Aarhus 10. jan. 2014

Til Kvalitets og efteruddannelsesudvalget i Region Midtjylland

Ansøgning om midler til en spørgeskemaundersøgelse om:

Håndtering af prøvesvar og opfølgning - i screeningsprogrammet for livmoderhalskræft - i almen praksis.

Baggrunden for undersøgelsen er, at sundhedsstyrelsen i 2012 anbefalede, at kvinder skulle have brevsvar med posten direkte fra patologisk afdeling, samt at de praktiserende læger skulle påmindes, hvis kvinden udeblev fra en anbefalet opfølgning. Anbefalingerne kom i kølvandet på opgørelser der viste, at ca. hver femte kvinde i screeningsprogrammet for livmoderhalskræft forsinkedes eller udeblev fra anbefalet opfølgning. Sundhedsstyrelsens to anbefalinger er aktuelt ved at blive undersøgt i en allerede fuldt finansieret ph.d.

Vi finder det naturligt, i forlængelse heraf - at afdække almen praksis holdning til breve og påmindelser. Vi ønsker med spørgeskemaundersøgelsen at afdække, hvordan sundhedsstyrelsens anbefalinger fungerer organisatorisk i almen praksis; hvorvidt almen praksis er tilfreds med ændringerne, hvilken betydning det har for kommunikationen med kvinderne, og hvordan praksis ellers håndtere prøvetagning og svarafgivelse af screeningsprøver. Vi ser undersøgelsen som en vigtig mulighed for, at dokumentere kvalitet i afgivelsen af prøvesvar i almen praksis.

Spørgeskemaet forventes udsendt i foråret 2014. Det forventes at tage ca. 10 min at udfylde skemaet, og derfor ansøges om i alt 53.498 kr. hvoraf 36.036 kr. er honorarer til deltagende læger.

Vi håber meget, at vedlagte ansøgning kan danne baggrund for at Kvalitets og efteruddannelsesudvalget kan finde at prioritere dette initiativ.

På projektgruppens vegne

Bettina Kjær Kristiansen, Sygeplejerske, Cand.Scient.San, Ph.d. stud.
Berit Andersen, Overlæge, Ph.d., Leder af Afdeling for Folkeundersøgelser, Randers Regionshospital.
Peter Vedsted, Professor, Forskningsleder af Cancer i Praksis, Forskningsenheden for Almen Praksis.
Flemming Bro, Prak. læge, MD, Professor, Forskningsleder af Forskningsenheden for Almen Praksis.

Vedlagt:
1) Ansøgningsskema.
2) Budget
3) Protokol
4) CV

FÆLLES ANSØGNINGSSKEMA
TIL KVALITETS- OG UDVIKLINGSMIDLERNE UNDER KEU

REGION:	DATO:	LØBENR.: (udfyldes af regionen)
Midtjylland	06.01.14	

STAMOPLYSNINGER

ANSØGERS NAVN, MAIL,TLF mm.

Bettina Kjær Kristiansen
B.kristiansen@alm.au.dk
Tlf. 61 65 19 32

PROJEKTANSVARLIG:

Bettina Kjær Kristiansen, Sygeplejerske, Cand.Scient.San, Ph.d. studerende

ØVRIGE DELTAGERE (samarbejdspartnere eller tilknytning til forskningsinst. el.lign):

Berit Andersen, Overlæge, Ph.d., Leder af afdelingen for Folkeundersøgelser, Randers regionshospital

Flemming Bro, Prak. læge, MD, Professor, Forskningsleder af Forskningsenheden for Almen Praksis, Aarhus Universitet

Peter Vedsted, Professor, Forskningsleder af Cancer i Praksis, Forskningsenheden for Almen Praksis, Aarhus Universitet

PROJEKTBESKRIVELSE

PROJEKTETS TITEL:

Opfølgning af uegenede og unormale celleprøver i screeningsprogrammet for livmoderhalskræft. Effekter af to interventioner.

PROJEKTETS (ANSØGNINGENS) EMNE:

Livmoderhalskræftscreening, opfølgning, organisation, patientadfærd.

OPDATERING VEDR. TIDLIGERE AFHOLDT PROJEKT (sæt x):

NYOPRETTET PROJEKT (sæt x):

X

FORMÅL:

At afdække hvordan prøvetagning og prøvesvar - i screeningsprogrammet for livmoderhalskræft i almen praksis i Region Midtjylland - organiseres.

PROJEKTBESKRIVELSE (kort resumé) – selve projektbeskrivelsen vedlægges som bilag, der kan linkes til.

Aktuelt forsinkes eller udebliver 20% af kvinder fra en anbefalet opfølgning i screeningsprogrammet for livmoderhalskræft. En sådan manglende rettigdig opfølgning kan hæmme de potentielle gevinster der er ved screening i form af forebyggelse og tidlig diagnostik af kræft.

Den manglende opfølgning kan skyldes både kvinden selv og screeningsprogrammets organisering, hvor formidlingen af svaret kan svigte både i indhold og med forsinkelse.

Sundhedstyrelsen har i 2012 anbefalet, at kvinden skal have brevsvar med posten direkte fra patologisk afdeling, samt at de praktiserende læger skal påmindes, hvis kvinden udebliver fra en anbefalet opfølgning. Disse to initiativer er aktuelt ved at blive undersøgt i en allerede fuldt finansieret ph.d.

Det er dog naturligt - i forlængelse heraf - at undersøge hvilken betydning de to initiativer har for almen praksis, og dennes måde at organisere prøvetagning og svarhåndtering. Derfor planlægges en spørgeskemaundersøgelse til alle lægepraksis i Region Midtjylland.

Næsten 400 kvinder i Danmark får hvert år livmoderhalskræft. Det er flere kvinder, end i de lande vi normalt sammenligner os med, på trods af, at alle kvinder tilbydes regelmæssig screening med et celleskrab hos egen læge. Således foretages der i Danmark ca. 400.000 celleskrab for livmoderhalskræft hvert år. Af disse prøver viser ca. 7% sig at have celleforandringer og 3% vurderes uegnet til diagnostik. Kvinderne tilbydes derfor behandling eller en genundersøgelse relativt hurtigt herefter. Det er i denne gruppe af kvinder at rettigdig opfølgning svigter.

EVALUERING (metode og tidsramme samt plan for implementering og formidling):

Spørgeskemaundersøgelsen udformes som et tværsnitsstudie, og vil bidrage med oplysninger om måden den enkelte praksis har organiseret prøvetagning, svarhåndtering, samt almen praksis tilfredshed med breve og påmindelser.

Spørgeskemaundersøgelsen vil blive en del af ph.d.en som også evaluerer sundhedsstyrelsens to initiativer: Første initiativ - brevsvar til kvinder - evalueres i et cluster randomiseret kontrolleret studiedesign hvor der sendes brevsvar til halvdelen af kvinder i Region Midtjylland, og andet initiativ - påmindelser af den praktiserende læge - evalueres nationalt i et design hvor en periode før, sammenlignes med en periode efter implementeringen af påmindelser.

Det primære udfaldsmål er andelen af kvinder med rettigdig opfølgning.

De primære datakilder er hhv. spørgeskema til praktiserende læger i RM, Danmarks Patologidatabank og Danmarks Statistik. Danmarks patologi databank har oplysninger om dysplasigrader og dato for prøvetagning hos alle kvinder i hele Danmark. Danmarks statistik vil bidrage med socioøkonomiske oplysninger om kvinderne, hvilke også kan have betydning for opfølgning.

Projektet foregår som et ph.d. studium i samarbejde mellem Afdeling for Folkeundersøgelser, Regionshospitalet Randers og Forskningsenheden for Almen Praksis, Aarhus Universitet.

Delelementerne i projektet skrives ind i en afhandling, konkluderes hver for sig og med en samlet konklusion. Derudover planlægges mindst tre artikler publiceret i internationale og peer-reviewed

tidsskrifter:
1) Opfølgning af unormale smearprøver i Almen Praksis - En dansk spørgeskema undersøgelse.
2) Kan opfølgning af unormale smearprøver forbedres ved at sende et svarbrev til kvinder - Et dansk kluster randomiseret studie.
3) Kan opfølgning af unormale smearprøver forbedres ved at påminde alment praktiserende læger - Et dansk longitudinal studie.

START- OG SLUTTIDSPUNKT (evt. forventet):
Aktuelt er der gennem ca. 1 år sendt brevsvar til kvinderne hos halvdelen af Region Midtjyllands praktiserende læger, og næste step er at undersøge, hvordan almen praksis har organiseret prøvetagning og svarhåndtering vha. et spørgeskema.
Spørgeskemaet er aktuelt ved at blive udformet, planlægges pilottestet i februar, og udsendt i marts 2014.
Den samlede Ph.d. forventes færdig i 2016.

BUDGET	
ANSØGT BELØB[1]:	53.498 kr.
BEVILLING (indeværende år og evt. efterfølgende år):	0 kr.
ANSØGT MIDLER SPONSERET FRA ANDRE SIDER:	0 kr.
BUDGET FORDELT PÅ ÅR: 2014	53.498 kr.
TOTALBUDGET: 2014	53.498 kr.

AFSLUTTENDE RAPPORT/ARTIKEL SENDES TIL DET REGIONALE SEKRETARIAT:

SUPPLERENDE OPLYSNINGER:

Ansøgning til Multipraksisudvalget er afsendt den 10. jan. 2014

BILAGSFORTEGNELSE:
1. Udspecificeret budget (s.5)
2. Projektprotokol (s.6)
3. CV Bettina Kjær Kristiansen (s.17)

[1] Et udspecificeret budget vedlægges, hvor det er markeret præcist hvilke midler der ansøges om hos KEU.

Udspecificeret budget **BILAG 1**

Udgifter til spørgeskemaundersøgelse blandt praktiserende læger i Region Midtjylland.

Antagelser bag beregningerne:
Der sendes 1 spørgeskema pr. praksis (ca. 420 stk.), hvor der forventes en svarprocent på 50 %.
Herefter genudsendes spørgeskemaet til de resterende 50 % (210 stk.), hvor yderlig 20 % forventes at svare.
Således forventes at der i alt sendes ca. 630 spørgeskemaer, med en svarprocent på ca. 70 %.

Estimerede omkostninger:

Antal	**Budgetposter**	**Stk. pris**	**I alt**
630	Tryk af spørgeskema	5,4 kr.*	3.402kr.
630	Rudekuverter til udsendelse	1,65 kr.	1.040 kr.
630	Porto til udsendelse	13 kr.**	8.190 kr.
630	Fortrykte svarkuverter	1,6 kr.	1.008 kr.
294	Porto til svarkuverter til de 70 % af praksis, der forventer at deltage.	13 kr.**	3.822 kr.
294	Honorar til de 70 % af praksis, der forventer at deltage.	122,57 kr.***	36.036 kr.
Udgifter totalt			**53.498 kr.**

*8 sider med forside
**B post, breve<100g
***Der udbetales et modul (svarende til 10 minutters arbejde, kr. 122,57) pr. udfyldt spørgeskema.

Follow-up of abnormal and inadeqaute test results in the Danish Cervical Cancer Sreening Program. Effects of two interventions.

1. Background

Problems with follow-up care of abnormal test results in screening may threaten the effectiveness of the Danish Cervical Cancer Screening Program. It has been a surprise that 20% (8 000) of all Danish women each year - in need for a follow-up - do not have the recommended follow-up timely (1). Therefore it is feared that the full benefits of screening, to detect and treat preinvasive disease or downstage invasive disease, will not be realized.

In Denmark approx. 5 000 women are treated for Cervical Intraepithelial Neoplasi (CIN) by cone biopsy and 400 women are diagnosed with cervical cancer each year. This is more than in other Nordic countries. Half of the diagnosed women is under 45 years of age and the relative 5-year survival is 65% (2).

All women in Denmark aged 23–65 years are regularly invited to screening using the Papanicolaou Smear Technique (PAP-smear) to identify possible CIN or asymptomatic cancer (1).

Through written invitation a woman is encouraged to make a GP appointment. A PAP-smear is performed and sent to the pathologist departments for diagnosis and follow-up recommendations. Afterwards the result is sent back to the GP who eventually conveys the results to the woman. Approx. 7% of all test results show CIN and 3% are inadequate (cannot be used for diagnosis), and these women are therefore advised to have a follow-up immediately or after 3, 6 or 12 month, respectively (3).

It is the objective from The National Steering Committee for Quality Assurance in Screening Program that 98% of abnormal or inadequate results are followed up as recommended. This is not achieved in approx. 20% of all cases, and in 5% of the most severe lesions (carcinoma, HSIL, AIS, ASCH and AGC) which need a gynaecological examination within three months (1).

The consequences of delayed follow-up are a potential progression of the CIN into cancer, consequently rendering perhaps more far-reaching treatment strategies necessary. It is not predictable which lesions will progress into an invasive cancer (4), and it is difficult to give exact estimates on how many lesions will become invasive, because many lesions will go on undetected. Yet it has been estimated that 5-12% of moderate and severe lesions will develop into cancer (5). A review of 833 cases of women with cervical cancer in the USA, showed that 13% was not followed up as recommended (6). A comparable Danish study of 286 women showed that 5% had delayed their recommended follow-up (7). Additional to this, it is well known that 10-20% of women after cone biopsy treatment develop new precancerous lesions; 40% within four months and 80% within two years (8). Timely follow-up is therefore essential both before and after treatment.

The reasons for this is multi factorial, but among other reasons it is hypothesised to be due to missing standards on how women are conveyed by their GP about the screening results or if they are reminded if the recommended follow-up is missed (8,9).

Missed follow-up can be related to interactions between the women, the GP and the organization of the screening system (Appendix 1: Conceptual Framework: Model of realized access to follow up care after abnormal screening test): Related to the women misinterpretation of the GPs message, fatalistic anxiety or neglecting the importance of follow-up can be a contributory factor that causes women to make a conscious or unconscious choice about postponing or deselecting follow-up (9-18). The group of women who is delayed are younger, with lower levels of education, many children, low income, single, depression, anxiety, and little knowledge about screening (19,20). All fragile groups that presumably have more difficulties acting in complex communication scenarios. This is underpinned in a telephone survey which

found, that women who did not know the results of the smear or who incorrectly understood their results were significantly less likely to return for colposcopy. The survey, among 270 women with abnormal results requiring colposcopy, concluded that effective communication of results is the single most important factor related to follow up (22). Related to the GP it is noticed that GPs have various ways to convey a PAP-smear result to the women, entailing that the communication can fail either in content or with delay (9,10,19). A study in the county of Aarhus (2006) found that out of 152 general practices, 119 (78%) expressed that the PAP-smear result was delivered when the women initiated contact (9). A recent Danish status showed that by almost all practises 10-30% of the women were delayed (21). This indicates that the problem can be more complex than a few careless GPs and may be linked to the women and resources or administrative difficulties in daily practice. In line with conclusions from Yabroff et al. (review 2003) who from a organizational point of view identified difficulties with manual monitoring of follow up, as well as if the women had long distance to clinics offering colposcopy (22).

Previously there has been focus on increasing timely follow-up by activating the women with conflicting results: A systematic review of ten intervention studies showed that cognitive initiatives which increased the women's knowledge about screening (e.g. education by telephone or leaflets) had the greatest impact, with an increase in follow-up from non-significant to 31.3% (95%CI: 11.7-50.9)(10). The results are supported in a newer systematic review (8). Several studies have also tried to influence the GP to increase timely follow-up: For example a Dutch randomized study showed that reminding the GP could increase the follow-up with 9% compared to GPs that were only reminded in the most severe cases. Without this intervention, 11 persistent abnormalities per 1 000 women with abnormalities would have been missed (23). Similarly in Canada, they increased follow-up with 10% (24) and in USA the median time to biopsy was shortened 14 days (25) when reminding the GP. However, the generalization to the Danish population can be problematic due to various definitions for abnormality, follow-up recommendations and differences between healthcare systems.

Trying to solve this problem The Danish National Board of Health recently recommended that the test result with follow-up recommendations is also send to the women. This should ensure that all women are notified, still with the opportunity to contact or be contacted by the GPs. Furthermore, it is assumed that a significant part of GP contacts regarding delivery of normal test results can be avoided (8, 26). In addition, a system where GPs are reminded if women do not have the recommended follow-up has recently been implemented (8). However, these initiatives are not based on scientific rigorous knowledge and we need knowledge about the effect on follow-up, cancer diagnosis and health care utilisation.

2. Aims and hypothesises

To investigate the effect of alerting women about test results and reminding GPs about non-follow-up testing the hypotheses:

1. A personal letter with the test result to the women will increase the proportion of women with a recommended follow-up and decrease the contacts to general practice.

2. The automatically sent reminders to the GPs about women with no follow-up will increase the number of women with follow-up.

3. Method and material

1st intervention: PAP-smear results sent by letter to women

In a cluster randomised controlled 1:1 study the women receives the PAP-smear result either as usual (from the GP) or by a personalised letter. The unit of randomization is the general practice and all general practices in Central Denmark Region are included. Nearly all (98%) Danes are registered with a specific general practice with whom they must consult for medical advice and for women, the ordinary PAP-smear. The GP is not blinded because it is essential and ethically most correct that the GP can inform the woman that she should expect the test result by letter. The letters will be sent through a period of 14 months. The primary outcome measures will be:

a) Proportion of women with a recommended follow-up according to four predefined clinical relevant timeframes, depending on the recommendation for follow-up. Follow-up is defined as a new PAP-smear test, cone biopsy or hysterectomy.
b) Frequency of GP contacts (consultations/telephone calls /e-mails) regarding conveying the PAP-smear result.

2nd intervention: Automatic reminders of the GP for women with late follow-up

In a nationwide, register-based study the proportion of women with a follow-up is compared before and after the introduction of reminding the GP of the women with no follow-up.
The primary outcome measure will be:
c) Proportion of women with follow-up.

Inclusion:
Re a) Women in the Central Denmark Region with a recommendation for follow-up
Re b) Women in the Central Denmark Region with a PAP-smear.
Re c) Women in Denmark who is recommended further examinations before 1st May 2011, compared to women after 1st February 2012 and 10 months ahead. Divided by a period where the initiative is implemented.

Exclusion:
<23 years, emigration or death in the study period.

Observation period:
Re a and c) Minimum five months after the recommended follow-up
Re b) Three months after the PAP-smear test.

Data:
The national Danish Pathology Databank collects data from all regional pathology departments and private specialists in pathology. The system gives the opportunity to search PAP-smear results and the recommendations for follow-up (SNOMED-codes), including dates for new PAP-smears or dates for a possible hysterectomy or cone biopsy (27). At the research centre we have in-house data from National Health Service Registry, Statistics Denmark, the Central Office of Civil Registration and the Department of Public Health Programmes in the Central Denmark Region. These data are stored in the comprehensive CAPS-database. This gives data on: age, level of education, occupation, address, possible emigration or change of GP, health insurance status, ethnicity, civil status, number of children, pregnancy in the study period, earlier use of health services including breast and cervical cancer screening, pathology department - where the test was performed, active signing-off from the screening program, HPV vaccination, earlier dysplasia and if the test was performed opportunistically, by invitation or because of dysplasia control/monitoring.

Statistical analysis:
Re a) the proportion of women followed up will be calculated as cumulated incidence proportions according to four timeframes (undesirable early, as recommended, late, very late), and be compared by relative risks. The results will be presented in totals and separately depending on the test result (normal/inadequate/CIN stage/HPV). The analysis will be adjusted with a priori chosen confounders (age, calendar time, socio-economic position and geography) in a binomial regression using logarithmic link function to accommodate estimation of relative risks.

Re b) the two randomisation groups will be compared with respect to contacts with GP after the PAP-smear test in two ways. First, applying a negative binomial regression model to the total number of visits within pre-specified timeframes of interest (i.e. the first days, weeks and months after notification of a screening result). Second, considering the time from screening to the first GP contact in a Cox-regression model censuring women at time of first event, end of observation period, emigration or death - whatever comes

first. Separate analysis will be performed for different types of GP contacts (telephone, mail, consultation) and test results (normal/inadequate/CIN stage/HPV). All analysis will be adjusted for age and the woman's frequency of GP contacts the year previous to the screening.

All analyses in relation to a) and b) will be based on intention to treat. To ensure independent observations each woman will only be included in the analysis for the first recommended follow-up.

Re c) This part will be analysed using the methods outline above and in addition the results are estimated per annum to illustrate a possible time trend over the years.

To account for possible homogeneity of women belonging to the same GP practices, cluster robust estimation of standard errors will be performed in all above mentioned analysis.

Power calculation and dimensioning:

Re a) the calculations are based on the most severe lesions since this is the smallest and most relevant subgroup. Around 4.7% (95%CI:3.8-5.8) was not followed up timely in the Central Denmark Region, 2010. Assuming the possibility of reducing the proportion of women delayed to the goal of 2% a total of 769 women in each randomisation group will provide a power of 80% in a simple two-sided test at a 5% significance level. Within the scheduled inclusion period of 14 months a total number of 2 200 of the most severe lesions can be expected in the region (1), thus allowing a good overhead to account for design-effect or possible improvements due to e.g. increased attention.

Re b) in the Central Denmark Region 85,000 PAP-smear tests is performed yearly (1) and 350,000 women (aged 23-65) had 2.9 mill. GP contacts (consultations, emails or telephone) (Statistics Denmark), equalling 8.29 per woman. Of these result 90% were normal and demanded no further follow up. Conservatively, it is assumed that 38 000 women can be included in each randomization group, and assuming a SD of 5.0 (corresponding to a marked over-dispersion from a Poisson distribution) a reduction to 8.18 GP contacts per woman per year is detectable implying a difference of 4 180 GP contacts between the two groups is detectable with a 90% power.

Re c) among women with the most severe lesions 5.4% (95%CI:4.9-5.9) are not followed op timely, and after 15 months 1.6% (95%CI:1.4-1.9) are still not followed up in all of Denmark, 2010. If women are included over a three year period before and a half year after implementation, it is possible to include 24 000 and 4 000 with the most severe lesions, respectively, and thus detect a reduction from 1.6% to 1% with a power of 85%.

Validity:

The strength of this study is the randomized study design which minimizes the possibilities of confounding and other effects being responsible for any observed change. As well as very few criteria for exclusions, meaning that all women in the region are included making this an effectiveness study in relation to daily practice. Self-reported screening attendance is often a source to bias(28), and it is a strength that the present study use variables from very complete registers, making it possible to see if the women have had a follow-up anywhere in Denmark (27). As all PAP-smears are identified in the registers, selection and information bias is at a absolute minimum (29). The SNOMED code for a follow-up recommendation is missing in an around 3% of abnormal results (30). Sensitivity analysis will be performed to see if the missing codes are connected to a special diagnosis. However, they are expected to be unrelated to the women and the GPs organisation of the follow-up. Furthermore, part one use relatively new data from the Danish Pathology Databank and in this period the classifications system for the test results have been the same (Bethesda (31)), minimising potential information bias. The 2nd intervention is compromised by comparing a period before the implementations of automatically reminding the GPs with a period after the implementation. This can generate bias in the form of confounding, because not all relevant variables are available from the registers. These problems will be assessed and discussed.

4. Research Plan, practical feasibility of the project and agreements

The PhD thesis will be conducted in cooperation between The Department of Public Health Programmes at Regional Hospital Randers (Executive Consultant, PhD, Berit Andersen), The Research Unit of General Practice in Aarhus, Aarhus University (Professor, Dr.Med.Sci., Flemming Bro) and Center for Research in Cancer Diagnosis in Primary Care – (CaP), Aarhus University (Professor, PhD, Peter Vedsted). The project supervisors has a thorough insight in the prevention and early diagnosis of cancer, the specific screening conditions in the region, the GPs daily practice, and a close contact with the National Steering Committee for Quality Assurance in Screening Program (members). Statistician Morten Fenger-Grøn, will be closely attached to the project. The Research Unit of General Practice will supply a workplace and CaP ensures statistical supervision, data management and access to registers. At the moment we are negotiating a deal with Logica, Aarhus (the supplier of technology systems to The National Danish Pathology Databank), about the development of a system to continuously handle data from The National Danish Pathology Databank and link these to predefined letter templates and addresses of women. The letter templates (Appendix 2: Letters) are defined from The National Board of Health and The Department of Public Health Programmes will daily facilitate the print and distribution (Appendix 3: PhD Time-schedule).

Ethics and data management:

We have applied the Data Protection Agency for permission to establish a private research registry for CAPS, a comprehensive collection of registry data at The Research Unit for General Practice and Statistics Denmark (j.nr. 2009-41-3471) and to supplement this with data from The National Danish Pathology Databank (j.nr. 2010-41-5646). Regarding the 1st intervention an inquiry has been made to the Regional Research Ethics Committee, which did not require an official application (j.nr. 211/2011). The project will be conducted according to good clinical practice for randomised controlled trials.

Reporting:

At least three articles is planned to be published in international peer-reviewed journals:

1) Can the follow-up of abnormal PAP-smear test results be improved by sending a result letter to women? - A Danish cluster randomized study.

2) Can the follow-up of abnormal PAP-smear test results be improved by reminding the GP? - A Danish longitudinal study.

3) Consumption of services in a free Health Care System after changed organisation of delivery of PAP-smear test results - A Danish cluster randomized study.

5. Perspectives

The results will be of great importance to the future organisation of cervical- and colorectal cancer screening programmes in Denmark. They will also have international interest, as similar problems with follow-up are observed internationally (10,19,23,32-39). Currently there is a unique opportunity to investigate the effects before it becomes daily practise in Denmark.

Each year about 360 000 PAP-smear tests are performed by Danish GPs, of which 90% is normal. Presumed that 80% can be conveyed without GP contact, there will be a potential cost saving estimated to approx. 700 000 Euro per year (8). If the number of women delayed can be reduced by a hypothesised 30%, an additional 2 400 women will each year be treated as recommended. However, the effect is unknown.

The implementation of HPV vaccination in Denmark (2008) will presumably in a decade imply fewer abnormal test results. It is thereby predicted that the basis for screening will change by time, but the next 50 years there will still be birth cohorts in the screening program which have not been offered a HPV vaccination (8,40,41).

Unintended misunderstandings or missed delivery of test results are regretfully a well known problem in health care (42,17). This study explores if there is an effect on letter patient involvement without removing legal responsibility from the doctors, and can be useful in other contexts, where delivery of many test results can be partly standardised. It is imaginable that the study results can be generalized to other ways of delivering the test results, e.g. by the personalized e-box.

Bibliography

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Conceptual framework **Appendix 1**

Yabroff et al. is one of the first to integrate health behaviour models at the provider and patient levels within a framework of realized access to care.

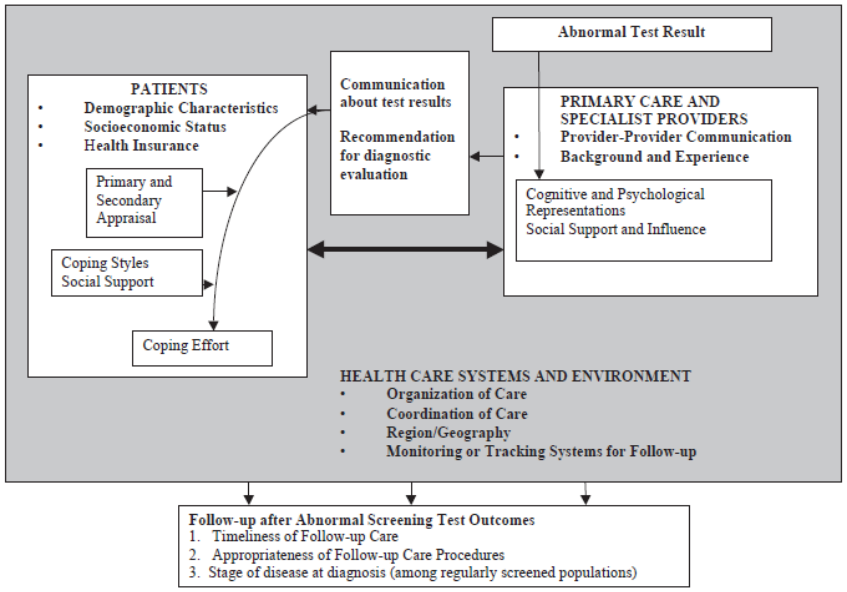


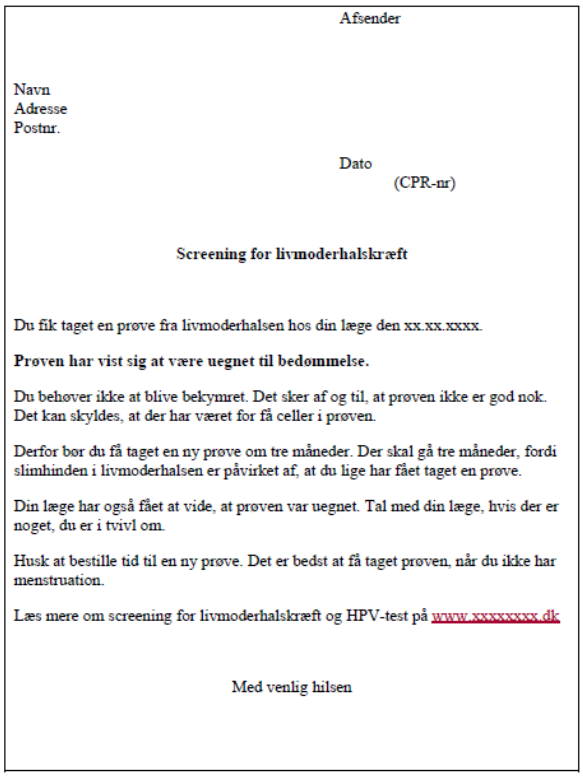
FIGURE 1 Model of Realized Access to Follow-Up Care after Abnormal Screening Test

..." The model build on the work of Andersen and Aday (Andersen 1968, 1995; Aday 1980), integrates **the Diagnostic Evaluation Model** developed by Myers and colleagues (Myers et al. 1999) at the health care provider level and **the Transactional Model of Stress and Coping** (Lazarus and Folman 1969; Lerman and Glanz 1996) at the patient level, and graphically depicts the conceptual framework.

The Diagnostic Evaluation Model was developed specifically to explore factors that influence providers' recommendations for a complete diagnostic evaluation after an abnormal screening test (Myers et al. 1999). In addition to physician background and experience, components of this model include physician cognitive and psychological representations (e.g., perceptions about screening or diagnostic evaluation) and physician social support and influence (e.g., perceptions about standard practice). Since primary care providers (PCPs) are usually responsible for screening referral, reporting findings to patients, and referral to specialists for additional testing, both primary and specialty care providers are included in the model. We have also added provider-provider and provider-patient communication as key components of our model.

The Transactional Model of Stress and Coping (Lazarus and Folman 1969; Lerman and Glanz 1996) focuses on a patient's perception of a specific external event—notification of an abnormal screening test—and how differences in the perception of that event and existing resources can affect completion of follow-up. The primary components of the model are primary appraisal of the event as threatening or benign and perceived control over the outcomes or self-efficacy, or secondary appraisal. Coping efforts are the strategies based on primary and secondary appraisal that may or may not lead to completion of recommended follow-up. Coping styles, such as dispositional optimism, information seeking, or locus of control, as well as social support can modify the association between perceptions about the abnormal screening test and adherence. Outcome measures in this model include the timing of diagnostic resolution; the appropriateness of, or quality of, diagnostic services; and, among populations undergoing regular screening, stage of disease at diagnosis..." (22).

Letter templates, predefined by The National Board of Health (8)**.** **Appendix 2**



Afsender

Navn
Adresse
Postnr.

Dato
(CPR-nr)

Screening for livmoderhalskræft

Du fik taget en prøve fra livmoderhalsen hos din læge den xx.xx.xxxx.

Prøven har vist sig at være uegnet til bedømmelse.

Du behøver ikke at blive bekymret. Det sker af og til, at prøven ikke er god nok. Det kan skyldes, at der har været for få celler i prøven.

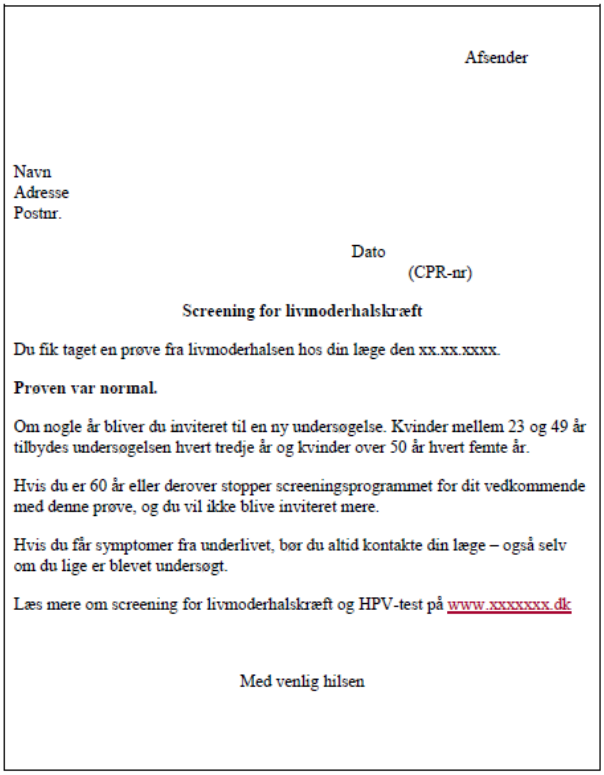
Derfor bør du få taget en ny prøve om tre måneder. Der skal gå tre måneder, fordi slimhinden i livmoderhalsen er påvirket af, at du lige har fået taget en prøve.

Din læge har også fået at vide, at prøven var uegnet. Tal med din læge, hvis der er noget, du er i tvivl om.

Husk at bestille tid til en ny prøve. Det er bedst at få taget prøven, når du ikke har menstruation.

Læs mere om screening for livmoderhalskræft og HPV-test på www.xxxxxxxx.dk

Med venlig hilsen



Afsender

Navn
Adresse
Postnr.

Dato
(CPR-nr)

Screening for livmoderhalskræft

Du fik taget en prøve fra livmoderhalsen hos din læge den xx.xx.xxxx.

Prøven var normal.

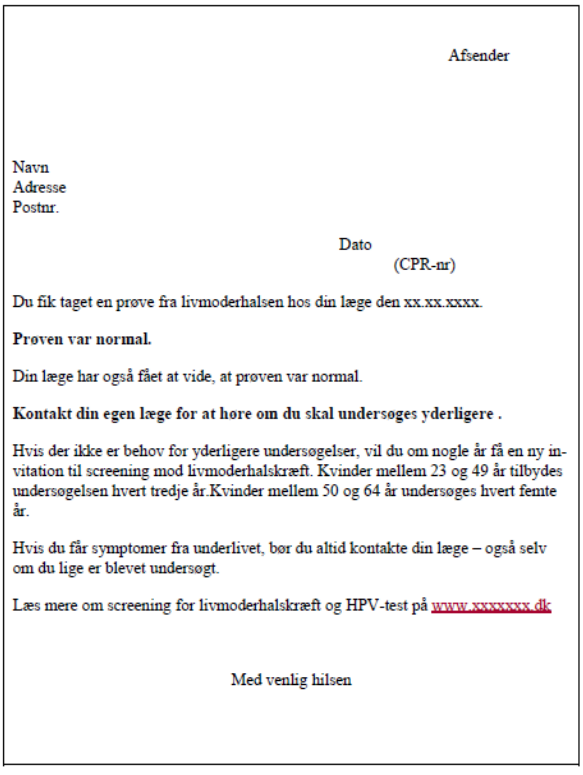
Om nogle år bliver du inviteret til en ny undersøgelse. Kvinder mellem 23 og 49 år tilbydes undersøgelsen hvert tredje år og kvinder over 50 år hvert femte år.

Hvis du er 60 år eller derover stopper screeningsprogrammet for dit vedkommende med denne prøve, og du vil ikke blive inviteret mere.

Hvis du får symptomer fra underlivet, bør du altid kontakte din læge – også selv om du lige er blevet undersøgt.

Læs mere om screening for livmoderhalskræft og HPV-test på www.xxxxxxx.dk

Med venlig hilsen



Afsender

Navn
Adresse
Postnr.

Dato
(CPR-nr)

Du fik taget en prøve fra livmoderhalsen hos din læge den xx.xx.xxxx.

Prøven var normal.

Din læge har også fået at vide, at prøven var normal.

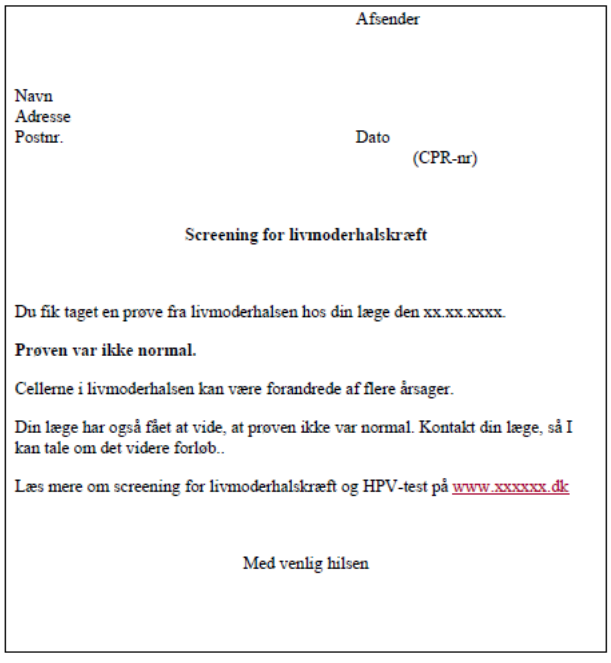
Kontakt din egen læge for at høre om du skal undersøges yderligere .

Hvis der ikke er behov for yderligere undersøgelser, vil du om nogle år få en ny invitation til screening mod livmoderhalskræft. Kvinder mellem 23 og 49 år tilbydes undersøgelsen hvert tredje år.Kvinder mellem 50 og 64 år undersøges hvert femte år.

Hvis du får symptomer fra underlivet, bør du altid kontakte din læge – også selv om du lige er blevet undersøgt.

Læs mere om screening for livmoderhalskræft og HPV-test på www.xxxxxxx.dk

Med venlig hilsen



Afsender

Navn
Adresse
Postnr.

Dato
(CPR-nr)

Screening for livmoderhalskræft

Du fik taget en prøve fra livmoderhalsen hos din læge den xx.xx.xxxx.

Prøven var ikke normal.

Cellerne i livmoderhalsen kan være forandrede af flere årsager.

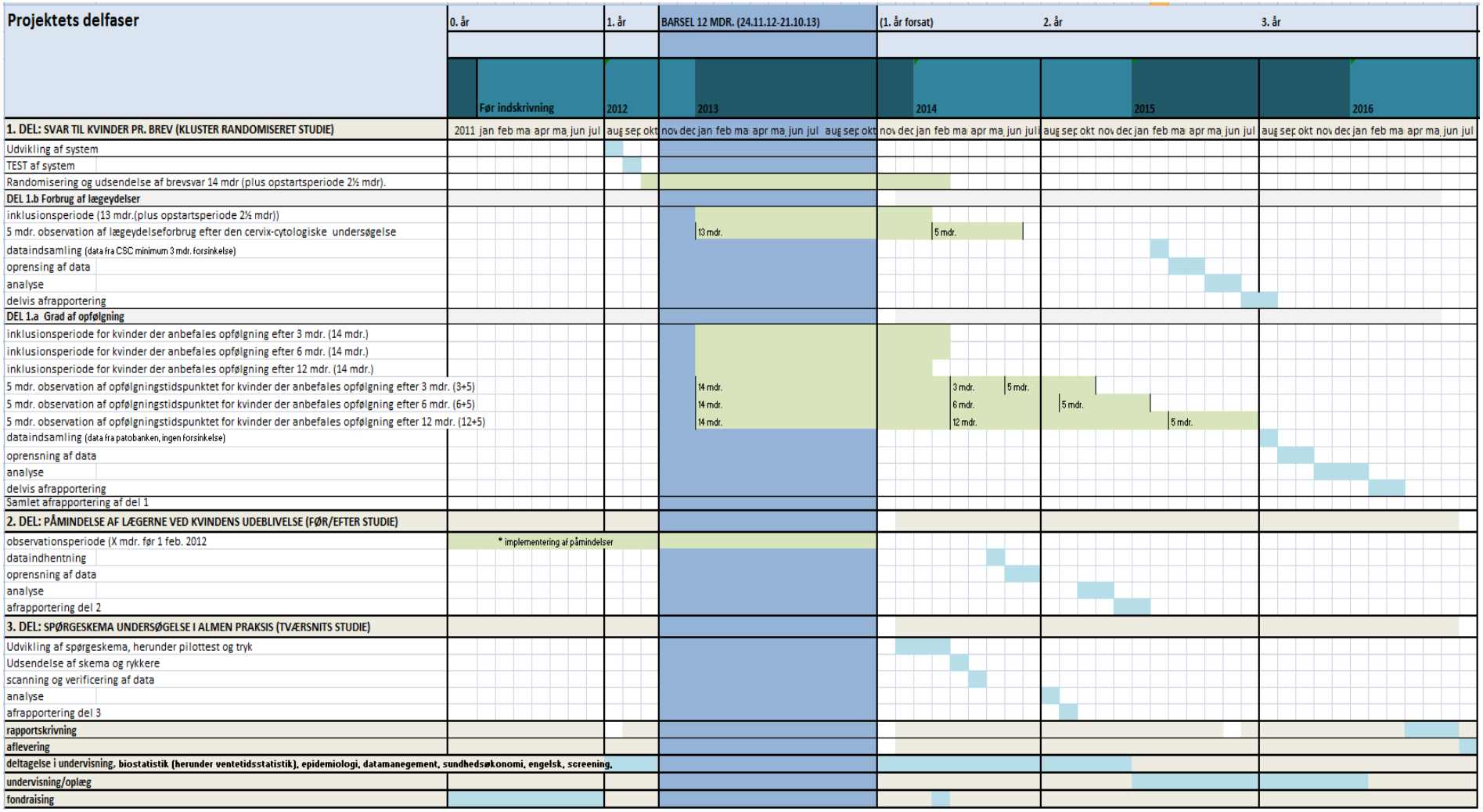
Din læge har også fået at vide, at prøven ikke var normal. Kontakt din læge, så I kan tale om det videre forløb..

Læs mere om screening for livmoderhalskræft og HPV-test på www.xxxxxx.dk

Med venlig hilsen

The predefined letter templates will be modified, so that the woman besides information regarding if the result is normal, abnormal or inadequate, will get a time-recommendation for follow up as well (either immediately, in 3 months, in 6 months, in 12 months or a recommendation to follow normal screening intervals).

Time schedule for the PhD thesis Appendix 3



CV projektansvarlig **BILAG 3**

FORSKNINGSENHEDEN FOR ALMEN PRAKSIS
Århus

Aarhus, den 6. januar 2014

CV
Bettina Kjær Kristiansen **16.11.1976**

Ansættelser:

- **Aug. 2012 -** **Ph.d. studerende**
- **Okt. 2011 - Jul. 2012 Videnskabelig medarbejder.**
  Forskningsenheden for Almen Praksis, Aarhus Universitet.
  Udarbejdelse af forskningsprotokol, og udvikling af kodealgoritme der oversætter snomedkode-prøvesvar fra patologisk afdeling til simplificerede brevsvar til kvinder i lægmandssprog. Samarbejde med Patologisk Afdeling og Afdeling for Folkeundersøgelser, Randers Regionshospital, samt It firmaet CGI.
- **Jan. 2011-Okt. 2011 Projektmedarbejder**
  Forebyggelse af trykskader, støttet af Statens ABT-fond, i samarbejde med Thoraxkirurgisk forskningsenhed, Skejby og et europæisk sårselskab (EWMA).
  Dataindsamling: hos patienter (i form af klinisk undersøgelse) og hos personale (fokusgruppeinterviews og tidsstudier). Planlægning/koordinering af undervisning til tværfaglig personalegruppe.
- **Dec. 2002 – Nov. 2010 Sygeplejerske**
  Intermediær thoraxkirurgisk afdeling på Skejby Sygehus.
  Daglig koordinator og bl.a. ansvarlig for ernæring, dokumentation, undervisning/implementering af del af den Elektroniske Patient Journal, samt udvikling af klinisk retningslinje for obstipation.

Uddannelse:

- **2011 Can.Scient.San**

  Speciale: At afdække om der er sammenhæng mellem kvinders manglende deltagelse i livmoderhalskræft-screening og forsinket lægesøgning ved kræftsygdomme.

  Gruppe opgave: Medicinsk teknologivurdering af opgaveglidning fra radiologer til radiografer.

  Gruppe opgave: Har lobektomerede lungecancer patienter færre komplikationer, efter implementering af et accelereret patientforløb?

  Valgfag: Kvalitetssikring, Forebyggelse, Projektledelse, Farmakologi og Logistisk regression.
- **2004 Professionsbachelor i sygepleje.**
- **2002 Sygeplejerske.**
- **1996 1-årig højere handelseksamen**
- **1995 Matematisk student**

Yderligere

- 2013 Barselsorlov
- 2009 Barselsorlov
- 2006 Barselsorlov
- 1997/98 Højskole, Kibbutz og Asien rundrejse.

Aarhus Universitet • Bartholins Allé 2 • 8000 Århus C
Tlf. 8942 6010 • Fax 8612 4788 • fe.aarhus@alm.au.dk • www.almen.dk
Forskningsenhederne for Almen Praksis • København • Århus • Odense