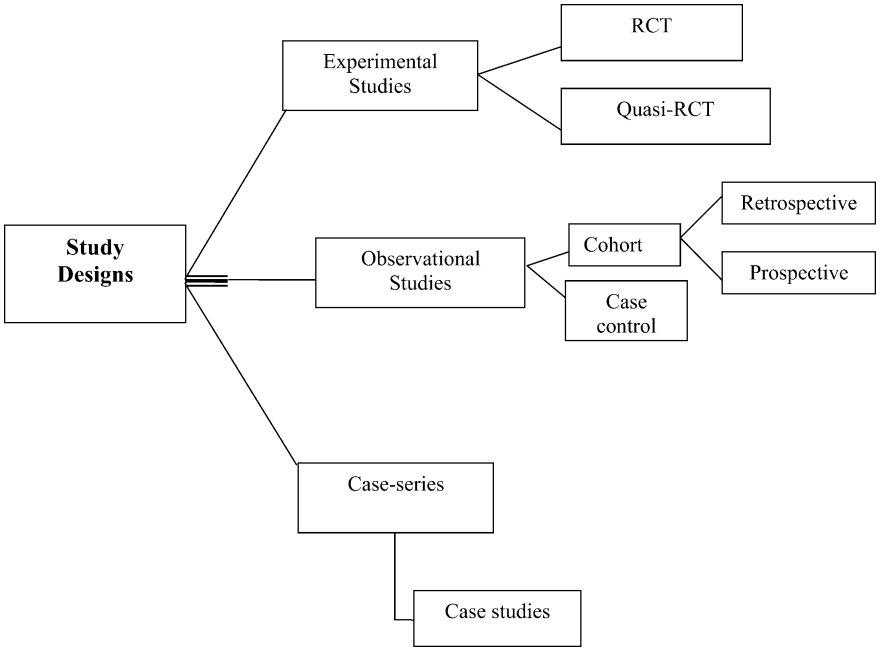

Figure 1 Study designs.

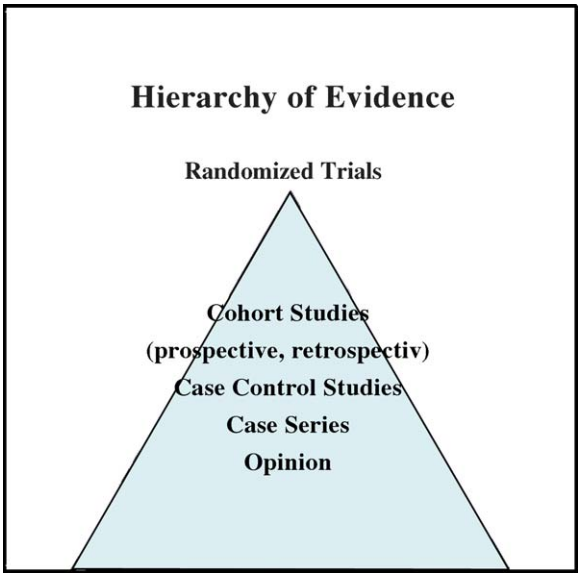

Figure 2 Hierarchy of evidence provided by different study designs.

over the course of a study. In other words, a participant's treatment allocation should not be revealed until he/she has been officially enrolled. This is known as *concealment*. Furthermore, the randomization should occur as late in the study as possible. This helps to prevent the bias that can arise when either caregivers, or patients, delay enrolment until they think that the chances are better of their receiving a desired intervention.[4] This ensures that factors influencing eligibility, or consent to participate, are not disproportionately divided into treatment groups. The most popular methods for allocation concealment include:

- Having a central study office that performs the randomization and is telephoned upon participant enrolment.
- Using sequentially numbered, sealed, opaque envelopes that contain treatment group assignments.

RCTs that use non-concealed randomization are known as *Quasi-RCTs*. These are studies in which the allocation of participants to different forms of care is not truly random, for example, allocation by date of birth, day of the week, medical record number, month of the year or the order in which participants are included in the study (e.g. alternation). This type of allocation is more prone to selection bias.

Sometimes patients in a clinical trial are assigned to one treatment group, but for a variety of reasons, receive the other treatment. When this occurs, subjects should be analysed as if they had completed the study in their treatment groups, which were formed by randomization. This is called *intent-to-treat*. Any alteration in the composition of each treatment group in the analysis negates the intention of the randomized trial design—to have a random distribution of unmeasured characteristics that may affect outcome (i.e. confounders). When this happens, the randomized trial, in effect, is converted to an observational trial.[4] For example, in a trial comparing reamed to unreamed tibial nailing, it is possible that a patient randomly assigned to receive an unreamed nail ends up requiring reaming. This patient should be analysed as if he/she did not receive the reaming.

Intent-to-treat analyses are the best way to ensure that confounding will not play a role here. The price paid, however, is typically an attenuation of any observed associations between treatment and outcome—any treatment effect found in an intent-to-treat analysis is likely to be a conservative estimate of efficacy.[4]

Three other study designs, lower on the evidence pyramid, are the cohort study design, the case—control design and the case-series.

Cohort studies

Cohort studies are characterized by:

- Comparing the outcomes of people whose treatment differs "naturally" (i.e. not as the result of random assignment).
- Identifying study participants *based on treatment*, and then comparing their outcomes.
- The eligible participants' not having experienced the outcome of interest at the time when treatment groups are defined.[5]

While the RCT is considered the "gold standard" of all study designs, the cohort study is often referred to as the "gold standard" of observational studies because of its ability to establish a temporal relationship between the treatment and the outcome of interest. In other words, the treatment clearly precedes the outcome. Since other factors than treatment alone (such as prognostic factors) can also influence the outcome, an imbalance between treatment and control groups with respect to these factors may result in a biased outcome. Furthermore, these factors often influence which treatment the patient receives. As a result, cohort studies can lead to misleading results, if these factors are not carefully identified and controlled for, thereby either overestimating or underestimating the treatment effects. Cohort studies may be divided into those that are prospective and those that are retrospective, based on the time of study initiation. *Prospective cohort studies* involve the

ascertainment of treatment status at the outset with follow-up for outcome to occur in the future. *Retrospective cohort studies*, on the other hand, are characterized by the treatment and outcome having already occurred at the time of study initiation. Even though retrospective cohort studies tend to be cheaper and faster than prospective cohort studies, the retrospective nature of the study can introduce additional bias. Furthermore, retrospective cohort studies are limited to outcomes and prognostic factors that have already been collected, and may not be the factors that are important in answering the clinical question.

Case—control studies
Case—control studies are characterized by:

- Comparing the frequency of past ''exposure'' between *cases* that develop the outcome of interest and *controls* that do not have the outcome.
- Controls are chosen to reflect the frequency of ''exposure'' in the underlying population to the risk from which the cases arose.
- Study participants are identified *based on outcome* and then compared for presence of ''exposure''.

''Exposure'' can refer to a treatment, or any other factor that may influence the outcome, such as fracture severity, degree of osteoporosis and age, to name a few.

The case—control design is an alternative to the cohort design for investigating, or comparing, the effects of a treatment(s) (or risk factors) on an outcome, generally when the outcome of interest is rare. Examples of rare outcomes in musculoskeletal traumatology include pulmonary embolism, implant failure, mortality and others that occur at rate of less than 5% of all treated subjects. A *case—control study* compares the odds of a past treatment, or a suspected risk factor, between cases (individuals with the outcome of interest) and controls (individuals who are as similar to the cases as possible without the outcome of interest).

Case-series
Case-series are characterized by:

- Collection of multiple noteworthy clinical occurrences.
- Description of an unusual combination of signs and symptoms, experience with a novel treatment or a sequence of events that may suggest previously unsuspected causal relationships.
- Being descriptive studies, unlike the previously described analytical studies, because they are undertaken without a particular hypothesis in mind and lack a comparison group.
- The need for caution in generalising the results to patients in other settings.

Despite being the weakest with respect to providing evidence for treatment superiority, case-series are frequently published in musculoskeletal traumatology.

Blinding

Blinding, or masking, refers to keeping persons involved in a trial (RCT, cohort or case—control study) unaware of which study subjects are in which treatment arm. The main reasons for doing this are:

- to avoid possible influences of this knowledge in assessing the outcome;
- to minimize a differential attrition loss-to-follow-up between treatment groups.

When determining who should be blind, ask these three questions:

- Can I blind the patients? The best way to avoid the placebo effect is to prevent the patient from knowing if he/she received the treatment of interest.
- Can I blind the clinicians? Differences in patient care, other than the intervention (such as rehabilitation care), can bias the results.
- Can I blind those who evaluate the outcomes? If study personnel are privy to the treatment, outcomes assessed by these personnel, such as radiographs or clinical status, may reflect the assessor's bias (conscious or subconscious).

Generally, a trial is *double-blind* if both the patients and research staff members responsible for measuring outcomes are kept unaware. A trial is *single-blind* if only one of these parties (usually the subjects) is kept unaware. Blinding may also be extended to people with other roles, such as those performing the statistical analyses of the data. If blinding is not logistically, or ethically, possible, you should, at a minimum, enlist independent (i.e. disinterested) observers to evaluate important outcomes.

Prognostic variables

Prognostic variables are those that may be associated with the outcome, but are not necessarily the treatment interventions being evaluated. These should be discussed up front, especially if you have

the desire to explore their association with the outcome. These are especially important for prognostic studies that seek to identify those patients at a greater risk of a poor prognosis. A thorough literature review is the best way to identify what these factors are. Additionally, clinical experience should also contribute to identifying those factors that may have not been identified in the past. Furthermore, prognostic variables may also be potential confounding variables that accentuate the importance of measuring them. A good example is fracture severity, or classification. The more severe fractures tend to be treated differently from the less severe fractures and often lead to worse outcomes, independent of the treatment intervention.

Outcome measures

A perfectly designed study that clearly demonstrates the superiority of one treatment over another may provide insufficient evidence, or even be harmful, if it fails to measure "important" outcomes. Some of the best studies leave us with more questions, because the authors failed to put thought into their outcome selection. For example, while one treatment method may lead to fewer short-term complications, when compared to another, the same method may also result in decreased function, or an inferior quality-of-life. Were these outcomes measured? What is critical to any clinical, or research, setting, with respect to measuring treatment effectiveness, is identifying and measuring clinically "important" outcomes. That which is deemed "important" may lie in the eye of the beholder; however, much thought should go into their selection. The following should be considered when selecting outcomes:

- They should be directly tied to the specific aims and capable of measuring the outcomes of interest.
- They should be important to patients.
- Patient-reported outcomes should be considered.

Emerging patient-reported outcome (PRO) measures are doing a better job of measuring aspects of patients' lives that they consider important. Furthermore, they are generally more carefully developed and tested. Generally, PROs are questionnaires, or instruments, that patients complete by themselves, or, when necessary, are completed by others on their behalf, to obtain information in relation to functional ability, symptoms, health status, health-related quality-of-life and results of specific treatment strategies. It is increasingly recognized that traditional clinician-based outcome measures need to be complemented by measures that focus on the patient's concerns, in order to evaluate interventions and identify whether one treatment is better than another.[7] Interest in PROs has been fuelled by an increased importance of chronic conditions, where the objectives of treatment are to restore, or improve, function, while preventing future functional decline.[1]

There is now available a large array of such instruments for musculoskeletal conditions. For a thorough discussion on the selection of appropriate outcomes and an evaluation of more than 150 musculoskeletal outcomes instruments, cited in the literature, see the *AO Handbook. Musculoskeletal Outcomes Measures and Instruments*.[8]

Complete follow-up

It is important to develop a subject follow-up plan that minimizes losses to follow-up. It is not uncommon for the results of a study to be reported, by utilizing only a proportion of the subjects who entered a study. A high rate of follow-up (e.g. $>$90%) will help to avoid a bias that can arise as a result of an association between factors determining dropping out and the outcome. For example, 12-months after surgery for a tibial pilon fracture, patients who are having excessive pain, or difficulty with function or activities of daily living may be more likely to present for follow-up than patients who are doing well. If one treatment method is superior to another, and the follow-up rate is low (e.g. 60%), this treatment method may appear inferior to another method, if only those with poor outcomes attend for follow-up. The following are some strategies to improve your follow-up rate:

- Upon study entry, you should obtain the following:
  - Patient's mailing address, telephone number and e-mail address.
  - The name and address of the patient's primary care physician.
  - The name, address and phone number of three people at different addresses, with whom the patient does not live, who are likely to be aware of the patient's location.
- You should call patients and remind them of upcoming study visits from the study coordinator.
- Study personnel should contact patients no less frequently than once every three months to maintain contact and be aware of change in residence.

Statistical analysis

There should be a description in your protocol for how you handle descriptive and analytical statistics. The presentation of descriptive data on the study population is important for a number of reasons:

- It enables you to determine the comparability of study groups at baseline and to evaluate the likelihood of any selection bias, or confounding.
- Descriptive tables presented typically describe all enrolled patients. This can allow the reader to determine, when not explicitly stated, the extent of loss to follow-up.
- The baseline characteristics of the study population can help in determining the generalisability of the results to your own study population.

The purpose of analytical statistics is to report the effects of treatment and the risk factors for specific outcomes. These rely on the testing of statistical hypotheses. The testing of a statistical hypothesis (sometimes called testing of statistical significance) will be an important application in your clinical study. Statistical tests aim to distinguish true differences (associations) from chance. It is worth going back to the basics and revisiting *The Scientific Method* which serves as the foundation for all research.

The sequence of events outlined by The Scientific Method is the following:

- Start with an idea or question.
- Develop a testable hypothesis.
- Specify a null hypothesis.
- Reject (or fail to reject) the null hypothesis.
- Repeat the experiment.

A classical example is the rolling of dice. The null hypothesis is that the dice are fair. If it turns out that the dice are not fair, then this is an extremely rare event, or the die is not balanced. When the null hypothesis is false, the research hypothesis and the researcher's "hunch" may be correct. When the null hypothesis is true, the research hypothesis is false and the researcher's "hunch" was wrong. For example, you may hypothesize that surgical treatment of distal radius fractures in elderly women is more effective than conservative management. The null hypothesis is that there is no difference between these treatment methods. The research hypothesis is that surgical management provides better patient outcomes among elderly women than conservative management. Let us assume that the *truth* (for this discussion) is that there is no difference between these two methods. In this case, the null hypothesis would be correct. If your data lead to the conclusion that surgical management is more effective, then a true null hypothesis could be rejected and a Type I error could occur. *The P-value can help avoid this mistake*. If, however, the null hypothesis is incorrect and your data lead to acceptance of the false null hypothesis, then, unfortunately, it may appear that surgical management is no more effective. Accepting a false null hypothesis is a Type II error. *The power analysis should help avoid this mistake*. Type II errors occur when the null hypothesis is wrong, but we fail to make that conclusion based on limitations in our data set. A common explanation is a sample of subjects that is too small. Failure to achieve statistical significance, when comparing two groups, is more likely to be due to inadequate power than there being no difference. This is why a power analysis is so important in the study planning process. The power analysis considers the number of subjects needed, the differences to be detected, a specified *P*-value and the variability in the data. The power gives us some degree of assurance (80%, 90%, 95%, etc.) that, if there is no statistical difference found, the conditions of the study design were appropriate to detect one, if there was one to detect. By convention, power is usually set at 80% or 0.80. This means that 80% of the time it is correct to say "no difference", and 20% of the time incorrect to say "no difference". Depending on the importance of avoiding Type II errors, the power may be set much higher. It is important to note that you do not have to know how to do a power analysis or a sample size estimate to know when one needs to be done. It is advisable to have an epidemiologist, or statistician, on whom you can count for this aspect of the study planning.

By convention, *P*-values of 0.05, or less, are accepted as statistically significant. The following are important characteristics of *P*-values:

- They help to determine the probability that the conclusions reached are due to chance alone.
- They are mathematical representations of the probability that the researcher is wrong if the null hypothesis is rejected.
- They are a probability estimate of the possibility that the null hypothesis is false.
- They are *never* a clear yes or no—merely a guide to action.

There is nothing magical about 0.05. A significance level of 0.05 means that there is a 1-in-20 chance of being wrong.

The use of effect measures, such as relative risks (RR), odds ratios (OR), relative risk reductions (RRR), number needed to treat (NNT) and their corresponding confidence intervals, can provide more useful information than a *P*-value. A much more thorough

Table 6 Methodological principles applied to the evaluation of therapeutic studies

Principle
Statement of concealed allocation[a]
Intention to treat principle[a]
Independent blind assessment
Patient-reported outcomes
Complete follow-up of >90%
Adequate sample size
Appropriate analysis and use of effect measures
Controlling for possible confounding
Inclusion and exclusion criteria

[a] Evaluated in randomized controlled trials only.

description of these useful tools can be found in the "Clinical Studies" section of the AO Foundation website: http://www.aofoundation.org/wps/portal/Home. Table 6 is a checklist that you may use when writing your protocol, or evaluating a therapeutic study that has already been published.

Step 3: implementing the study plan

Whether you are conducting a small study at your local institution, or a large international multi-site trial that will require oversight by the United States (US) Food and Drug Administration (FDA) (http://www.fda.gov/oc/gcp/default.htm) and/or European Union (EU) (http://europa.eu.int/pol/rd/index_en.htm), it is prudent to get into the habit of following Good Clinical Practice (GCP) procedures. GCP is an international, ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected (consistent with principles that have their origin in the Declaration of Helsinki) and that the clinical trial data are credible. A discussion on adhering to Good Clinical Procedures, including developing the study operations manual, site initiation visits, recruiting and enrolling subjects, entering data and correcting errors, study site visits, handling missing data and subject withdrawals and final study closure, will be reserved for another publication. The key is to be organized, establish a process and adhere to it, pursue follow-up aggressively and be willing to modify, or enlarge, a study, if you see potential problems. It is better to address these issues early, than to wait and have a reviewer of your manuscript identify them.

Step 4: reporting the results

Once you have developed your study idea, developed your study plan, and executed your study successfully, you can begin to discover the truth behind your study questions. Is treatment A better than treatment B? Does it depend on what group of patients received the treatment (e.g. young versus old)? Are patients really better off receiving this new implant or surgical technique? Is it possible that the old way is the best way? Is it possible that it does not matter which technique is used?

Finding these answers is the motivating force behind performing a clinical study. Although it depends on the standards of the journal to which you choose to submit your manuscript, a general outline that you can follow for writing your manuscript may include the following sections: introduction, methods, results, discussion and conclusion.

In general, the *introduction* motivates the purpose of the research, outlines the objectives and why they are important, and why your hypothesis makes clinical sense.

The *methods* should provide sufficient detail for a reader to be able to reproduce your study. It is very important to discuss your statistical methods and to demonstrate that you did a power analysis.

When reporting *results*, it is important to report the actual data, not just *P*-values, so that the reader can differentiate between statistical and clinical significance. Furthermore, reporting effect measures (e.g. RRs, RRRs and NNT), when appropriate, makes the findings more clinically useful. Concise tables and graphs are good supplements to the text and may be a more efficient way to report some of your data.

The *discussion* section allows you to describe the significance of your results, contrasting statistical and clinical significance. It also allows you to discuss your strengths and weaknesses (Table 7). It is better

Table 7 Guidelines to consider when writing the discussion section of your manuscript

Guideline	Complete
Discuss the implications of the primary analyses first	√
Distinguish between statistical and clinical significance	√
Discuss any weaknesses and strengths in your research design, or problems with data collection, analysis or interpretation	√
Discuss the results in the context of the published literature	√
Discuss the generalisability of the results	√

Table 8 Guidelines to consider when writing the conclusion section of your manuscript

Guideline	Complete
You should provide equal emphasis on positive and negative findings	√
Results of secondary or post hoc analyses should be presented as explanatory	√
Conclusions should be based on fact and logic, not supposition or speculation	√
Studies using surrogate endpoints (e.g. muscle strength, range of motion, perhaps even bony union) should be interpreted with caution. In other words, just because a patient has good shoulder strength and range of motion does not necessarily mean they have a good final outcome if they cannot perform activities of daily living	√

to be honest than to have a reviewer, or reader, point out issues that you had neglected to address. Finally, be careful not to use this section as a platform for clinical opinion. It is very refreshing to read a discussion that is clear and concise and that stays within the boundaries of the study being reported.

The *conclusion* allows you very briefly to summarize the principal findings of your study. Limit your conclusions only to those supported by the results of your study. Unsupported conclusions are very common in scientific research. Consider the guidelines outlined in Table 8.[6]

Step 5: submitting for publication

Before submitting for your manuscript publication, it is important to have your peers review it. In fact, it is a good idea to have a number of people review it, as you develop it. For example, you may want to have your methods section reviewed before you write up the results. Changes in your methods section will undoubtedly affect the way you report the results. Expect this process to be lengthy. Time spent having your colleagues review your paper is time saved when you submit it to a journal. It may even be the difference between acceptance and rejection. If you are asking colleagues to review your manuscripts (whether they are co-authors or not), be sure to be prepared to return the favour.

Theoretically, one of the following three things will be likely to happen when you submit your manuscript to a journal:

- rejection;
- revision request:
  - acceptance implied,
  - acceptance possible;
- acceptance.

The following are some important principles that you should consider when submitting your manuscript for publication[3]:

- Select a journal that is most appropriate for the audience you want to reach.
- Consider writing to the editor of one or more journals to determine whether or not they are interested in publishing your topic, especially if it is unique.
- Make sure that you adhere strictly to the selected journal's guidelines for formatting and submission.
- Ensure that your paper is statistically sound. Most editors take a close look at the statistical plan and power analysis.
- If rejected, do not be discouraged. There are plenty of other journals out there.
- Whether rejected, or revision is requested, read the reviewers' comments carefully and unemotionally.
- If you make the requested revisions, your paper has a high likelihood of being accepted. Make sure that you respond to the reviewers' comments in a timely and organized fashion.
- Do not be afraid respectfully to argue your case, if you feel that you have been misinterpreted, or misunderstood; however, be careful with this. Comments and criticisms are generally informed and should be considered seriously. Debate may make acceptance less predictable.
- Persevere and be patient.

Conclusions

There are five major steps that one must navigate successfully to take a study idea and turn it into a publication that may have an impact on clinical practice. These steps include developing the study question(s), developing the study plan, implementing the study plan, reporting the results and submitting the manuscript(s) for publication. Each step is a process in itself and should be treated as such. Patience is a virtue in clinical research, but when practised will lead to significant contributions and improvements in the area of patient care.

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Presenter: Tom Walsh

Training from the trainees perspective

Notes:

Presenter: Jonathan Carter

Do we need a CGO examination?

In deciding upon whether an examination is required for Certification in Gynaecologic Oncology, one needs to consider the function of the exam and what is to be achieved by the examination process. In essence the goal is to confirm that at the end of training the candidate is competent in the practice of gynaecological oncology. The process of determining competence is complex. Currently our process includes ongoing assessment by training supervisors during training, culminating in a written and oral examination. Presumably candidates are considered competent by assessment prior to sitting the written and/or oral examination. To replace such a system, one would need to be assured that the "new" assessment process is adequately able to measure competence (whatever that means), is transparent, validated and reproducible.

It does seem a little strange that after 3 years of supervised training, with regular supervisor assessment and having passed an oral examination, that a candidate may be failed by a brief encounter in oral examination process. Is it that the examination has identified a candidate who is "not competent", implying the assessment process failed to do so? Or has "failure" at the oral barrier incorrectly identified a competent candidate.

One of the ongoing criticisms of our current examination is that we are instructed to mark to the minimally acceptable pass mark and that a candidate may fail many of the questions in the oral exam, do extraordinarily well in a couple and pass overall. The criticism is valid, but the process is mandated by the College.

Whilst not perfect, the process of examination has served us well for a number of decades and before embarking upon a new assessment process, we need to be assured that the process is fair, that candidates are passed or failed on specific criteria, that personality issues do not influence the process and the results are reproducible. I await with eager anticipation the views of the College on what is the next step.

Notes:_____

Session:	**Thursday 25th March 2010** **CERVICAL CARCINOMA** **10.30am -12.00pm**
Session Chair:	**Chris Dalrymple**
Topics & Presenters:	**STAGING: the laparoscope, the magnet and the isotope** Laparoscopic staging **– Penny Blomfield** MRI Staging **– Kailash Narayan** PET Staging **– Andy Garrett**

Presenter: Penny Blomfield

Laparoscopic staging

Notes:_____

Presenter: Kailash Narayan

MRI Staging

FIGO staging had traditionally defined both, prognosis and treatment modalities in the management of cervical cancer. Gradually, clinical research helped define several other prognostic factors in addition to FIGO staging. These factors included tumour volume, nodal metastases, lymphovascular space invasion and depth of tumour invasion. Subsequent clinical research related to post operative and radical concurrent chemotherapy led to improved loco-regional control and survival. It also resulted in a better understanding of treatment related toxicities in patients treated by surgery and post operative radiotherapy. Meanwhile, laparoscopic nodal staging in non-operable cervical cancer patients resulted in more accurate definition of treatment portals in these patients. Recently, application of modern imaging modalities, eg. MRI, PET and PET/CT have confirmed the importance of surgically accessible prognostic factors non invasively. This has resulted in prevention of dual treatment toxicities in selected so called operable cases as well as better coverage of disease in the radical radiotherapy treatment portals. Based on these observations the definition of advanced cervical cancer will be refined. Patient workup for advanced cervical cancer patients, disease mapping and prognostic factors for treatment selection and tretment outcome will be described.

Notes:

Presenter: Andy Garrett

PET Staging

Cervical Carcinoma is a clinically staged disease. More advanced imaging techniques are available in developed countries and PET scans are becoming more commonly used. PET scans have a role in staging of the primary lesion, evaluation of nodal metastases, providing pre-treatment prognostic information, optimizing treatment options and in post treatment surveillance. PET scans show an overall sensitivity of 97% for staging accuracy and better sensitivity and specificity than CT and MRI for nodal disease. A complete PET scan response seen at 3 months post treatment correlates with a 5YS of 78-83%.

Notes:

Session:	**Thursday 25th March 2010** **OCCUPATIONAL WELLBEING IN THE GYN ONCOLOGIST** **12.00pm – 1.00pm**
Session Chair:	**Yee Leung** Keepad Survey Live in Real Time **Discussion**
Topic:	Doctor's health 2010
Presenter:	**Geoff Riley**

Presenter: Geoff Riley

Doctor's Health 2010

This session will look at expressed sources of stress and distress in Gynaegological Oncologists and compare them to the profession as a whole. It will then turn to theoretical ways of understanding and thinking about these issues with a view to rehearsing effective individual and systemic solutions.

Notes:

Session:	**Friday 26th March 2010** **8.30am – 10.30am**
Topic:	**Tumour Board**
Presenters:	**Ian Hammond and Yee Leung**

This interactive Tumour Board will present ‘tricky’ management situations occurring in gynaecologic oncology. Six real cases have been put up for discussion and will be presented using the interactive Turning Point keepad system. This will allow for all participants in the session to 'vote' on the various options for management. Sufficient time has been allowed for full discussion of these cases and their management. Your participation is critical to the success of the session. Yee Leung and Ian Hammond will be facilitating the case presentations. Many thanks to Penny Blomfield, Rhonda Farrell, Russell Hogg, Yee Leung, Jim Nicklin and Stuart Salfinger for providing the cases.

Notes:

Session:	**Friday 26th March 2010** **FOLLOW UP OF GYNAE CANCERS** **11.00am – 1.00pm**
Session Chair:	**Jonathan Carter**
Topics:	ASGO current practice FU Gynae Cancer **– Rhonda Farrell** Overview FU Gynae Cancers **– Rob Rome** Evidence base for FU Ovarian Cancer **– Jane Francis NBOCC** To image or not to image: that is the question! **– Martin Buck**
Discussion:	Moving toward National consensus **– Rhonda Farrell**

Presenter: Rhonda Farrell

ASGO current practice FU Gynae Cancer

Notes:

Presenter: Rob Rome

Overview FU Gynae Cancers

The Western and Central Metropolitan Integrated Cancer Service (WCMICS) in Victoria commissioned a project to develop consistent guidelines for follow-up of several tumour streams including the gynaecological tumours. A Project Officer was appointed who conducted structured interviews with 13 practitioners involved in the management of women with gynaecological cancer in Victoria. The most common practice relating to intervals, duration, tests etc. was determined. The project also reviewed the literature and addressed the rationale for follow-up. The Report was completed in 2009 and contained a series of recommendations to improve the consistency, efficiency and safety of follow-up. The presentation will expand on some aspects of the Report.

Notes:

Presenter: Jane Francis - NBOCC

Evidence base for FU Ovarian Cancer

National Breast and Ovarian Cancer Centre (NBOCC) is undertaking a review of the information about Follow up in the Clinical practice guidelines for the management of women with epithelial ovarian cancer. The approach will incorporate the latest evidence about appropriate medical review to support the physical and emotional needs of women following treatment. An initial background scan of the published literature on follow-up for ovarian cancer indicated limited evidence and few definitive guidelines in this area. This presentation will outline the evidence about follow up for women with ovarian cancer from a systematic review undertaken by NBOCC.

Notes:

Presenter: Martin Buck

To image or not to image: that is the question!

Notes:

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REFERENCE: 1. GARDASIL Product Information 2010. MINIMUM PRODUCT INFORMATION: GARDASIL™ [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant vaccine] **#INDICATIONS:** GARDASIL is indicated in females aged 9 through 45 years* for the prevention of cervical, vulvar, and vaginal cancer, precancerous or dysplastic lesions, genital warts, and infection caused by Human Papillomavirus (HPV) Types 6, 11, 16, and 18 (which are included in the vaccine). GARDASIL is indicated in males aged 9 to 15 years for the prevention of infection caused by Human Papillomavirus (HPV) Types 6, 11, 16, and 18 (which are included in the vaccine). *Immunogenicity studies have been conducted to link efficacy in females aged 16 to 26 years to the younger populations. **CONTRAINDICATIONS:** Hypersensitivity to vaccine, including excipients. **PRECAUTIONS** Febrile illness, impaired immune response, thrombocytopenia or any coagulation disorder. This vaccine is not intended to be used for active treatment. Routine cervical screening and detection and removal of cervical lesions should be continued in individuals who receive the vaccine. #Syncope (fainting) may follow any vaccination, especially in adolescents and young adults. Syncope, sometimes associated with falling, has occurred after vaccination with GARDASIL. Therefore, vaccinees should be carefully observed for approximately 15 minutes after administration of GARDASIL. **Use in Pregnancy (Category B2). Use in Lactation** GARDASIL may be administered to lactating women. **ADVERSE REACTIONS:** Injection site (pain, swelling, erythema, hemorrhage, pruritis), fever and very rarely, bronchospasm. All cause common systemic adverse experiences include pyrexia, diarrhoea, vomiting. **#Post-marketing Reports** The following adverse experiences have been spontaneously reported during post-approval use of GARDASIL. Because these experiences were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish a causal relationship to vaccine exposure. Blood and lymphatic system disorders: idiopathic thrombocytopenic purpura, lymphadenopathy. Nervous system disorders: acute disseminated encephalomyelitis, dizziness, Guillain-Barré syndrome, headache, syncope sometimes accompanied by tonic-clonic movements. Gastrointestinal disorders: nausea, vomiting. Musculoskeletal and connective tissue disorders: arthralgia, myalgia. General disorders and administration site conditions; asthenia, chills, fatigue, malaise. Immune system disorders: Hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria. **DOSAGE AND ADMINISTRATION** Administered intramuscularly at day 0 and then at 2 and 6 months after initial dose. In clinical studies, efficacy has been demonstrated in individuals who have received all 3 doses within a 1-year period.

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Session:	**Saturday 27th March 2010** **ENDOMETRIAL CARCINOMA:** **CONTROVERSIES IN MANAGEMENT** **8.00am – 10.00am**
Session Chair:	**Alex Crandon**
Topics & Presenters:	ASGO Survey on current practice **– Yee Leung** 'Laparoscopic Approach to Carcinoma of the Endometrium: First Results on short-term outcomes and Quality of Life' **– Andreas Obermair/Monika Janda** Current status of surgical staging **– Marcelo Nascimento** Current status of radiation therapy **– Robyn Cheuk & Serena Sia** Current status of chemotherapy **– Andrew Dean**

Presenter: Yee Leung

ASGO Survey on current practice

Notes:_____

Presenter: Andreas Obermair/Monika Janda

'Laparoscopic Approach to Carcinoma of the Endometrium: First Results on short-term outcomes and Quality of Life'

Background: Endometrial cancer is the most common gynaecological malignancy in countries of the developed world. Current standard treatment includes total abdominal hysterectomy (TAH), which provides excellent survival prospects, but it's associated morbidity is significant. Total laparoscopic hysterectomy (TLH) has been pioneered in Australia and retrospective data suggest a decrease in the incidence of asurgery-related adverse events and similar disease-free (DFS) and overall survival (OS). The LACE trial is a randomised controlled clinical trial initiated in 2005 to assess whether TLH is equivalent to or better than TAH with regards to patient QoL and to establish equivalence in DFS.
Methods: For the QoL substudy of the trial, a total of 361 patients were enrolled (TAH n= 141, TLH n=191). Before surgery, at 1 and 4 weeks (early), and 3 and 6 months (late) post-surgery, patients completed the Functional Assessment of Cancer Therapy-General (FACT-G) Version 4 questionnaire, as well as measures of endometrial cancer-specific wellbeing, body image and a visual analogue scale of QoL. Improvements in QoL from baselines of >5% were defined as clinically significant. Intention-to-treat analysis was performed using generalized estimating equations on differences from baseline for the early and late QoL periods.
Results: Patients' mean age was 62.7 years (range 34-93 years). The majority of patients (85.6%) were overweight or obese. There were eight conversions from assigned treatment (2.4%; one from TAH to TLH, seven from TLH to TAH).
In the early phase of recovery (up to 4 weeks post-surgery), patients undergoing TLH reported clinically and statistically significantly greater improvement of QoL from baseline compared to TAH (ranging from 14% better for functional wellbeing ($p < 0.001$) to 2% better for social well-being, $p=0.04$). Improvements in QoL up to 6 months post-surgery continued to favour patients with TLH, in particular for functional wellbeing (6%, $p=0.01$) and body image (5.4%, $p <0.001$). Overall, 52% of patients with TLH experienced clinically important improvements in their QoL from baseline to 4 weeks following surgery compared with 30% of patients treated with TAH ($p<0.001$). By 6 months post-surgery theses proportions increased to 68% for TLH compared to 55% for TAH ($p= 0.01$).
Conclusions: QoL improvements from baseline during early and later phases of recovery significantly favour TLH compared to TAH for patients treated for Stage I endometrial cancer.

Authors: M Janda, V Gebski, A Brand, I Hammond, R Hogg, T Jobling, R Land, Y Leung, T Manolitsas, A McCartney, M Nascimento, J Nicklin, D Neesham, M Oehler, G Otton, L Perrin, S Salfinger, T Walsh, P Sykes, H Ngan, A Garrett, M Laney, TY Ng, Tam, Chan, D Wrede, S Pather, B Simcock, R Farrell, A Obermair.

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Presenter: Marcelo Nascimento

Current status of surgical staging

Notes:

Presenters: Robyn Cheuk & Serena Sia

Current status of radiation therapy

Debate: To irradiate or not irradiate?- Endometrial Carcinoma
In this session, views for and against adjuvant radiotherapy will be presented along with supporting literature.

Notes:

Presenter: Andrew Dean

Current status of chemotherapy

Notes:

Session:	**Saturday 27th March 2010** **SURGEONS CORNER** **10.30am – 11.30am**
Session Chair:	**Tom Jobling**
Topics & Presenters:	Surgical approaches to the upper abdomen **– Paul Moroz** Endoscopic approaches to the retroperitoneum **– David Sofield**

Presenter: Paul Moroz

Surgical approaches to the upper abdomen

The supracolic compartment of the abdomen contains a high density of vital organs and major vascular structures and so represents a major challenge for all surgeons. This challenge is greatly amplified in the presence of disseminated peritoneal malignancy. The successful treatment of such disease demands that the supracolic compartment be thoroughly and safely navigated. In addition to a thorough anatomical knowledge of this region, the operating surgeon must also have the capability to perform procedures such as greater and lesser omentectomy, splenectomy, cholecystectomy, partial gastrectomy, distal pancreatectomy, liver resection, portal hilar dissection, portal vein dissection (and repair), hepatic vein dissection, peritoneal stripping of diaphragms, central tendon and crura, dissection of the caudate and IVC. To achieve a satisfactory clearance of disease, some or all of these procedures will be necessary in most peritonectomy procedures. This presentation will systematically demonstrate the navigation of the supracolic compartment during a peritonectomy procedure.

Notes:_____

Presenter: David Sofield

Endoscopic approaches to the retroperitoneum

Laparoscopic surgery in the retroperitoneum The development of direct laparoscopic approaches the retroperitoneum has enabled a wide range of procedures including nephrectomy , radical prostatectomy , lymph node dissection, reconstructive and vascular procedures to be accomplished in a minimally invasive manner.

This approach offers significant benefits over transperitoneal approaches - direct and rapid access to major vessels, avoidance of bowel dissection, eliminating pain due to intraperitoneal CO2 and reduced operating time.

This presentation will illustrate the range of procedures being performed highlighting recent experience in gynaeoncology.

Notes:

Session:	**Saturday 27th March 2010** **OVARIAN CARCINOMA: RADICAL DEBULKING SURGERY** **11.30am – 1.15pm**
Session Chair:	**A J McCartney**
Topics & Presenters:	ASGO survey on current and future practice **– Stuart Salfinger** QCGC experience in radical debulking surgery **– Jim Nicklin** Evidence for radical upper abdominal debulking **– Jane Francis** A surgeons view: Pseudomyxoma Peritoneii **– Paul Moroz** The Heidelberg view **– Simon Hyde**

Presenter: Stuart Salfinger

ASGO survey on current and future practice

Notes:_____

Presenter: Jim Nicklin

QCGC experience in radical debulking surgery

Survival from advanced epithelial ovarian cancer (EOC) is inversely proportional to the volume of residual tumour. The ultimate goal of surgical debulking for advanced EOC is complete removal of all macroscopic disease. There has been an evolution in the approach to this surgery at QCGC involving the pelvis and omentum, the left upper quadrant and the right upper quadrant. Optimal debulking rates (to nil residual) at QCGC will be presented as well as survival and morbidity data. Aggressive cytoreduction to nil macroscopic disease is feasible in a significant percentage of cases with minimal and acceptable morbidity.

Notes:

Presenter: Jane Francis - NBOCC

Evidence for radical upper abdominal debulking

National Breast and Ovarian Cancer Centre (NBOCC) is undertaking a review of the Clinical practice guidelines for the management of women with epithelial ovarian cancer. Chapter 10 'Surgery for invasive ovarian cancer' does not contain any recommendations regarding radical upper abdominal surgery (RUAS). However, there are no agreed guidelines around the use of RUAS, such as patient selection criteria, acceptable levels of morbidity, the skill base and specialty of the surgical team, or supportive care. This presentation will outline the evidence about radical upper abdominal surgery from a systematic review undertaken by NBOCC.

Notes:

Presenter: Paul Moroz

Pseudomyxoma Peritoneii – A Surgeon's View

Pseudomyxoma peritoneii (PMP) is a condition that has traditionally been viewed with nihilism. Over the past two decades the procedure of cytoreductive surgery (CRS) combined with hyperthermic intraperitoneal chemotherapy (HIPEC) and early postoperative intraperitoneal chemotherapy (EPIC) has demonstrated a clear benefit for selected patients. Unfortunately PMP remains an undertreated and often mismanaged clinical entity while its treatment with CRS/HIPEC evokes controversy. This presentation will review PMP and describe its treatment with cytoreductive surgery/HIPEC/EPIC and the achievable outcomes.

Notes:_____

Presenter: Simon Hyde

The Heidleberg view

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