

The Clinical database of DBCG

(Danish Breast Cancer Cooperative Group)

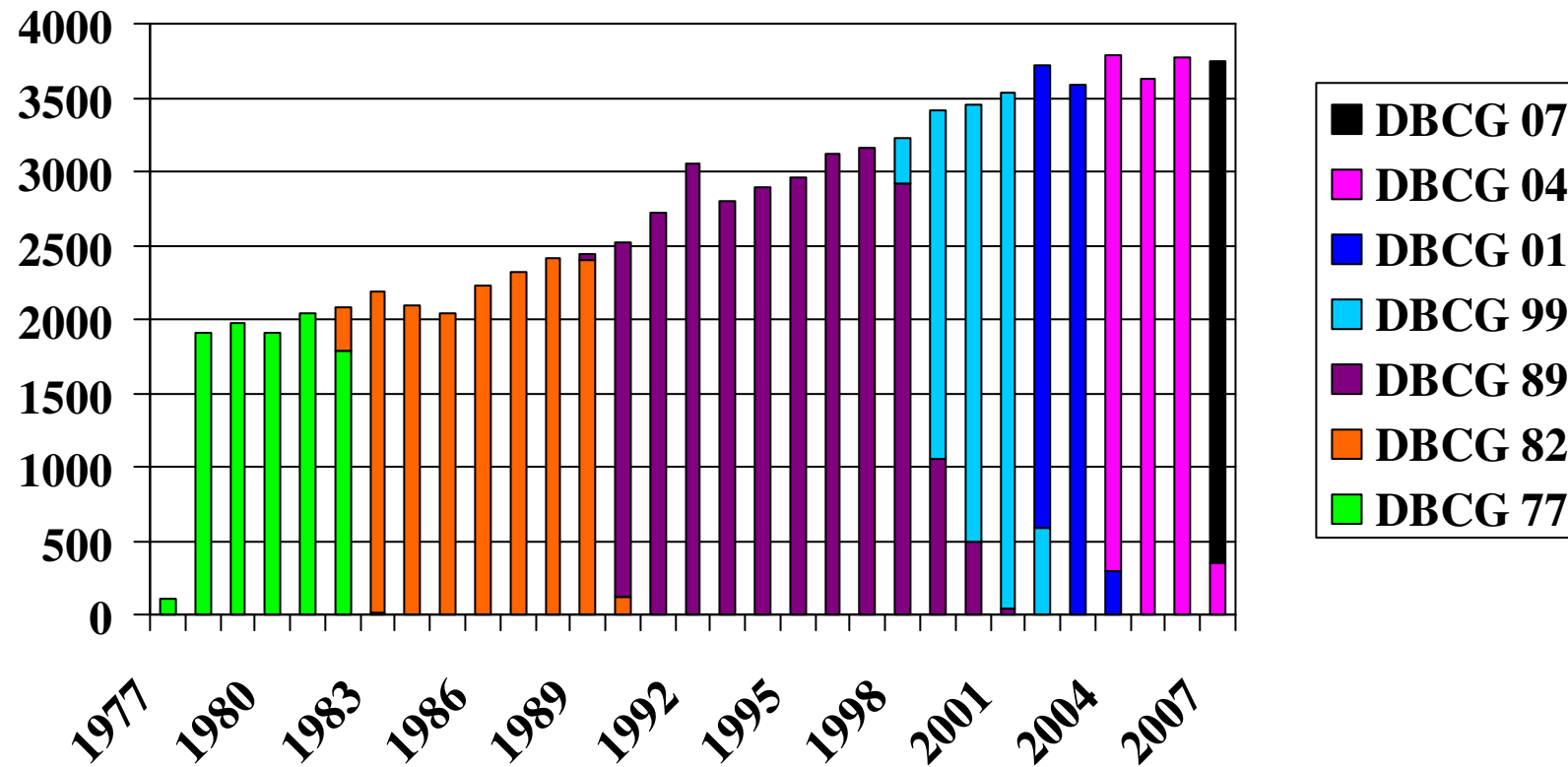
1977-2008

Susanne Møller

DBCG secretariate

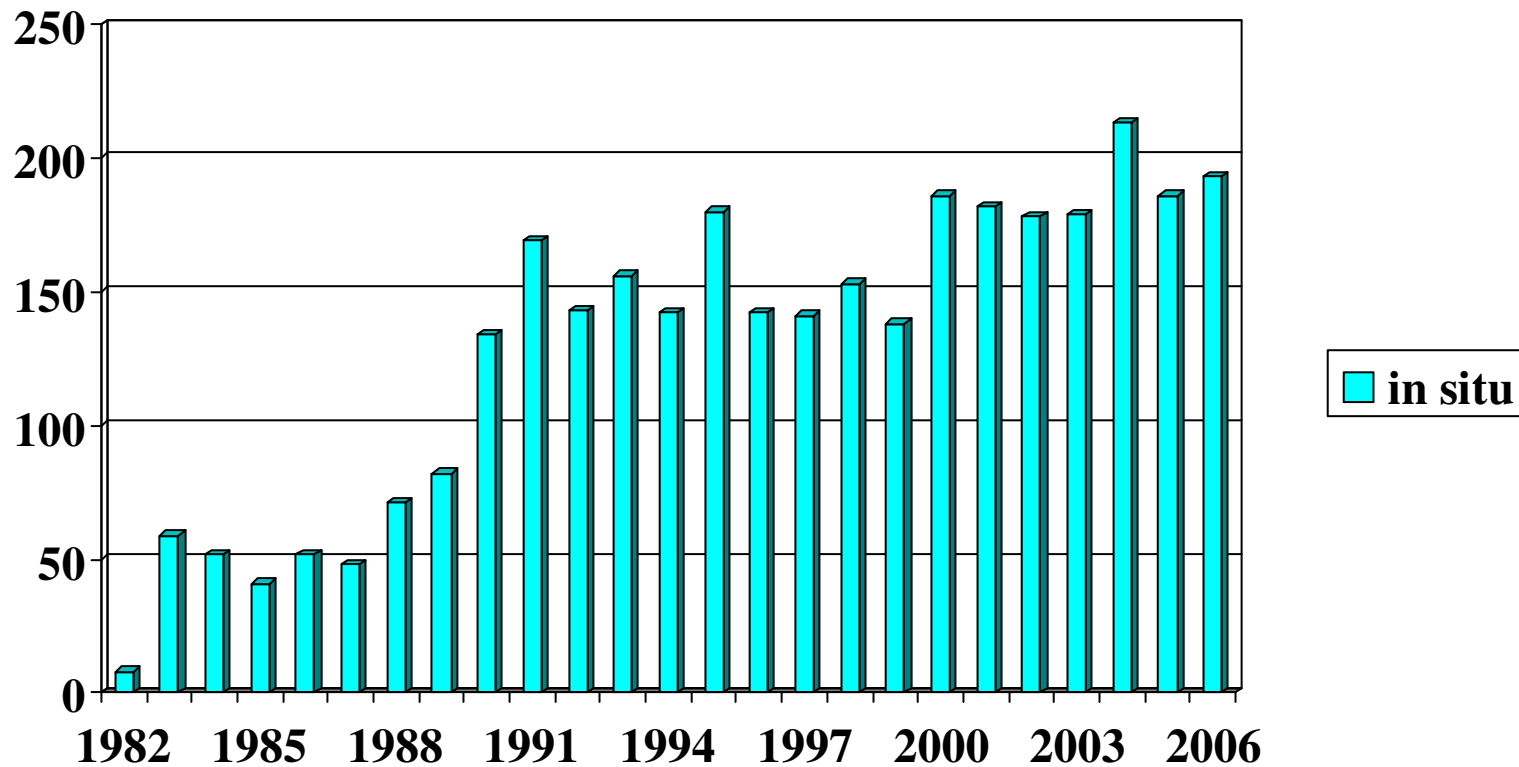
Copenhagen University Hospital

Number of patients with invasive breast cancer 1977-2007 (n=84833)



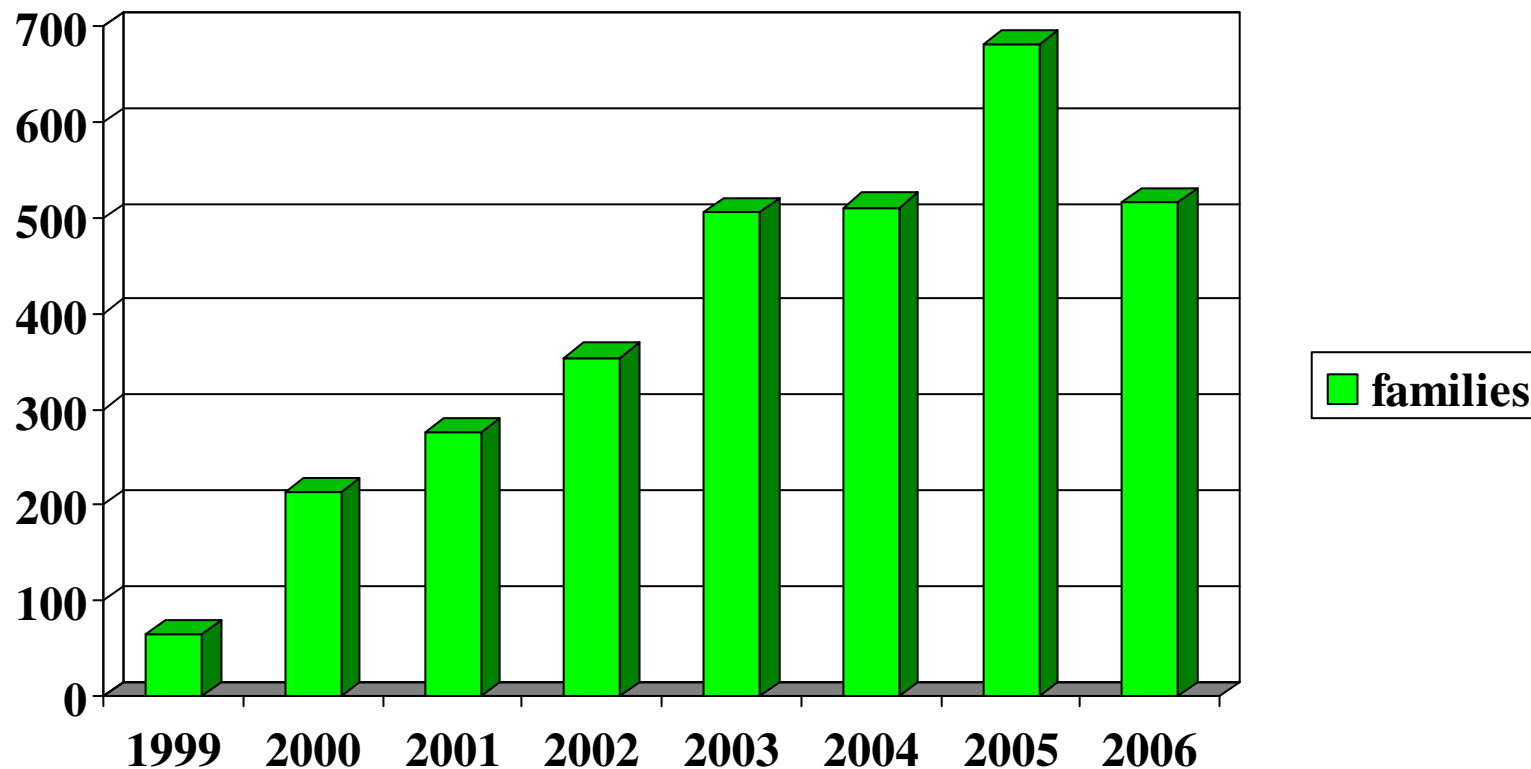
In situ carcinoma, DCIS LCIS

1982-2006, n=3228



Hereditary Breast and Ovarian Cancer Registry (HBOC)

1999-2006 , 3121 families

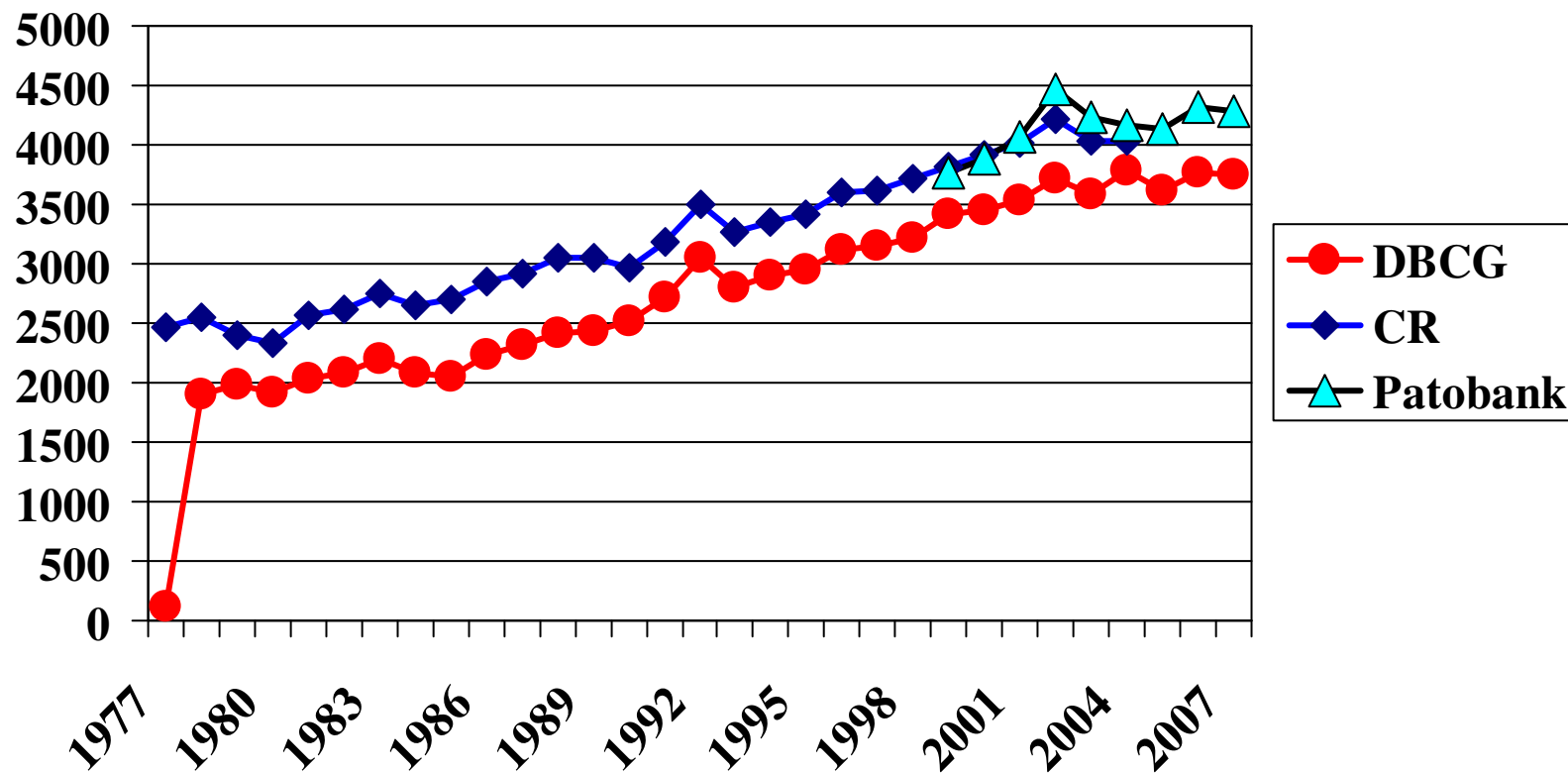


Restrictions of the database

- Only one record of each patient , primary key of the database is the unique civil personal registration number (CPR)
 - If bilaterel breast cancer, only one side
 - If new breast cancer during follow-up or after 10 years, only the first event can be recorded
- Data reported just from clinical centers in charge of breast cancer patients.
 - If no surgery, greater risk of no registration

Completeness :

Number of patients with primary invasive breast cancer in DBCG vs CR vs Patobank



Registrations of individual patient data in DBGC

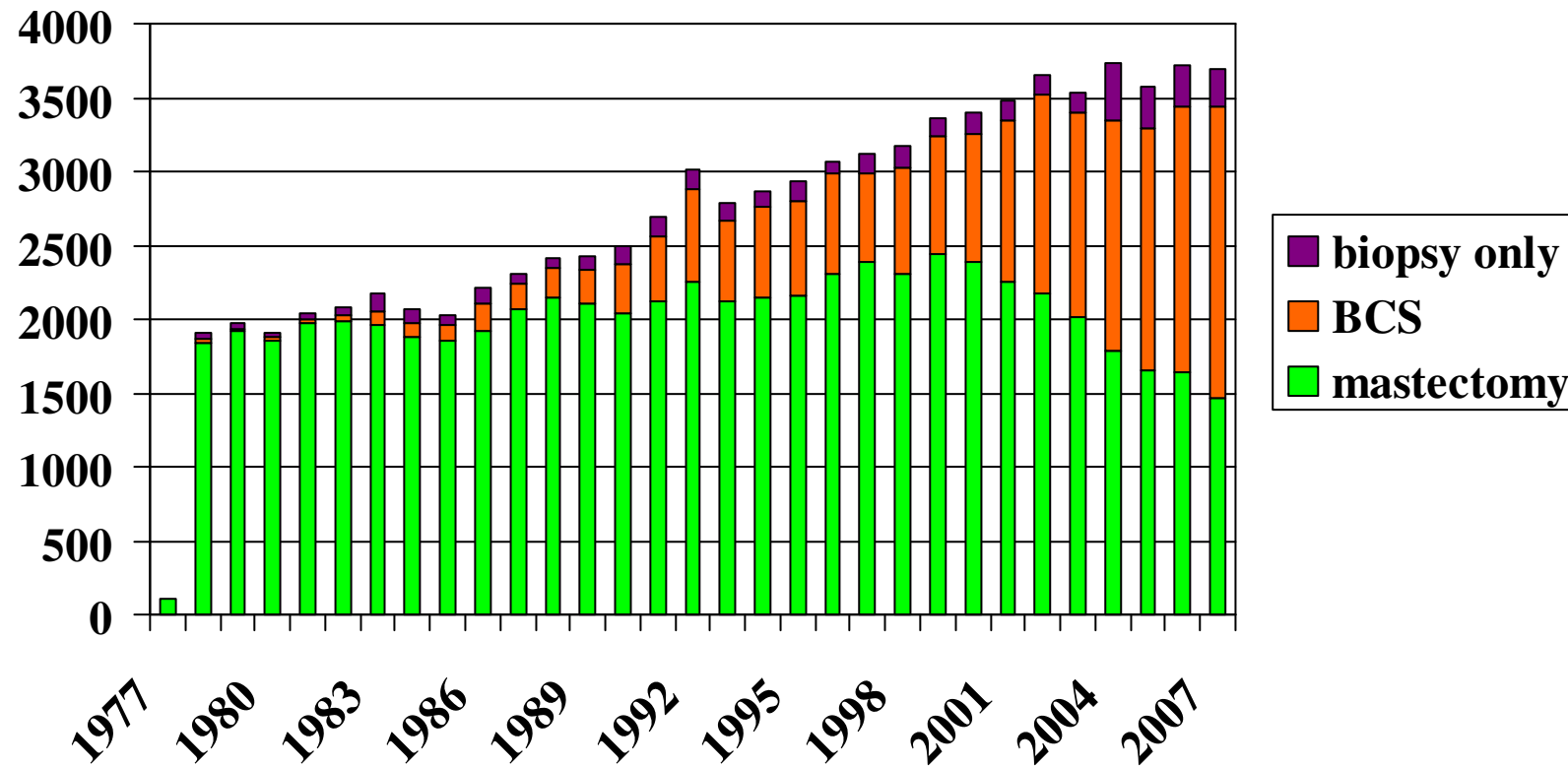
- All units involved in diagnosis and treatment contributes
 - Demographic data
 - Histo-pathological variables
 - Type of surgery
 - Systemic therapy (chemo-, endocrine- and biological-)
 - Radiation therapy
 - Follow-up until 10 years
 - Death

Histo-pathology CRF

A

Biopsidato: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr></table>								Side: <input type="checkbox"/> Højre <input type="checkbox"/> Venstre	Kommunikation mellem aksil- og mammakavitet <input type="checkbox"/> Ja <input type="checkbox"/> Nej
Lumpek- tomidato: <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr></table>								Lokali- sation (evt. flere afkryds- ninger): <input type="checkbox"/> Øvre lateral <input type="checkbox"/> Øvre medial <input type="checkbox"/> Nedre lateral <input type="checkbox"/> Nedre medial <input type="checkbox"/> Central	Suspekte mikroforkalkninger efterladt <input type="checkbox"/> Ja <input type="checkbox"/> Nej
Biopsitype: <input type="checkbox"/> Excision <input type="checkbox"/> Nål-cytologi <input type="checkbox"/> Incision <input type="checkbox"/> Nål-histologi		Papil fjernet <input type="checkbox"/> Ja <input type="checkbox"/> Nej							
		Bundfascie på præparat <input type="checkbox"/> Ja <input type="checkbox"/> Nej							
		Palpabel tumor <input type="checkbox"/> Ja <input type="checkbox"/> Nej							
		Nålemarkeret proces <input type="checkbox"/> Ja <input type="checkbox"/> Nej							
		Klinisk Mb. Paget <input type="checkbox"/> Ja <input type="checkbox"/> Nej							

Type of surgery by year



Mamma –CRF: Definition of risk groups according to demographic and histopathological variables

C: DBCG GRUPPE – UDFYLDES AF KIRURGISK AFDELING.								
Alder	Tumor størrelse	Positive lymfeknuder	Type og malign. grad	Receptor status	HER-2 status	TOP2A status	DBCG gruppe	
> 35 år	< 20 mm	0	Duktal I, ? Lobulær I-II, ? Anden type	Positiv/ Ukendt Medulær(neg)	Negativ/ ukendt	Normal/ukendt	<input type="checkbox"/> I	
						Abnorm	<input type="checkbox"/> II	
						Positiv		<input type="checkbox"/> II
						Negativ		<input type="checkbox"/> II
				Duktal II-III Lobulær III			<input type="checkbox"/> II	
			> 1				<input type="checkbox"/> II	
	> 20 mm						<input type="checkbox"/> II	
< 35 år							<input type="checkbox"/> II	

Mamma –CRF: Protocol allocation

D: POSTOPERATIV BEHANDLING– UDFYLDES AF ONKOLOGISK AFDELING.						
DBCG gruppe	Alder	Receptor status	HER-2 status	Standard behandling *)	Behandlingsprogram **)	Protokol
I				Ingen	<input type="checkbox"/> 2007 – a	
II	< 60 år	Positiv / ?	Positiv	KT, ET, T	<input type="checkbox"/> 2007 – b,t	FACE(postmen.)
			Negativ / ?	KT, ET	<input type="checkbox"/> 2007 – b	FACE(postmen.)
		Negativ	Positiv	KT, T	<input type="checkbox"/> 2007 – d,t	
			Negativ / ?	KT	<input type="checkbox"/> 2007 – d	
	> 60 år	Positiv / ?		ET	<input type="checkbox"/> 2007 – c	FACE
		Negativ	Positiv	KT, T	<input type="checkbox"/> 2007 – d,t	
Negativ / ?	KT		<input type="checkbox"/> 2007 – d			
<p>*) KT (kemoterapi) = EC x 3 ? Doc x 3. ET (endokrin terapi) = for præ (på diagnosetidspunkt): TAM i 5 år for post (på diagnosetidspunkt): TAM i 2½ år ? aromatasehæmmer i 2½ år. T = trastuzumab.</p>						
<p>***) Patienter med et eller flere af følgende kriterier indgår ikke i DBCG's behandlingsprogrammer for inv. c. m. Sæt evt. flere kryds.</p> <p><input type="checkbox"/> Fjernmetastaser <input type="checkbox"/> Sarkom/phyllodes <input type="checkbox"/> DCIS, LCIS, PDN (udfyld In situ skema) <input type="checkbox"/> Andet:</p>				<p>Patienter med en eller flere af følgende kriterier bør følges og indberettes i henhold til DBCG' behandlingsprogrammer. Afvigelser fra standardbehandling angives på Flow Sheet:</p> <p><input type="checkbox"/> Tidl. malign. incl. c. mam. (undt. c. cutis & c. colli ut. in situ) <input type="checkbox"/> Bilateral c. mammae <input type="checkbox"/> Kontraindikation for standard behandling <input type="checkbox"/> Teknisk inoperabel <input type="checkbox"/> Ikke opereret iflg. DBCG's kirurgiske procedure</p>		

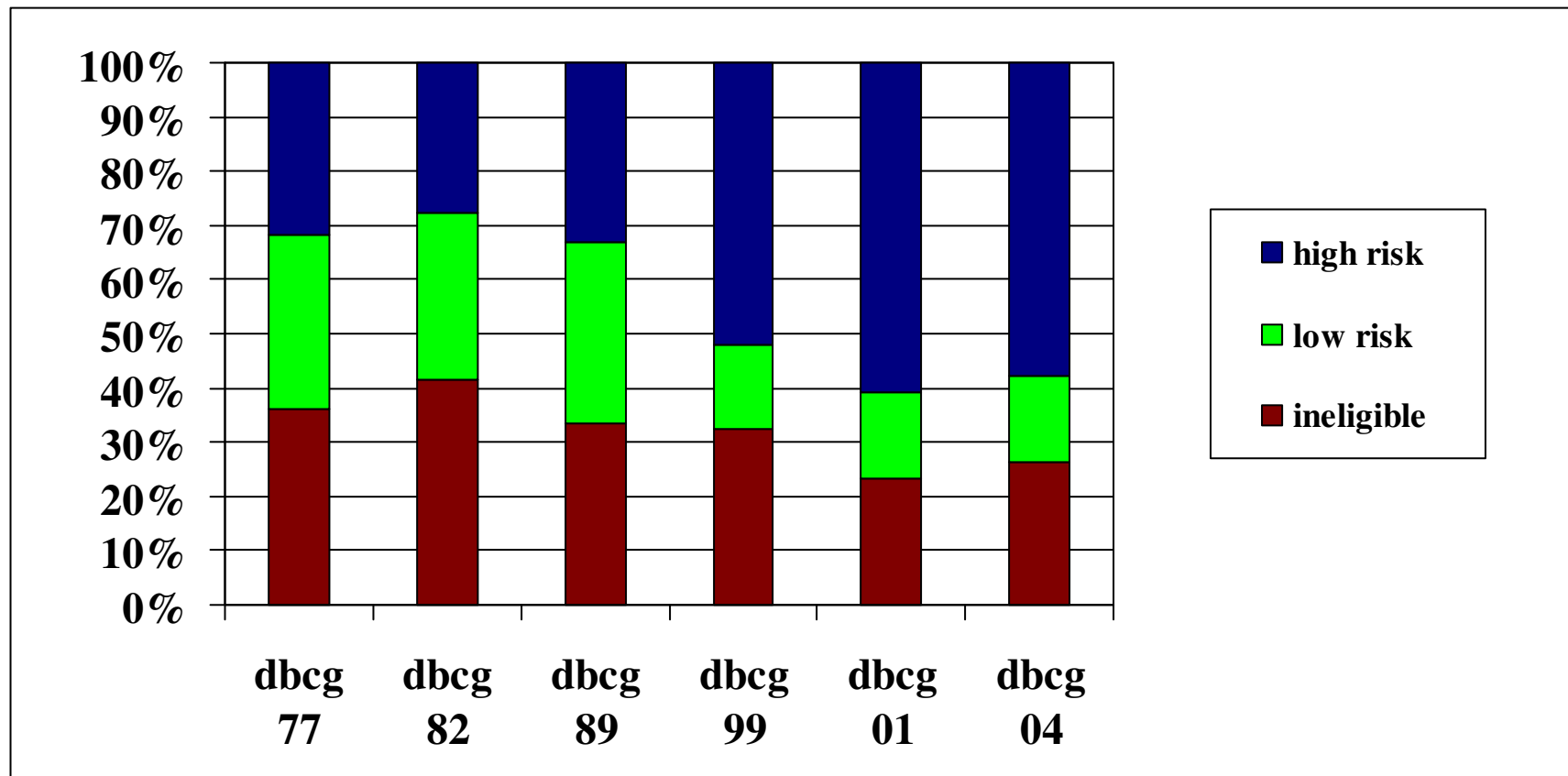
Definition of Patient population

- Patients with invasive breast cancer,
surgery according to DBCG 95.4%
- No surgery (biopsi only) 4.2%
- Other diagnoses 0.4%
 - Sarcoma
 - Padget
 - Fibroadenoma

Patients ineligible to DBCG programmes

- Due to diagnosis 5.9%
 - Distant metastasis 1.5%
 - Previous malignancy 2.1%
 - Bilateral breast cancer 1.7%
 - Other reasons 0.6%
- Due to noneligibility for systemic therapy 24.3%
 - Contra indication due to medical condition incl. age 15.3%
 - Inflammatory breast cancer 0.2%
 - Surgery not according to DBGC guidelines 1.8%
 - Patient do not want to participate 1.1%
 - Protocol violation (misclassified or not treated according DBCG) 2.2%
 - Unknown 3.8%

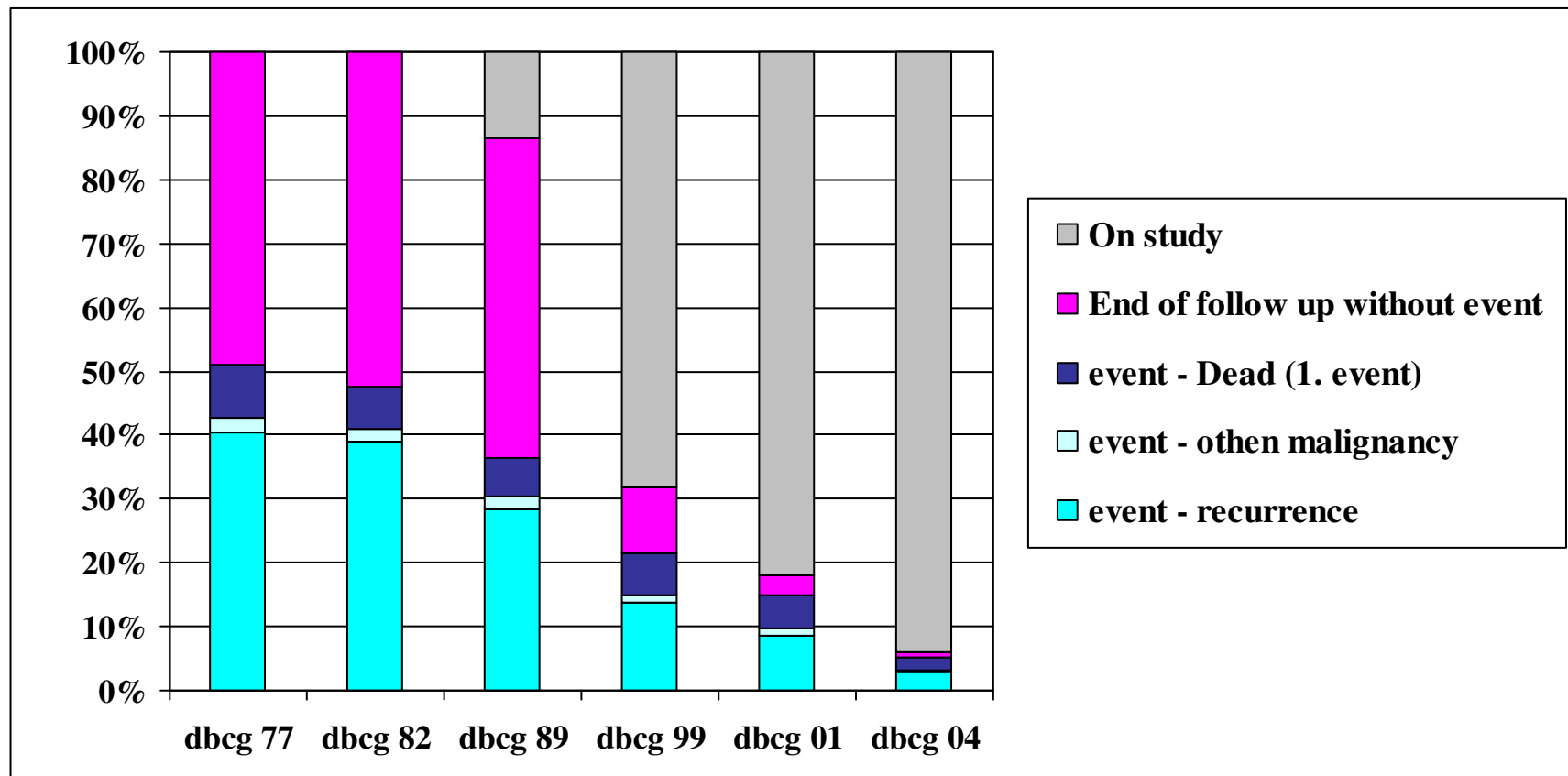
Protocol allocation in DBGC programmes



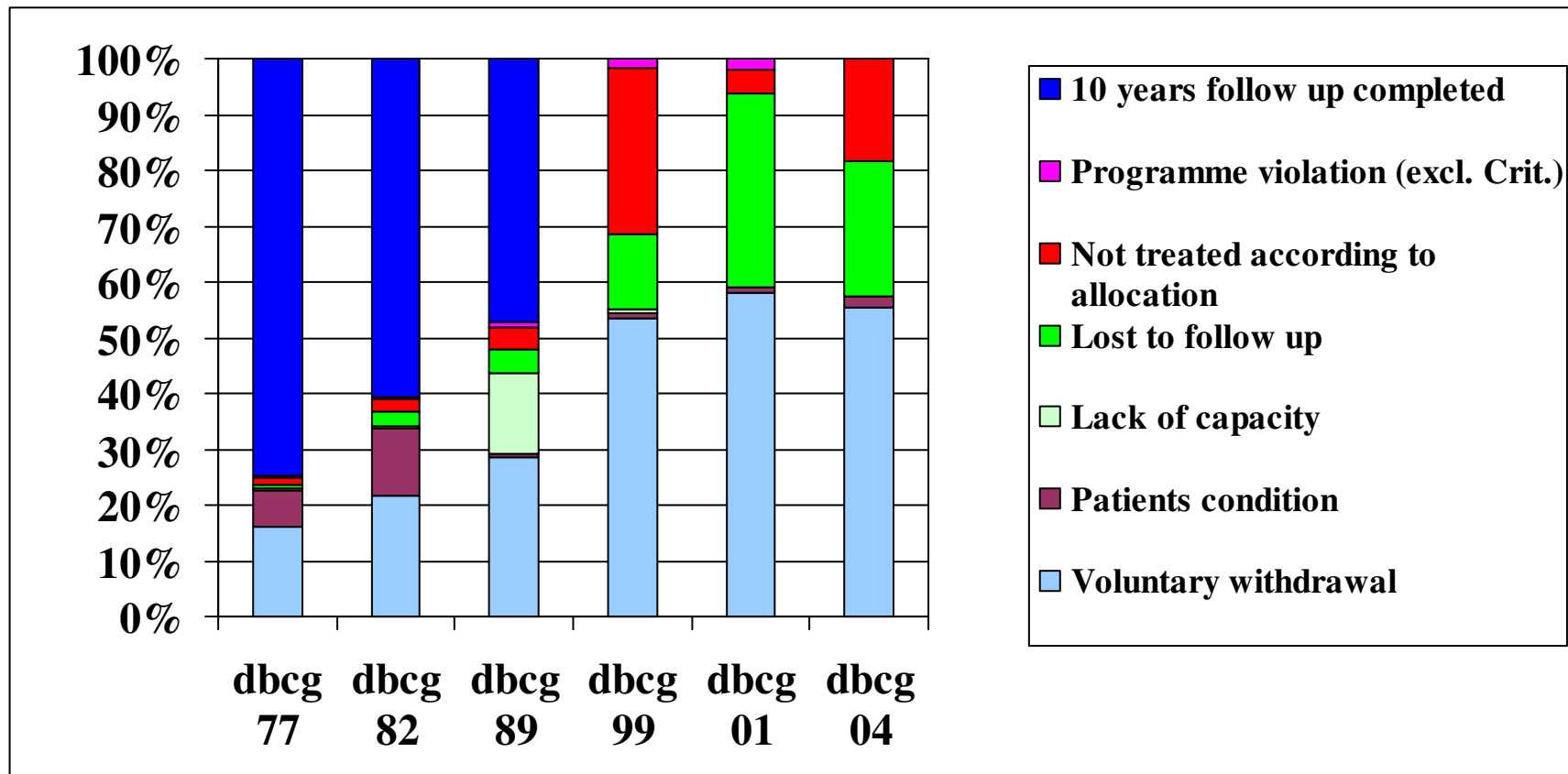
Follow-up of enrolled patients during treatment and after treatment for 10 years (currently 30.000 patients)

- Systemic therapy
 - Chemotherapy (type, dose, number of series, 18-48 weeks)
 - Endocrine therapy (type, dose, 1-5 years, + extended)
 - Trastuzumab (1 year)
- Radiotherapy (target, dose, number of fractions)
- Adverse events, targeted dependent on treatment
- Recurrence
 - loco-regional, distant, contralateral breast, other malignancy
 - death as first event
- Death for all patients (by linkage to CPR)

Events in DBGC programmes



Reasons for withdrawal without event in DBGC programmes



IT systems

- Oracle database , many tables
- Programming language : SQL
- Data entry
 - in the secretariate: Forms6
 - From the clinical units: on-line system
- Statistical analyses language: SAS and R
- Mirror of the database in SAS-files
 - Historic samples

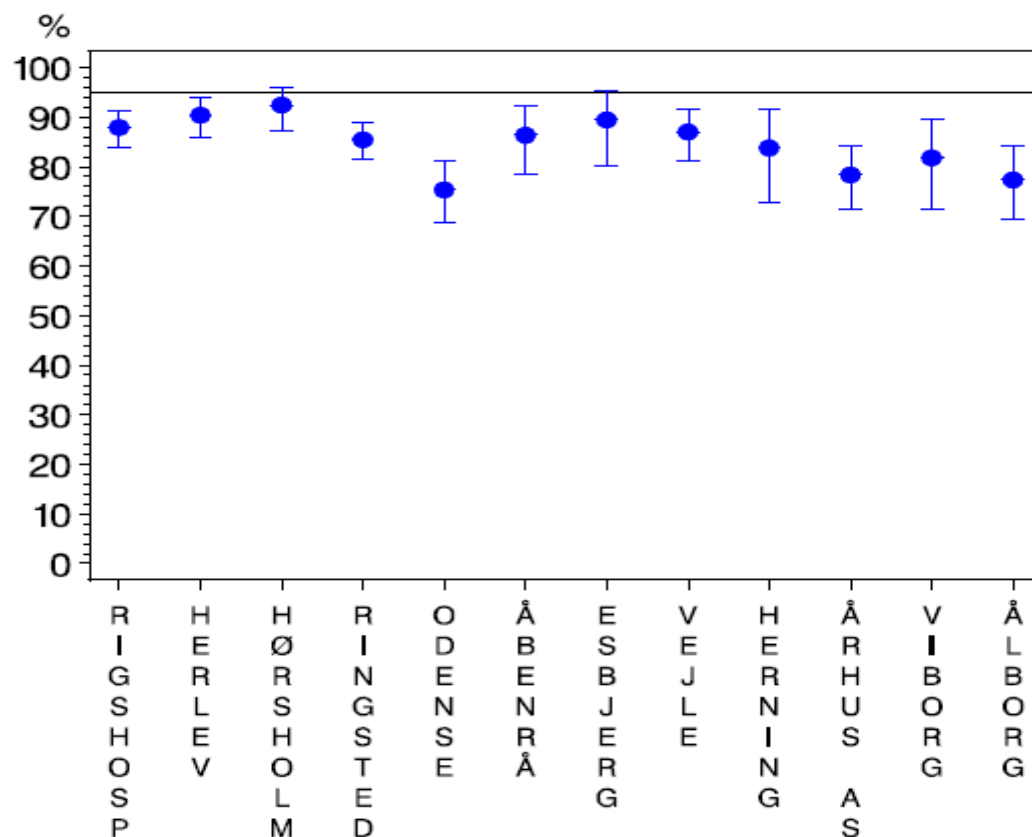
Data validation

- At data entry:
 - validating values of individual variables
 - consistency of data from the same CRF
 - check of protocol allocation
- Daily validation of
 - double entry
 - consistency of data between CRFs
- Regular check for missing CRFs
 - Gap in the flow of CRFs
 - Too long time since last follow-up

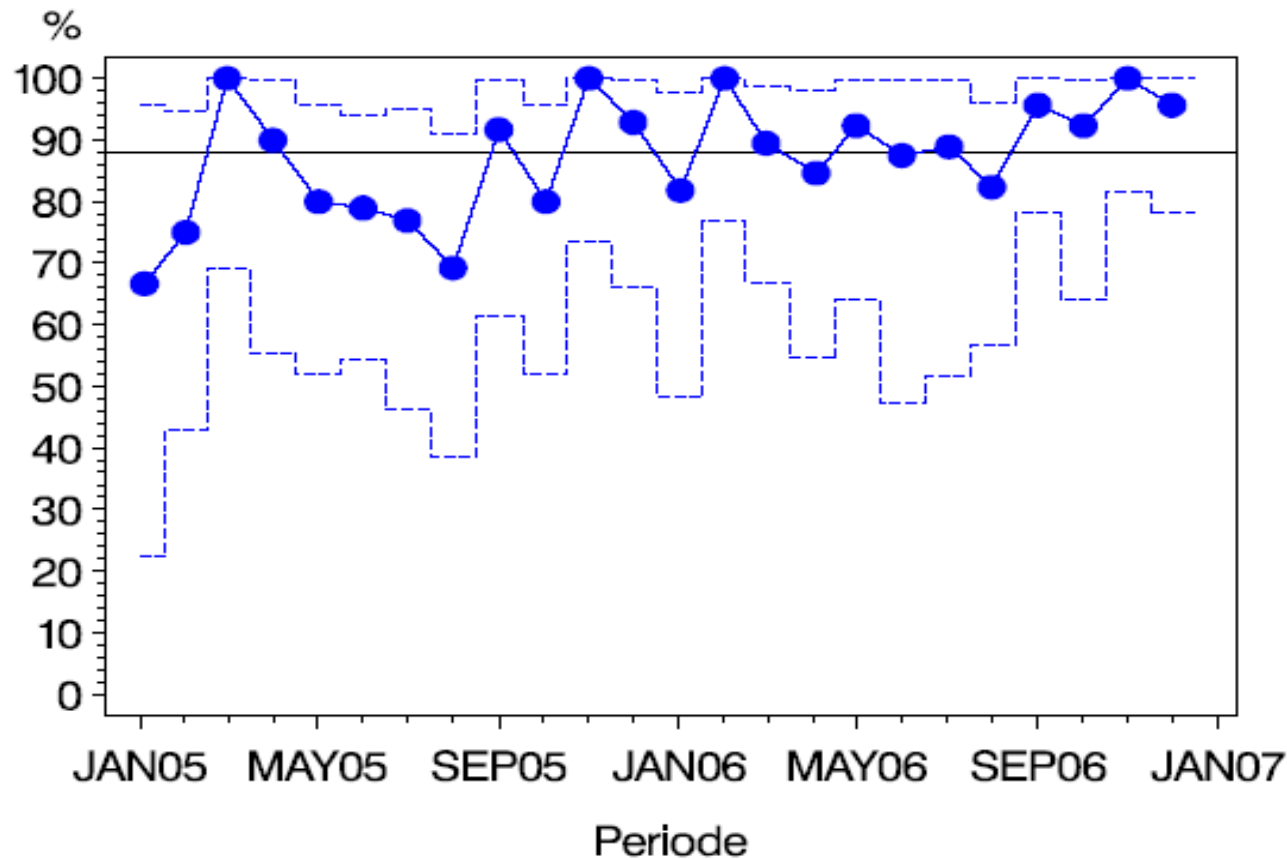
Clinical quality database

- 11 indicators of clinical quality are defined for breast cancer treatment (june 2005).
- Yearly reports : mean values by units and time trend
- Example: Indicator no 4
 - Rate of node negative patients,
 - suitable for SN methods,
 - whose nodal status is determined by SN.
 - Reference value was 95%
 - 2005-6 the numbers were: 1659 / 1975, rate=84 %

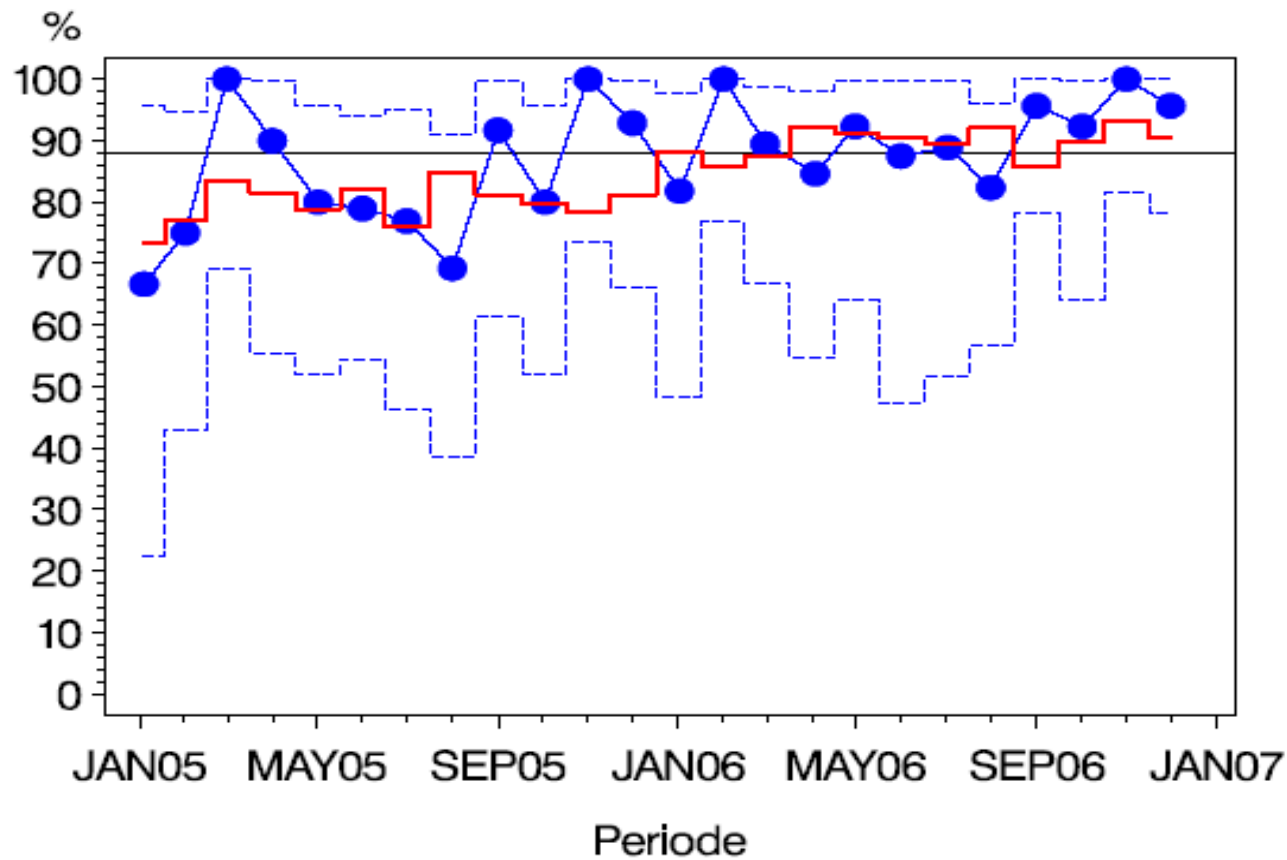
**Rate of node negative patients, suitable for SN methods,
whose nodal status is determined by SN for each unit.**



Rate of node negative patients, suitable for SN methods, whose nodal status is determined by SN for a single unit vs. total mean for the same units according to time.



**Rate of node negative patients, suitable for SN methods,
whose nodal status is determined by SN
for a single unit vs. nationwide means according to time.**



Achievements from the DBCG database

- The establishment of the multidisciplinary breast cancer group with its associated database has provided the opportunity to
- improve the quality of the diagnostic and therapeutic aspects of breast cancer (guidelines)
 - run trials, national or in international collaboration.
 - the clinical data combined with the availability of tumour tissue has provided the ideal conditions for translational research.

Achievements from the DBCG database

- Clinical trials, nationwide, international.
- Translational reseach, connection to tumor tissue.
- Supply data as well as statistical expertise for specific research.
- Epidemiological research.
- Guidelines.
- Quality control, nationwide, international (EBCTCG)
- International collaboration- early warning
- Tools for information and education, professional- and public-

SLUT