Version 1
Rewritten by: Rino Bellocco
Date: Nov 14, 2006

Manual for abstracting form, Cahres - ovarian prognosis

Column 1: File and Items (bold if needed) in abstracting form	*Column 2:* Information on criteria for filling in the form and instructions on where to find the information in the medical record.	*Column 3:* Necessary additional information, notes.
File 1: Personalia	Personal Data	The information is as complete as possible in order to avoid mistakes. Both names and ID-numbers are given to eliminate errors. When information comes from medical record it is easier to confirm the identity by checking with Statistics Sweden's population register
Accessed	Consecutive number	
lopnr	Sequential number in the database Embla	
pnr	Personal Number	
ename		
Fname		
Dosp		
Dclin		
Astatus		
Acompl		
Connx		
exclude		
no_records		
Edited		
Lastconcode		
Lastconttext		
Idcheckok		
Idcheckfail		

Version 1
Rewritten by: Rino Bellocco
Date: Nov 14, 2006

File 2: Diagnosis		In order to create a uniform measure for follow-up, we've chosen a PAD (histopathological code) at first surgery as basis of diagnosis. This gives us the possibility to follow all participants in a uniform manner with regard to time. Usually PAD at surgery also is the method that confirms the diagnosis. When surgery has not taken place (most often at advanced illness) we start at the PAD or the cytology which was the basis of the diagnosis ovarian cancer. Usually the date of diagnosis from the cancer registry matches the date in the medical record. We then simply use the date from the registry. Only when the date differs with more than 1 month between the record and the register we change the date, as the date may have been registered wrongly in the register.
person		
lopnr		
Diagdat	Date of diagnosis according to the national Cancer Registry, if this does not differ from the information in the medical record. If discrepancy is more than 1 month, date from medical record is used.	
Fupdat	Date of last follow-up at specific site of follow-up (if last date of note is less than 5 years after date of diagnosis and the participant has not died, follow-up is not complete.	The information is given to ensure complete follow-up, that is to say that the patient is followed-up at least five years after diagnosis, or until recurrence or death.
fuphosp	If complete follow-up can not be done in this medical record, seek information on department to which the patient has been deferred.	Hospital and department of follow-up can be entered into the database and you can then "link" the participant so that information about the record for the same needs to be traced further, and where, will automatically come up in the abstraction lists created by the database.
fupclinic	If complete information cannot be collected in this medical record, seek information on where the patient was followed-up	The open care unit is a care-giving unit and the participant can, as with hospital/department be linked to the place in question through Embla. Also private physicians have codes that enable "linkage" of the participant to them.
fupvc	Comments	

File 3: cause		
person		Reason for diagnosis, why the examination which leads to diagnosis is carried out, which may influence stage of disease , which in turn influences prognosis, which the study wants to examine. The information is needed to avoid systematic error in the analyses of data. It could also be of value at analyses to know for how many participants this information is missing, as it influences the interpretation of the findings.
lopnr		
na0301	NOT STATED	
gyinv	Specify if the cancer was detected during a routine examination without previous suspicion or symptoms of ovarian cancer	
symptoms	Specify if participant has or has had symptoms giving reason for the examination	
other	All other reasons for examination, specify the real reason	

File 4: Status		
Ascites at diagnosis / surgery	If specified in the report from the surgical procedure	The status gives a picture of the general health status at diagnosis, and indirectly an indication of when in the disease progress the ovarian cancer is detected. Information is sought to make it possible to separate women with different stages of ovarian cancer from each other in the analysis of prognosis. It's also important to know if information is missing, because women with missing information here are removed from the above analysis. Ascites is an indirect sign of how much the cancer has spread in the abdomen at diagnosis. If the abdominal fluid is judged as pathological sign (ascites) or if normal is often a matter of the physician's subjective opinion. So in abstraction it is difficult to give clear directives for how the information should be interpreted and instead we choose to use the judgment made by the surgeon. In the definitions we state for this data, this subjectivity will be noted for the analysis.
person		
lopnr		
na0501	not stated	
ascy	Specify if ascites was present, regardless of amount.	
ascn	If stated that there was no ascites at the operation.	
na0502	not stated	
capremt	??	
capre	value for Ca-125 PRE	Ca-125 is a tumour marker which shows the activity of the disease. A high value indicates a high activity and a worse prognosis, and a low the opposite. Date of test is crucial for interpretation. A test taken in connection with invasive procedure like an operation, gives a falsely high value. It is therefore important to state if the test was taken pre- or post-operatively, and as an extra precaution, also the date. The standard in Stockholm is to take the first test at first chemotherapy and after surgery. If a pre-operative value is given¸ it gives a better platform for future analysis, and probably it says more about the future disease development. If both pre- and post-operative values are given, make note of both.
capred	Date of sampling	
Not given		
capostmt	??	
Ca-125 postoperatively	value for Ca-125 PRE	
Date of sampling	Date of sampling	
na0503	not stated	

File 5: Operations		
person		When operating ovarian cancer it is common that only a part of the tumour mass, that which is within reach for surgery without damaging the surrounding tissue, is removed, non-radical primary surgery. The treatment then continues with systematic chemotherapy with the aim to reduce the tumour size, before further surgery, intervention surgery, is carried out. Sometimes the second surgery is only carried out to check that the systematic treatment has in fact reached its goal, tumour free by naked eye (often called second-look).
lopnr		
notop	If patient has not gone through a surgical procedure	
opy1	Fill in if there was a primary surgery procedure at occasion 1	
opdat1	date	
na0601_1	not stated	
oprad1	Radical means that all microscopically visible tumour was removed.	
opnrad1	Visible tumour tissue was left in the abdominal cavity at time of surgery. Regarding amount see below.	
na0603_1	non stated	
rescm1	A measure on the amount of residual tumour in the abdominal cavity is given in the medical record.	It tumour mass was left in the abdomen a description of the size is given. In order to be able to analyse this information later, it is important to state the size as clearly as possible. Residual tumour is probably an important prognostic factor. It is usually difficult to get an accurate description of the tumour as it may be spread in the abdomen and along the abdominal wall. This makes it impossible to state the real amount of residual tumour. When the tumour is widespread in the abdomen, the surgeon. Usually chooses to state the size of the largest residual tumour. In the abstraction work we then settle for this information.
restxt1	The amount of residual tumour given in other way than in cm. Usually by making a reference to i.e., child's head etcetera.	
resnm1	Radical surgery has not been accomplished, amount of residual tumour not possible to measure.	

na0602_1		
	Here are specified those procedures that are meant to be treatment. Procedures meant to be palliative, as in treatment of recurrences or progressive disease, should be classified as secondary surgery or surgery for palliative purposes.	The mode of surgical procedure is one of the treatment methods this study aims to investigate, and how this and number of operations of different types influences diagnosis. A number of modes of surgical procedures can be carried out. For this study we are only interested in what they are called, only about what was removed and what date the procedure was done.
hyst1	hyesteroctomia Uterus including the cervix removed	Operation number 2 and 3 may be of the following modes: 1. Tumour reducing surgery during ongoing chemotherapy, planned procedure (intervention surgery) 2. Second-look: planned operation on patient in remission after systematic treatment with chemotherapy with the purpose to verify that there indeed is no tumour, often carried out without removing any tissue. 3. Secondary surgery: tumour reducing surgery later in the disease stage, palliative treatment may be called secondary surgery, but here it only means curative treatment. If there have been more than 3 separate occasions of surgery, contact the project coordinator in charge for possibly changing the form.
subhyst1	Uterus removed, cervix left behind.	
soeuni1	One ovary on the one side removed.	
soebil1	Salpingo-ooforektomi, ovaries on both sides removed.	
oment1	Also denoted as resection of omentus???. Means removal of the oment to the extent possible	
lgllbuk1	Removal of all lymph nodes in the abdominal cavity, for example along the aorta	
Ophoter1	Other specific procedures, besides those given above. Specified in the free text column	
Occasion 2	As above. Same variables with _2	
Occasion 3	As above. Same variable with _3	
	Secondary surgery, for palliative purposes	Surgery with palliative purpose, tumour reduction or for the purpose of reducing pressure etc may be assumed to increase the survival (except for reduction of symptoms) in patients with incurable disease. Information is wanted to find out how often this
sekopn	No	
sekopy1	YES	

Date		is the case.
sekopd1	date	When the purpose no longer is to cure the patient, but o ease the symptoms, the modes of operation are unending and impossible to structure, the mode depends on the individual's disease. Therefore mode of operation is not sought, only date. We drew the limit at 2 times, further times are not noted.
sekopy2	same as above, for 2nd and 3th	
sekopd2		
sekopy3		
sekopd3		

Version 1
Rewritten by: Rino Bellocco
Date: Nov 14, 2006

File 6: properties	For all tumour characteristics, information as regards the first occasional surgery.	The category tumour characteristics here includes localisation, spreading, tumour type, malignancy, and if possible DNA-typing. This is background information in order to discern differences in disease status which thereafter will be compared with previous hormone therapy (before diagnosis, information will be collected from previously filled out questionnaires), treatment given, and survival in the study population.
person		
lopnr		
	Location of tumour	
na0701	not stated	Tumour localisation, and its size, according to free text in medical records and/or PAD, The doctor's description of the disease found in the individual woman at diagnosis by surgery. For non-surgery size is stated at time of diagnosis. Gives a picture of how the disease has appeared for the individuals. A solid tumour is often surrounded by a watery cyst, but the differentiation of cyst/tumour may be difficult. Also the size of the cyst is of crucial importance for diagnosis, and for the study we have chosen to state the size of the largest finding, solid tumour or cyst. This means that for many women we will state largest size of cyst instead of size of the sold tumour. We only use one size, cyst or tumour. Sometimes one ovary is stated as primary local and metastasis in the other. This is called bilateral. ??
siduni	The tumour unilaterally	
sidbi1	The tumour originates blilaterally	
	Peritoneal carcinosis: Growth of cancer found on the walls of the abdominal cavity or on the peritoneum.	
na07015	not stated what?	
sidcar	The report from the procedure or from the histopathological examination specifies the presence of peritoneal carcinosis.	
sidcarno	??	
na0702		
maxdia	The greatest observed size of malignant cyst or solid tumour. If given, state the exact information	
maxtxt	Expressed in another way than in centimetres. Give the exact statement.	
na0703.	**????**	
	Disease stage according to Figo	

	Staging can be given directly in the medical record. If not, interpretation needs to be done from the extent and invasiveness of the tumour.
	I : Tumour growth only in the ovaries.
figoia	Tumour in the one ovary, no tumour visible on the surface, intact walls.
figoib	Tumour in both ovaries. No ascites, no growth on the surface, intact walls.
figoic	As in Ia or Ib plus tumour growth on the ovarian surface and/or ascites
figoix	
	II: Tumour growth in one or both ovaries including extension to the pelvis.
figoiia	Tumour growth/metastasis to the uterus or to the uterine tube.
figoiib	Tumour growth/metastasis to other tissues in the pelvis.
figoiic	Stages IIa or IIb plus tumour on the ovarian surface and/or ascites.
figoiix	
	III:Tumour spread to the abdominal cavity outside of the pelvis and/or retroperitoneal lymph nodes and/or inguinal lymph nodes and/or surface metastatis on the liver. Spread to the small intestine or omentis.
figoiiia	Microskopic carcinomatosis on the peritoneal surfaces.
figoiiib	Carcinomatosis less than 2 cm. Negative lymph nodes.

Figo is the system of disease stage classification which is commonly used in Sweden. The system takes into account localisation and extent of tumours. It gives a good picture of how far the disease has developed, the possibilities for curative treatment, and what therapy should be given.

In the study information is collected in order to if possible get a measure that can be compared on how sick the participants were when diagnosed and started their treatments.

In a majority of records, the Figo-code should be given. When missing, the abstractor may, according to information on tumour extent at surgery which is given in the text, make an interpretation with the help of the schedule over Figo stages which is included in the manual.

If the abstractor is unsure about the interpretation or if the record is unclear: first go by the data given in the text of the record (copy the text or write it down), take it back to the department for assessment by Dr Bo Frankendal (specialist gynecological oncology). Secondly, if the abstractor feels that the necessary information for assessment of Figo is not available, this is stated that Figo is unavailable for interpretation in the abstraction sheet.

If there is a change in stage at abstraction this is stated as stage being your own interpretation, as well as a comment that stage is given according to journal and the reason for the change.

figoiiic	Abdominal cavity metastasis more than 2 cm and/or positive retroperitoneal or inguinala lymph nodes.	
figoiiix		
figoivx	IV: Distant metastasis and /or pleural effusion with malignant cells. Liver metastasis.	
		State in the comment what the interpretation is based on.
figofr	Information on Figo stage directly given in medical record	
	Information on Figo stage is based on:	
figofo	Interpretation: Figo stage not given, but can be inferred from information in the medical record, by interpretation of the abstractor	
figoni	Not interpretable: Information on Figo stage not given and not possible to interpret.	
	Malignancy	Classification on tumour tissue, pathology and cytology. Gives a picture of how aggressive the disease may be and is therefore one parameter to be used when prognosis of participants with different disease type are compared in the analaysis.
na0704	Information on the invasiveness of the tumour is missing.	Borderline tumour or invasive tumour give a measure of the malignancy of the tumour and is one of the variables that can explain differences in survival.
malbor	Specified as borderline in the medical record.	
malmal	Specified in medical records as malignant or invasive tumour.	
	Tissue type	Ovarian tumours may originate from a number of tissue types all originating from the ovaries. The most common type (80 % of all ovarian tumours) is that the tumour originates from the epithelial surrounding the ovaries.
tisepi	In the medical record it's specified that the tumour is epithelial or belongs to any of the subgroups into which epithelial tumours are classified	

tisnepi	In the medical record is stated that the tumour is no-epithelial, or belongs to any of the subgroups specifying non-epithelial tumours.	For the study we have chosen to gather material only from epithelial tumours. Disease development and prognosis differ too much between epithelial and non-epithelial (better prognosis for non-epithelial) so we can't make meaningful comparisons between the groups. The material of non-epithelial tumours among the cases is too small to be analysed in itself. Examples of epithelial tumours originating from the ovaries are: serous, mucinous, endometroid, clear cell (??), Brenner, non-classifiable tumours and non-differentiated carcinoma. Examples of non-epithelial cancers of the ovaries are ?????, and steroid tumours. For a complete classification, see the list included in the manual.
	Grade of differentiation, according to WHO	
	The information is often available in the histopathological report. If several degrees of differentiation have been given, note the least differentiated level.	Grade of differentiation tells us how developed and how similar to the original tissue the tumour tissue is. A higher differentiation often gives a less aggressive tumour which is more likely to respect tissue limits. A low-differentiated tumour cell may be so unlike normal cells that it is difficult to distinguish the original tissue.
na0706	not given	
whohi	Highly differentiated, According to histopathological report.	
whome	Moderate	
wholo	undifferentiated	
	P^{53}, mutation	
	Information is often given in the histopathological report PAD-svar, somtimes as specific information for genetic analysis, DNA.analysis. May be performed at other laboratory.	P^{53} is a gene believed to be needed for reparation of cells under division which might hinder a tumour transformation. A mutated, injured gene looses this protective function.
na0707		

p53y	Mutation of P^{53} is present.	
p53n	not present	
na0708	not given	
	Ploidi	
	Ploidi, if assessed, usually to be found in a histopathological report.	A measure of the cell's ability to divide. A normal cell is diploid, it contains one chromosome pair, that is, two identical DNA-strings. A cell that divides copies the DNA-strings and until the division itself, the cell contains four DNA-strings, the cell is tetraploid. In the tumour development, the cell's division process may be interrupted and the DNA-strings may divide without control, which leads to tumour cells containing different amounts of DNA, different numbers of DNA-strings. So ploidi gives a measure of how disturbed the cell's normal division ability is. A aneuploid cell population is related to a worse prognosis for the patient. We look for information in order to connect ploidi to prognosis, but also development of diploid and aneuploid tumour, respectively, depending on previous HRT (information on previous HRT is collected from the main study, Cahres I, II and III).
plodi	Cell nucleus in tumour tissue contains single (diploid) or double (tetraploid) set of chromosomes.	
ploan	Cell nucleus in tumour tissue contains other set of chromosomes.	
na0709	**not given**	
	Proliferation : Information is mostly from a specialized laboratory (DNA-analysis)	A measure of the tumour cells' and thereby the tumour's growth speed (is that what proliferation means?!)
		The proliferation is given as the fraction of DNA-synthesised cells in %. The interpretation of the result is also influenced by the ploidi of the tumour cells. A diploid cell population is considered highly proliferative at a slightly lower fraction than a aneuploid population. The measurement is done by flödescytometry??? of frozen tissue material. Sometimes it is stated in the answer e.g. somewhat elevated, or increased. This is classified as intermediate. According to pathologist ??? KS.
prohi	Often unspecified measures on the fraction of cells in the various categories.	
proim		
prolo		
spha	S-phase (%)Given if specified in medical records.	
whola	Place and laboratory for analysis.	

	Oestrogen receptors (ER): Results of SA often found in histopathological reports, sometimes in response from DNA-analysis.	Analysis of the concentration of oestrogen and progesterone-receptors in the tumour gives an indication of how sensitive it is for hormonal influence. Such analyses are used in breast oncology as a basis for systematic treatment with anti-oestrogens. From breast oncology we know that a high ER/PR concentration is related to a favourable prognosis. Within gyn-oncology these analyses have not been used to the same extent. We are looking for the information in order to relate tumour characteristics to prognosis and earlier HRT-use. The method of analysis is immuno-histochemistry (??) carried out on freshly frozen tissue. In the last years methods of analysis for tissue in paraffin have been used, but it was probably not carried out during the diagnosis years of the study population. It is uncertain to which extent we will find answers as hormonal analysis during the diagnosis period was not generally used. Is noted only if analyses were done for primary tumour.
na07010	not given	
erdna	fmol ER / µg DNA	
erpro	fmol ER / mg protein	
erhipos	Instead of direct measures of concentration, sometimes specification by the pathologist into one of these categories	
erpos		
erlopos		
erneg		
	Progesterone receptors (PgR) As above for ER.	
na07011		
pgrdna		
pgrpro		
pgrhipos		
pgrpos		
pgrlopos		
pgrneg		
reclab		

File 8: Chemotherapy	Information on chemotherapy can be found in running text of the medical record, or on a special card for this therapy, next to the medical record.
person	
lopnr	
na08011	nformation is missing
chemoy1	Chemotherapy is specified in the medical record.
chemon1	No chemotherapy has been given.
	I.
	Type of chemotherapy
typpla1	Platinum compounds;
typcis1	Product names: Cisplatin® and Platinol®
typcar1	Product name: Paraplatin®
typtax1	Product names: Taxol® and Taxotere®
typot1	Specify name.
admiv1	IV administration
adpo1	OS
admia1	intraabdominal
admcnt1	continued treatment
cycles1	cyclical tr, number of cycles Give the number of treatment cycles given in the specified treatment session.
startd1	Specify the date when the first treatment round was given.
Last d1	Specify the date when the last treatment was given.

Curative treatment for ovarian cancer consists of surgery. Almost without exception chemotherapy is also given as ?? treatment to prevent recurrence. It is also common that the tumour is difficult to remove completely and chemotherapy is given in order to decrease tumour volume. In that case, the women undergoes second surgery after a number of treatments when the tumour has shrunk.

In this study we are looking at what chemotherapy the participants have received. What kinds of chemotherapy, how many treatments they have received and when in relation to diagnosis and surgery. A full treatment cycle consists of a planned number of treatments of a specific type. The number of treatments can change during the whole course depending on tumour response. The terms “first”, “second”, or “third line” treatment as less important than dates and time between treatments and type of chemotherapy are noted correctly. We are looking for information about chemotherapy to relate treatment to prognosis.

The primary type of chemotherapy for curative purposes is Cisplatinum, but you can also find Carboplatin, sometimes combined with Taxol, or Taxol only. Other types that have been used is most of all Adriamycin.

In cases of expected response, cure, did not appear in a first treatment cycle, a second cycle of other chemotherapy may be considered. In rare cases perhaps a third or more treatment may have been given.

Second line treatment	A second round of treatment is specified. Recorded according to principals above.
Third line treatment	Information on a third round of treatment, as above.

Version 1
Rewritten by: Rino Bellocco
Date: Nov 14, 2006

File 9: Radiation	Information about radiation can be found in the running text of the medical record, or in an annex radiation record
person	
lopnr	
na0901	
	Occasion 1
rady	The participant has received radiation therapy, as curative or symptom releaving, or palliative treatment.
radn	
abdtot	Field of radiation includes the entire abdominal cavity.
abdlow	Area of radiation covering the lower part of the abdomin.
pelvis	As specified
brach	Local radiation by inserted device in the vagina or the uterus.
areaot	Other extent
areana	Extent not given
	Total dose of radiation
extgy	External treatment, in Gy :Given dosage of radiation, in the measure of Grey.
brachgy	Brachyterapy in Gy :Given dose of radiation through inserted device
startd	Treatment started, date
Occasion 2	See above

Radiation is unusual in curative beginning. During the inclusion period there may be patients who were treated with radiation and as we look for information about treatment as completely as possible, we look for this information too in this low number of patients.
As for the above treatments, the goal is to link treatment to prognosis and survival. We look for information on all treatments given.

It is probably that radiation treatment given curatively towards a defined and specified part of the abdomin was given (for the few patients who had radiation) for one treatment cycle only.

It is harder to predict what other, palliative??, treatments have occurred. The sheet is therefore arranged so that only the first time of radiation has a number of choices on what types of treatment was given. For later times the abstractor has to state what areas of radiation was directed at. Also the abstractor has to state radiation field when other area than stated in the preprinted choices already at radiation treatment number 1.

Occasion 3	See above

Version 1
Rewritten by: Rino Bellocco
Date: Nov 14, 2006

file 10: hormons	Endocrine therapy
person	
lopnr	
na1001	not stated
enn	Endocrine anti-tumour treatment NOT given
eny	Endocrine anti-tumour treatment NOT given
	Product I
ensstd	Starting date
enprep	product name
enendd	Termination, date
	Product II
ensstd2	
enprep2	
enendd2	
	Prodcut III
ensstd3	
enprep3	
enendd3	
ennow	Endocrine treatment therapy still ongoing five years after diagnosis

Endocrine therapy hardly was used during the inclusion period of this study 1993-1995. However, we estimate that a number of patients have been given such treatment in order to prolong their lives. For the same reason, to be able to measure the effect of treatment given on survival, we need to abstract this information.

Two types of endocrine therapy were given most: Gestagen (Megace®, Provera®, Farlutal®) or anti-oestrogenes?? (Nolvadex®, Tamoxifen® and Ledertam®).

Changes of name of drug occur. If you're unsure, write down the name of the drug to check later or talk with the study coordinator.

As the final date of treatment is not clear from the records, we use endocrine therapy ongoing. For deceased patients I marked treatment ongoing.

File 10. hormons	HORMONE replacement **after diagnosis**: Hormone replacement therapy in the form of tablets or patches, local vagina treatment not to be noted.
na1002	not given
hrtn	
hrty	In medical record is specified that HRT has been given after diagnosis.
hrtstd	Started, date
hrtnow	HRT ongoing
hrtendd	HRT terminated, date

Women who have not reached menopause at diagnosis of ovarian cancer are to be given hormone replacement therapy after initial treatment according to most care programs in Sweden. The ovaries have been removed in surgery and the woman's own oestrogen production is not functioning. Participants after menopause may have asked for, and been given, HRT for other reasons.

We are interested in all participants, pre-menopausal or post-menopausal, and if they have been given general ?? HRT after diagnosis. Local vagina treatment is not interesting for the study, as we do not believe that such treatment can cause systemic effects that would influence the prognosis of the ovarian tumour.

Information on menopausal status will be collected from the questionnaires filled out at diagnosis. HRT after diagnosis will be related to prognosis in the analysis.

File 11: Progress	Progression, recurrence, distant metastasis
person	
lopnr	
	Locoregional recurrence
prfn	no
prfy	Patient has had a diagnosis of progression or recurrence within the five year period.
prfdat	Date of the relevant event subsequent to the date of diagnosis, i.e., regarding progression or recurrence
	Site or symptom
prfabd	Abdominal :Tumour or carcinosis in the abdominal cavity, and all other cases for which it is difficult to determine whether progress or recurrence is to be located to pelvis or abdominal cavity.
prfpel	Pelvis :Tumour recurrence in pelvis, see above.
prfasc	Ascites :Recurrence of ascites, containing malignant cells
prfca125	Ca-125 > 36:Blood sample showing this level of tumour marker.
	Verification
na1101	**not given**
lvercyt	Cytology /histopathological report Recurrence verified through tissue sample or cytology from ascites, showing malignant cells

The border between progress in an initial disease and recurrence after a period of no tumours in ovarian cancer may be hard to distinguish. For this study we have chosen to treat progress and recurrence in one paragraph without making any difference between them as variables. Progress/recurrence are counted only as lokoregional ??? tumours. We look for date of whatever conditions that occurs first. Tumour growth that has occurred *between* diagnosis and initial chemotherapy or radiation therapy does not count as progress. Tumour growth after initial treatment is classified as ??? disease.

Distant metastasis which are less common, are treated separately. We look for date of first found distant metastasis and location for it.

To be able to settle the reliability and the interpretation possibilities of information on new tumours afterwards, at analysis, we look for method of diagnosis.

It could happen that recurrence is diagnosed based only on high Ca-125 value. This method of diagnosis is impossible to define systematically, since patients may go through long periods with a high value (proven by test) and show no other symptoms of disease. In this study we therefore use only doctor's subjective assessment of Ca-125. I.e. a Ca-125 above 36 which is described by the doctor in the record as a recurrence is noted as such in the form. A test with the same or higher lever which has not been noted by the doctor as recurrence should not be noted.

Information on progress and recurrence, including distant

lverrtg	Tumour recurrence demonstrated on X-ray or ultrasound image	metastasis, is wanted from time of diagnosis until recurrence is one of the study's endpoints, a main aim of the study is to investigate prognosis as time until recurrence.
lverpalp	palpitation	
	Distant metastasis	
metn	NO	As lokalregionalt?? recurrence we include all organs, in abdomin and pelvis, e.g., spleen, pancreas, kidneys, vagina, urinary bladder, lymp nodes in the groin. Note! Livermetastasis are distant metastasis within leverparenkymet??? ???
mety	YES	
metdat	Date of diagnosis of the first detected distant metastasis	
metliv		
metpulm		
metpleu		
metbra		
metsucl	Supraclavicular lymph nodes	
metrepe	Retroperitonal lymph nodes	
metot	Other	
	Verification	
na1102	not given	
mvercyt	PAD	
mverrtg	Xray	
verpalp	Palpation	

Version 1
Rewritten by: Rino Bellocco
Date: Nov 14, 2006

File 12: New Tumor	New primary gynecological cancer	A new gynaecological tumour is dependent on how early the participants initially had surgery, in most cases after removal of genitals. In the cases where this has not occurred, the possibility of a new tumour arises, which is of interest.
person		
lopnr		
npcy	new gyn tumpor	
npcn	no new gyn tumor	
npcd	date	
npgova	ovarian	
enpgend	Endometrial cancer:New endometrial cancer within five years after diagnosis	
enpgcrx	Cervical cancer New cervical cancer within five years after diagnosis	

File 13. Deceased		The information about deceased persons is sought as one endpoint that the study wants to investigate, as part of the prognosis of the participants. Date of death and cause will also be found through the Cause of Death Register. It is plausible that at least cause of death is stated more accurately in the medical records than in the register, and therefore it is included.	person lopnr
person			
lopnr			
decn	The patient has not died within five years of diagnosis		
decy	The patient has died within five years of diagnosis		
decdat	Date of death		
causeca	: Ovarian cancer or cause related to ovarian cancer Cause of death for the patient is specified to be ovarian cancer or disease condition directly related, or triggered by the ovarian cancer.		

causeot	othe reasons
other reasons	text