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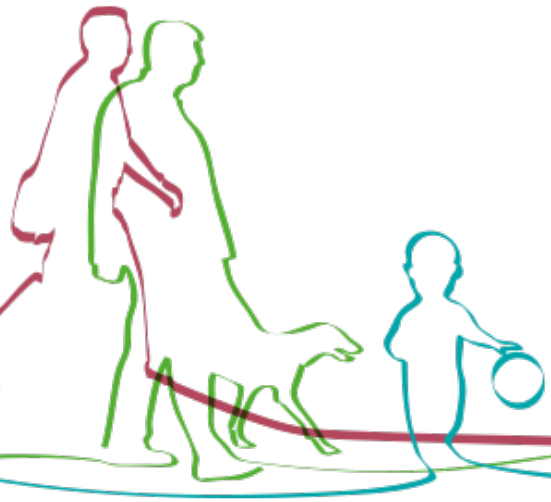
Institute of Health and Wellbeing

Protocol: Evaluating the impact of a leaflet to raise awareness in women of symptoms of gynaecological cancers in primary care.



2013

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1. Background

Gynaecological cancers have a combined incidence in women second only to breast cancer in the UK.[1] Ovarian, endometrial and vulval cancers are more common in older women and are associated with obesity and therefore, as the population ages and obesity rates increase, incidence is likely to rise.

There is evidence that earlier diagnosis of cervical and uterine cancers could reduce the survival gap between England and the European average,[2] and differences in ovarian cancer survival could also be reduced by earlier diagnosis, although care factors play a role. Although many analyses attribute the greater share of delay to patients rather than providers,[3,4] the GP-patient relationship is also influential. Almost half the respondents to a survey using the Cancer Awareness Measure expressed worry about 'wasting the doctor's time' which could cause them to delay.[5] Empowering patients to feel confident about help-seeking may reduce delay; although such initiatives need GP support.

An information leaflet detailing the symptoms of gynaecological cancers and encouraging women to present to their GP with any worrying symptoms has been developed through focus groups with experts, cancer survivors and members of the public.

A review[6] has identified four effective, individual-level studies (not on gynaecological cancers) demonstrating that educational leaflets can increase cancer knowledge, and in another recent study, an information booklet increased breast cancer awareness.[7] Support for the theory that this will also promote earlier presentation comes from evidence that information leaflets can increase attendance at screening,[8] and reduce stroke delay.[9]

The leaflet has been tested with members of the public and has been shown to have at least a short term impact by reducing women's perceived barriers to help-seeking, increasing their symptom knowledge and reducing their overall anticipated time to help-seeking. It is hoped that ultimately exposure to the leaflet will result in reduced delay in presentation for gynaecological cancer symptoms and thus potentially improve survival rates.

This project aims to extend a similar project being undertaken in London by Dr Alice Simons and colleagues (REC approval reference: 12/EE/0231). This will provide a geographical comparison to the London study, and will also include a control arm as a further methodological development.

2. Methods

2.1 Recruitment

The study practices will be selected from across Northamptonshire to represent a range of deprivation levels, settings (urban/rural) and practice sizes.

2.2 Participants

The gynaecological cancers leaflet (see Appendix 1) will be sent to a total of 8,027 women aged ≥ 40 years within the participating practices. They will be selected at random, without replacement (using IBM SPSS v20 random selection procedure) from those eligible women at each participating practice such that an approximately equal proportion of eligible women are selected from each practice. The records of those women who are sent a leaflet will be flagged using a project-specific Read code for later identification of data. Those eligible women who were not randomised to receive a leaflet will be flagged with a different code.

Exclusions (see below) will be applied in order to ensure that the women sent this leaflet are not those who might become over-anxious and also that they are not actively having treatment for a cancer during the time of the study.

Inclusion criteria: Women currently registered with the practice aged between 40years and 120y.

Exclusion criteria: Women on the oncology and palliative care registers, learning difficulties, and mental health (see Appendix 2; list of Read codes for inclusion and exclusion criteria).

The leaflet will be mailed out to each of the patients' home address, along with a covering letter from their GP. The leaflet includes the Cancer Research UK website address and helpline number in case women are concerned about anything they read.

2.3 Sampling

The study is not a longitudinal before and after study. Data will be extracted from three independent samples within each practice:

i) All eligible women – data from practice records relating to 2013 (baseline data)
ii) Eligible women who were sent a leaflet – data from practice records relating to 2014 (cases)

iii) Eligible women who were not sent a leaflet – data from practice records relating to 2014 (controls)

The required data will be extracted from each of the practices by a member of the research team, employed by the NHS. All of the participating practices will be using the same (SystmOne) electronic records system. There were over 109,000 women aged ≥40 years registered with Northamptonshire GP practices who use SystmOne and these practices provide a good geographical, demographic and practice size coverage.

2.4 Outcomes

The primary outcome will be the proportion of eligible women who consult their GP for symptoms indicative of gynaecological cancers.
Secondary outcomes will be the identification of predictors of GP consultation for symptoms indicative of gynaecological cancer and the proportions of women who consult their GP for these symptoms who subsequently have follow-up tests and referrals.

The SystmOne query will be constructed on the basis of a specific gynaecological Read codes list that has been developed by all those collaborating on the London research project. This Read code list includes all relevant codes relating to the symptoms in the leaflet, diagnostic tests ordered, test results, referrals and possible gynaecological cancer diagnoses.

Read codes have been grouped under higher order categories to reflect either the leaflet content (e.g. in relation to groups of symptoms) or meaningful clinical groupings that also allow for variation in codes used between different GPs. These higher order categories are shown in Table 1 below.

Table 1: **Higher order Read code categories**

Symptoms	Lab Tests	Referrals	Diagnoses
Abdominal pain/pelvic pain	CX smear/other process carried out	Urgent Referral codes	Ovarian
IMB/PCB/PMB	Cervical smear codes	Other (non-urgent) Referral codes	Uterus
Vaginal discharge	Cx smear results	Attended secondary care codes	Vagina
Longer/heavier periods	Cervical smears action needed	Attended secondary care - Urgent	Vulva
Bloating/constipation	Colposcopy	Did not attend	Cervix
Pain during sex	Transvaginal Ultrasound codes	Listed for admission	Endometrium
Lower back pain	Ovarian Tumour markers		Diagnostic codes suggesting cancer or abnormal smears
Pain, lump, ulcer etc of vulva	Urinary/Genitourinary test results		Other Diagnoses
Urinary/bowel frequency	Microbiology		
Loss of appetite/feeling full	Investigations		
Miscellaneous but relevant			
Multi symptom application			

The extraction will provide data for both time periods (2013 and 2014) on the following specific outcomes:

- Number of relevant contacts – summarising overall total relevant Read code hits for any one individual
- Symptom presentation
- Tests ordered
- Referrals made (split into 2 week wait and non-urgent)
- Gynaecological Cancer Diagnosis

In the data extraction process, the earliest six recordings of any relevant Read code following the given first date for the extraction will be identified for each patient. The earliest records will be chosen because the impact of the leaflet is likely to be greater soon after the mail out date. This limit is put in place so that the extraction file does not become exponentially large. However, in the London pilot data, the highest number of recorded Read codes within each symptom category did not exceed 4 records, so it is not expected that the limit of 6 will seriously truncate the available data.

2.5 Analysis

The data analysis for the baseline and case groups will follow the analysis plan established by the London project, with the addition of a control group in 2014.

Descriptive statistics will be used to describe the eligible sample size in both years, the number of women who joined and left the practice, and the demographic characteristics

of the samples- including ethnicity and postcode (which will be used to obtain IMD scores only). The numbers and proportions of women with relevant records ('visits'), symptoms present, tests and referrals in the 2013 sample and in the 2014 case and control sample will be calculated.

Logistic regression analysis will be used assess the contribution of a range of extracted variables (e.g. symptom, age group, IMD, time period, leaflet) to likelihood of consulting their GP about gynaecological symptoms. Chi-squared tests will be used to compare the proportions of women who consulted their GP about gynaecological symptoms between the baseline group (2013) and the cases group (2014) and between the cases group (2014) and the control group (2014). This will be repeated will repeat this process for relevant tests ordered and referrals made.

The number of cases of gynaecological cancers diagnosed will also be reported but numbers are expected to be too small for statistical analysis.

2.6 Sample size

For comparison of two independent proportions: comparison of a) proportions of similar groups from two years and b) proportions from case and control group within the same year.

Previous research[10] indicates that 44% of women have had symptoms indicative of gynaecological symptoms in the previous 3 months, and, of these, 30% had seen their GP about these symptoms. The target population for the leaflet intervention is all women (aged 40+), with an aim of increasing the GP attendance rates for those women who are symptomatic.

For a power of 95% of detecting a difference of 4% in the proportions of symptomatic women seeing their GP (e.g. from 30% to 34%) (an odds ratio of 1.13, or an effect size of 0.45[11]) would require group sizes of 3,532 symptomatic women (for α=0.05, two-tailed test) (using IBM SPSS SamplePower 3). As symptomatic women can be assumed to be 44% of the total sample group size, this requires total group sizes of 8,027 women. As the proportion of symptomatic women in the same will not be directly measured in this research, the outcome measure for analysis will be the GP attendance rates (for gynaecological cancer symptoms) in the whole group. This is expected to be 13% in the control groups (30% of the 44% of the group that are expected to be symptomatic). An increase of 4% in the attendance rates of symptomatic women (from 30% to 34%, OR=1.13) is therefore equivalent to an increase from 13% to 15% (OR=1.15) in the total group.

For logistic regression modelling

Sample sizes for logistic regression modelling are usually calculated on the basis of a minimum of 10 events per predictor (independent) variable where an event is defined as the least frequent of the possible outcomes[12]. Assuming that 13% of the eligible women see their GP (the least likely outcome), then the sample size above will produce c. 1,043 events, giving considerable redundancy for a model comprising of less than 20 variables.

3. References

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Appendix 1: Gynaecological cancers leaflet

Do you have any of these symptoms?

If the answer is **yes** to even **one** of these symptoms, it is important to call your GP to make an appointment.

It might help you to fill out this checklist and bring it to your appointment. This will make it easier to give your GP as much detail as possible on your symptoms.

Symptom	Tick if you have symptom regularly	When did it start?
Abdominal or pelvic pain that does not go away		
Bleeding between periods, after sex or after the menopause		
Vaginal discharge that is smelly or blood stained		
Longer or heavier periods that continue for a few months		
Bloating, gas or constipation that doesn't go away		
Pain during sex		
Lower back pain that doesn't go away		
Pain, lump, ulcer, soreness or persistent itching of the vulva		
Needing to go to the toilet more urgently or frequently than normal		
Feeling full quickly or loss of appetite over a period of time		

Make a promise to yourself:

If I have **any** of these symptoms I will call my surgery **today** to make an appointment with the GP.

Today's date _____

Date and time of your appointment _____

_____

If you are embarrassed or worried...

- You can ask to see a female doctor or ask to have a female member of staff accompany you to your appointment.
- Remember, your GP is used to dealing with sensitive issues and can support you.
- It can help to discuss your concerns with someone you trust among your friends or family.
- You can discuss with your GP any tests that may be offered to you before you choose whether to have them.

The earlier cancer is diagnosed, the better the chances of survival.

"I thought a normal smear test meant that I was OK. I didn't realise you could get cancer in other parts."

Meera, 51, ovarian cancer survivor

If you have any questions or concerns about gynaecological cancers, there is more information at:

www.cancerhelp.org.uk

Or call **0808 800 4040** (Mon-Fri 9am-5pm) to speak to a Cancer Research UK nurse

A MESSAGE FROM YOUR GP

Women's Health

GYNAECOLOGICAL CANCERS

know the signs

NHS

Dear Patient,

We are sending this leaflet to all women over 40 in the practice because we think it is important that women of this age know about the symptoms of gynaecological cancers.

Every year around 18,000 women of all ages in the UK are diagnosed with a gynaecological cancer.

*We want you to feel able to come to see one of us if you notice anything that is **not normal for you**.*

*In this leaflet you will find a **symptom checklist** that will help you to see if you need to make an appointment.*

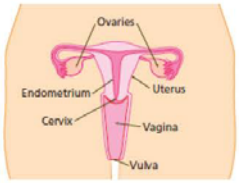
*If you are experiencing **any** of these symptoms please don't delay. **Come to see us**.*

*If you are worried about gynaecological cancer, please speak up. **You will not be wasting our time**.*

What are gynaecological cancers?

A gynaecological cancer is a cancer that occurs in your reproductive system:

- Uterus (womb) including endometrium (lining of womb)
- Cervix (neck of womb)
- Ovaries
- Vagina
- Vulva (outside part of the vagina)



Early signs and symptoms

These bodily changes are important ***if they are new, if they happen frequently or if they have gone on for some time***.

The **most common** symptoms of gynaecological cancers are:

- Abdominal or pelvic (low tummy area) pain that does not go away
- Bleeding between periods, after sex or after the menopause
- Vaginal discharge that is smelly or bloodstained
- Longer or heavier periods that continue for a few months
- Bloating, gas or constipation that doesn't go away
- Pain during sex
- Lower back pain that doesn't go away
- Pain, lump, ulcer, soreness or persistent itching of the vulva
- Needing to go to the toilet more urgently and frequently than normal
- Feeling full quickly or loss of appetite over a period of time

Remember, these are important if they are new for you or if they don't go away.

Common concerns

- Even if you don't feel ill, you should have your symptoms checked.
- These symptoms can seem mild and unimportant, but if you have any of these symptoms, it is important that you see your GP.
- You might think that your symptoms will just clear up on their own but it is better to see your GP.
- Even if you have been to your pharmacist or GP already, you should visit them again if your symptoms haven't gone away.

It is likely that these symptoms are not due to cancer, but it is important to have them checked.

"Cervical cancer never crossed my mind. I was really fit and healthy. I thought people like me didn't get cancer."

Sandra, 64, cervical cancer survivor

Appendix 2: List of Read codes for inclusion and exclusion criteria

INCLUDED

Currently registered

Aged between 40 years and 120 years

Female

EXCLUDED

Male

Aged under 40 years

B40-Maligneop uterus, part unspec

B41- Malignant neoplasm of cervix uteri

B42- Malignant neoplasm of placenta

B43- Maligneop body of uterus

B44-Maligneop ovary/uterine adnex

B45-Maligneopoth female genital

B4y-Maligneop genitourinary OS

B4z-Maligneop genitourinary NOS

B83- (- exceptions: Carcinoma in situ of breast, Carcinoma in situ of prostate, Carcinoma in situ of penis, Ca-in-situ male genital-other , Carcinoma in situ of bladder , Ca-in-situ urinary organs NOS)

13Z68- Speaks English poorly

9NU (-exceptions: Interpreter not needed)

9NQ0- Interpreter present

9Nm- Other interpreter present

9Nn- Further interpreter present

9Ndd- Dclnd con resarchaccclinrcd

AND THE FOLLOWING REGISTERS ARE EXCLUDED (the terms used for the registers, not the codes for the registers):

PC3- Palliative Care

LD2- Learning Difficulty

MH8- Mental Health

DEM1- Dementia

CANCER1- Cancer