

Systematic Review

The use, quality and effectiveness of pelvic examination in primary care for the detection of gynaecological cancer: a systematic review

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Abstract

Background. Urgent suspected cancer referral guidelines recommend that women with gynaecological cancer symptoms should have a pelvic examination (PE) prior to referral. We do not know to what extent GPs comply, their competency at PE, or if PE shortens the diagnostic interval.

Objectives. We conducted a systematic review of the use, quality and effectiveness of PE in primary care for women with suspected gynaecological cancer.

Method. PRISMA guidelines were followed. Three databases were searched using four terms: PE, primary care, competency and gynaecological cancer. Citation lists of all identified papers were screened independently for eligibility by two reviewers. Data extraction was performed in duplicate and independently. Paper quality was assessed using the relevant Critical Appraisal Skills Programme checklist. Emergent themes and contrasting issues were explored in a narrative ecological synthesis.

Main Findings. Twenty papers met the inclusion criteria. 52% or less of women with suspicious symptoms had a PE. No papers directly explored GPs' competence at performing PE. Pre-referral PE was associated with reduced diagnostic delay and earlier stage diagnosis. Ecological synthesis demonstrated a complex interplay between patient and practitioner factors and the environment in which examination is performed. Presenting symptoms are commonly misattributed by patients and practitioners resulting in misdiagnosis and lack of PE.

Conclusion. We do not know if pre-referral PE leads to better outcomes for patients. PE is often not performed for women with gynaecological cancer symptoms, and evidence that it may result in earlier stage of diagnosis is weak. More research is needed.

Key words: GP, gynaecological cancer, PE, referral.

Introduction

Gynaecological cancers are relatively common in the UK affecting >21 000 women each year (1), and despite recent improvements, UK survival rates for the five main gynaecological cancers, ovarian, endometrial, cervical, vulval and vaginal, continue to lag behind those in comparable

countries (1). This may reflect delayed diagnosis of cancer: the primary care interval, the time between patient presentation with symptoms suggestive of cancer and the point of referral by the GP to secondary care has a pivotal role in a patient's diagnostic journey and cancer outcomes may be improved by reducing delays in primary care (2).

Urgent suspected cancer referral guidelines have been developed by different agencies as one of a number of strategies to reduce diagnostic delay and improve patient outcomes (3,4). The National Institute for Health and Care Excellence (NICE) and the Scottish Referral Guidelines for Suspected Cancer recommend pre-referral pelvic examination (PE) but provide no peer-reviewed evidence. The clinical development group for NICE, comprised of non-specialists, predict the value of PE for suspected cervical, vulval and vaginal cancers, 'based on their clinical experience'. This indicates the divide between available evidence and professional opinion on the role of pre-referral PE to improve patient outcomes. Physical examination is an integral part of patient assessment, but the intimate nature of PE makes learning challenging (5), and subsequent exposure to maintain these skills can be limited; an average GP will see only one case of ovarian cancer every 5 years (6). In addition, there may be other factors which influence the decision to perform a PE and to interpret and act on the findings.

We aimed to conduct a systematic review and narrative synthesis of the evidence relating to the use, quality and effectiveness of PE in primary care in diagnosing gynaecological cancer.

Method

Research questions

A systematic narrative review was conducted to answer three research questions relating to PE in primary care and the diagnosis of gynaecological cancer:

- (i) Is PE used by GPs to assess women with symptoms suggestive of a gynaecological cancer?
- (ii) What is the quality of PE performed by GPs?
- (iii) What is the association between PE and referral outcomes?

The 'Preferred Reporting Items for Systematic reviews and Meta-Analyses' (PRISMA) criteria have been followed. A review protocol was registered and is available at https://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016035659. (Supplementary 1 Prisma checklist).

Search strategy

A comprehensive review of the published literature was performed by systematically searching MEDLINE, Embase, CINAHL from 1996 to present and ClinicalTrials.gov and the Cochrane Library from inception to present. The search strategy (Supplementary 2 Search strategy) was based around four terms and their synonyms and MeSH terms: PE, primary care, competency and gynaecological cancer. The grey literature was also reviewed (The New York Academy of Medicine; The Joanna Briggs Institute and Google Scholar). Additionally, reference lists from all included papers were hand searched. The search was limited to English language only. The search strategy was developed with the input of a medical librarian.

Inclusion and exclusion criteria

All original research papers of any design were included: controlled and uncontrolled quantitative studies and qualitative studies. We included studies which involved clinicians who were GPs or trainee GPs and patients over the age of 18. Studies were excluded if they were limited to patients under the age of 18, involved only clinicians who were not GPs or trainee GPs or were non-English language papers. Inclusion and exclusion criteria specific to individual research questions are detailed below:

- (i) Is PE used by GPs to assess symptoms suggestive of a gynaecological cancer?
Included studies with women diagnosed with a gynaecological cancer or who had symptoms potentially suggestive of a gynaecological cancer. Studies examining the facilitators and barriers for performing PE were also included. Studies were excluded if included non-diagnostic PE.
- (ii) What is the quality of PE performed by GPs?
Included studies involved bench top simulators or volunteer patients. Studies involved both diagnostic and screening PE: skill was assessed in terms of either technique or interpretation of examination findings.
- (iii) What is the association between PE and referral outcomes?
Studies had to include the referral of women with symptoms suggestive of a gynaecological cancer from primary to secondary care and involve diagnostic PE.

Study selection

All titles, abstracts and full papers were assessed independently at all stages by two researchers. All titles were screened against the inclusion and exclusion criteria. Following retrieval and removal of duplicates, the remaining abstracts were assessed for eligibility. Any disagreements were resolved by discussion between the two researchers. Full texts were obtained for all abstracts which met the inclusion and exclusion criteria.

Data extraction and synthesis

Data from the full papers selected were extracted independently by both reviewers to a data collection form (Supplementary 3 Data collection form).

Previous scoping searches suggested that papers would be heterogeneous in nature. As a result, data synthesis was narrative and followed the recommended sequence described by Popay: themes were developed initially which were then explored within and across included studies (7).

Thematic analysis was used to identify common threads that extended across extracted data from included studies to answer each research questions, while an ecological approach was used to explore the relationships between common threads within and between the studies and research questions unpicking the mutually interdependent relationships between patients, clinicians and their environments.

Assessment of data quality

Study quality was assessed using the appropriate Critical Appraisal Skills Programme tool and performed in duplicate by the same researcher. Poor study quality did not affect papers' inclusion.

Patient/public involvement was not included in this systematic review. Funding was from a personal Clinical Academic Training Fellowship, grant reference RG 13111-10, awarded to PW from the Chief Scientist's Office, Scottish Government. The fellowship application was externally peer reviewed. The funder played no part in conducting the research or writing the paper.

Results

PRISMA diagram for each research question is shown in Supplementary Figures S1–S3.

Result summaries can be seen in Tables 1–3.

Table 1. Characteristics of RQ1 included papers

Author and year of publication	Country of origin	Method	Number and nature of subjects	Summary of key results	Comments
Anorlu 2007 (11)	Nigeria	Cohort. Survey of cervical screening practices by GPs.	540 GPs; 31.6% worked in rural and 68.4% in urban practices. 68% were male, and 32% were female.	Post-coital and post-menopausal bleeding were the most common indicators for selective screening of patients, conducted by 25% and 21.6%, respectively. Speculum/visualization of the cervix would be used by 11% and 7.6%, respectively.	Self-reported methodologically sourced paper.
Goff 2000 (10)	USA	Cohort. Survey of women diagnosed with ovarian cancer.	1725 patients with ovarian cancer completed the surveys; from 46 US states and 4 Canadian provinces.	34% of respondents presented to a GP; 50% of GPs performed a pre-referral PE at the first consultation compared with 94% of gynaecologists.	Specialists described fewer perceived barriers to performing PE than family doctors. Poor quality study as it was impossible to verify the respondent's diagnosis and it was a highly selected population.
Lim 2014 (19)	UK	Interview study with additional analysis of patient records and cervical screening results.	128 patients <30 years of age diagnosed with cervical cancer.	Six patients had primary care provider delay: there was no visualization of the cervix for two while four did have their cervixes visualized prior to diagnosis; two were recorded as normal; one recorded as cervical polyp and one as cervical bleeding on contact. Advice to reattend was documented in only one of these patients' notes.	The most important factor for GP-delayed diagnosis was the use of hormonal or uterine contraception. Suggestion that for at least two patients PE delayed diagnosis. Good quality paper.
Macleod 2009 (29)	USA	Systematic review.	2 papers: 97 women with cervical cancer and 1725 patients with ovarian cancer.	Inadequate examination causes diagnostic delay. While Goff quantifies the percentage of GPs who performed pre-referral PE, Fruchter did not.	Robust systematic review.
Vandborg 2011 (9)	Denmark	Mixed methods cohort.	161 patients with gynaecological cancer; ovarian (63), endometrial (50), cervical (34) and vulva (14).	Pre-referral PE rates varied depending on presenting symptom: 52% for women presenting with vaginal bleeding, 18% in those with abdominal pain and 4% with abdominal swelling.	Misattribution of symptoms more likely if 'non-alarm' symptoms or non-gynaecological. Good quality paper although some self-reporting.

Themes

The initial ecological triangulation identified three main themes. These were patient factors, practitioner factors and the context in which the consultation took place. The interdependent relationships between these themes were explored for each research question using an ecological triangulation approach (8).

Research question 1

Use of PE by GP to assess symptoms

Five papers, one systematic review, three cohort and one mixed methods study were eligible. No paper looked specifically at the rate of pre-referral PE in women diagnosed with a gynaecological cancer. Four papers were conducted in countries of high-income countries (HIC) and one in low-/medium-income country (LMIC). Cervical cancer was examined in three papers; one paper looked at ovarian cancer with all gynaecological cancers investigated in another.

Pre-referral PE varied within and between studies. In a cohort of patients with various gynaecological cancers examination rates varied between 52% for women presenting with vaginal bleeding to 18% for abdominal pain and only 4% for abdominal swelling (9). In a North American survey of women with ovarian cancer, 50%

of those who had seen a primary care practitioner as their first contact received a PE before referral (10). In a Nigerian study of self-reported practice, rates of examination were lower: only 11.1% of GPs said they would perform a speculum examination on women presenting with post-coital bleeding; this figure dropped to 7.6% of women presenting with post-menopausal bleeding (11).

Research question 2

Quality of PE

Five eligible papers were identified. No paper looked specifically at GPs skill at performing PE. Proxies for skill were used instead: three papers audited the quality of cervical smear tests; there was one RCT evaluating the efficacy of training interventions, while one prospective cohort study evaluated the outcome of women referred to a colposcopy clinic with a 'clinically suspicious cervix'. All were conducted in HIC.

Two studies demonstrated no statistically significant differences between family doctors and gynaecologists in obtaining satisfactory cervical smear results (12,13). A randomized controlled evaluation comparing smear taking in GPs who had additional training found those doctors who received skills training performed more smears

Table 2. Characteristics of RQ2 research included papers

Author and year of publication	Country of origin	Method	Number and nature of subjects	Summary of key results	Comments
Curtis 1999 (12)	USA	Audit of smears test samples and the clinicians who obtained them.	176 clinicians who took 21, 833 smears, obtained over a 7-month period.	There were differences in the performance of obtaining smear tests between specialities: O&G specialists performed better than family physicians who performed better than interns. These differences were statistically significant.	
Jansen 2000 (14)	The Netherlands	Randomised controlled trial to evaluate the efficacy of a short course of technical skills to change performance in general practice.	59 GPs; 31 in the intervention group and 28 in the control group.	In this self-selected group of participants, an educational intervention led to increased knowledge of and taking of cervical smear test. There was no statistically significant increase in the quality of smears taken however.	
Harrison 2004 (20)	UK	Audit of cervical cytology data and the clinicians who obtained it.	Cervical cytology data from 100 general practices over a 2-year period.	23% of practices exhibit 'special cause' variation in cervical cytology samples which cannot be explained by chance.	Special cause is described in the Walter Shewhart theory of variation: it occurs as a result of unusual practice that is not an inherent part of the smear taking process e.g. the process, the resource, or the clinician taking the sample.
Fiscella 1999 (13)	USA	Audit of smears test samples and the clinicians who obtained them.	218 clinicians who obtained 34, 916 smears over a 2-year period.	No statistically significant differences between obstetrician-gynaecologists and family physicians (FPs), although FPs had higher rates of absent endocervical cells, a marker of quality.	
Milingos 2000 (15)	UK	Prospective cohort study.	86 women attending colposcopy clinic for 'clinically suspicious' cervix.	39% no abnormality; 41% benign cervical condition; 16% cervical intra-epithelial neoplasia and 4% invasive cancer.	92% referred by their GP; 8% by O&G trainees. The paper did not look at the speciality difference in results.

but with no effect on the adequacy of results. However, as the rate of poor-quality conventional cytology tests taken by GPs in the study was small ranging from 5.3% to 7.7% (14), it was insufficiently powered for this measure (14). Knowledge as demonstrated by multiple choice test results also increased as a result of this hands-on training.

A prospective cohort study of women referred to a colposcopy clinic with the diagnosis of 'clinically suspicious cervix' demonstrated that 80% of the women had either normal or benign pathology such as cervical ectopy or polyps. Eighty-one percentage of the referring clinicians were GPs with no breakdown of clinician type and examination findings (15).

Table 3. Characteristics of RQ3 included papers

Author and year of publication	Country of origin	Method	Number and nature of subjects	Summary of key results	Comments
Evans 2006 (17)	UK	Qualitative semi-structured interviews.	43 patients who had been diagnosed with ovarian cancer.	Patient delays: appraisal, illness, behavioural and scheduling. Treatment delays attributable at least in part to a doctor or health care system: non-investigation of symptoms, treatment for non-cancer causes, lack of follow-up, referral delays and system delays.	Symptom pattern at presentation could lead to misattribution, lack of examination and investigation and referral to a non-gynaecological speciality, often gastroenterology.
Goff 2000 (10)	USA	Cohort. Survey of women diagnosed with ovarian cancer.	1725 patients with ovarian cancer completed the surveys; from 46 US states and 4 Canadian provinces.	70% of patients had stage III or IV cancer; 77% presented with abdominal symptoms and 26% with pelvic; only 3% of stage III or IV cancer were symptomatic. Factors significantly associated with late, stage III or IV cancer, were no PE at first visit; not initially being investigated and being diagnosed initially with depression, stress, irritable bowel or gastritis.	Poor quality study as it was impossible to verify the respondent's diagnosis and it was a highly selected population.
Kirwan 2002 (16)	UK	Retrospective review of patient notes.	135 patients with epithelial ovarian cancer.	Only 21% had pre-referral PE; vaginal bleeding was significantly more common ($P = 0.025$) in those women who survived their diagnosis. Older age; late-stage diagnosis (stage III or IV) and non-specific symptoms were identified as significant variables affecting survival.	Low rates of PE and high rates of misattribution of symptoms: did this effect stage at diagnosis? Did not look at effect of pre-referral PE on survival outcomes.
Lim 2014 (19)	UK	Interview study with additional analysis of patient records and cervical screening results.	128 patients <30 years of age with cervical cancer.	31% presented symptomatically; 28% had delayed presentation. Symptoms dictate readiness to perform pre-referral PE, and if contraception use could be the cause of symptoms, this reduced the likelihood of examination.	Six patients had primary care provider delay: there was no visualization of the cervix for two, while four did have their cervixes visualized prior to diagnosis; two were recorded as normal; one recorded as cervical polyp and one as cervical bleeding on contact. Advice to reattend was documented in only one of these patients' notes.
Lim 2016 (24)	UK	Cross-sectional: patient interviews and retrospective data collection from patient records.	128 women <30 years of age diagnosed with cervical cancer. 107 had their records searched in addition to the interviews.	52% (56 of 107) patients had symptoms recorded in their primary care records; 89% reported symptoms at interview. 39% (22/56) had a documented cervical examination at presentation; only 4 were referred. Visualization identified 1/8 stage 1A and 3/14 stage 1B or worse cervical cancers.	Visual inspection has low sensitivity when used by GPs. High risk of measurement bias as what is recorded in notes is not always an accurate description of what took place during the consultation.

Table 3. Continued

Author and year of publication	Country of origin	Method	Number and nature of subjects	Summary of key results	Comments
MacLeod 2009 (29)	UK	Systematic review.	2 papers: 97 women with cervical cancer and 1725 patients with ovarian cancer.	The ovarian paper, Goff 2000, has already been discussed as part of this review. The additional paper, Fruchter, gave no figures to defend the statement that inadequate examination led to diagnostic delay.	
Reid 1997 (21)	Australia	Secondary analysis of retrospective cohort.	473 GPs.	GPs were less likely to examine whether they were less experience, had no postgraduate qualifications, worked in a metropolitan practice, if the patient was older or new to them.	
van Schalkwyk 2008 (18)	South Africa	Qualitative semi-structured interviews.	15 women with advanced cervical cancer (data saturation was achieved after 12 interviews).	Lack of knowledge and awareness among health professionals resulted in low suspicion and misdiagnosis.	Qualitative evidence that lack of examination contributed to delays.
Vandborg 2011 (9)	Denmark	Mixed methods cohort.	161 patients with gynaecological cancer, ovarian (63), endometrial (50), cervical (34) and vulva (14).	Diagnosis was delayed if no pre-referral PE was performed (OR = 5.36, $P = 0.044$). PE was less likely to be performed if the woman did not present with vaginal bleeding.	Misattribution of symptoms more likely if 'non-alarm' symptoms or non-gynaecological.
Yu 2005 (30)	UK	Retrospective cohort.	105 women diagnosed with cervical cancer; 22 < 35 years of age.	Median time to diagnosis significantly longer in those patients < 35 years of age: 9 versus 2 months ($P = 0.0009$). Delay was due to a lack of cervical visualization at initial presentation for the majority of women.	Poor quality study. No quantification of extent of failure to visualize the cervix at initial presentation. However, confirmation as in other studies that abnormal vaginal bleeding in younger women is often attributed to hormonal causes leading to changes in oral contraception rather than cervical examination.

Research question 3

PE and referral

Two qualitative, three cross-sectional, two cohorts, one systematic review and one case-note review were identified as meeting the inclusion and exclusion criteria. Nine were from HIC and one from LMIC. Four papers investigated ovarian cancer, five investigated cervical cancer and one looked at all gynaecological cancers.

Pre-referral PE was associated with early-stage (stage I/II) cancer at diagnosis: compared with stage III/IV cancer; this difference was significant (P value = 0.001) (10). No examination was associated with long (>90 days) delays in diagnosis (OR = 5.36) (9). Twenty-one percentage of patients diagnosed with ovarian cancer had a pre-referral PE: the paper by Kirwan (16) described factors that cause referral delay, but there was no investigation of the association between pre-referral PE and stage at diagnosis or effect on morbidity/mortality. Abnormal vaginal bleeding at presentation was more common in survivors (16). Two studies identified lack of knowledge of the significance of symptoms or misattribution of symptoms delayed diagnosis were associated with late diagnosis (17,18). Two out of six

women diagnosed with cervical cancer who experienced provider delay during their diagnostic journey had no pre-referral PE. For the four women who were examined results were documented as normal or benign with only one patient receiving safety-netting advice; the author suggests pre-referral PE delayed diagnosis (19). There are two components to the association between PE and referral outcomes:

- (i) Promotion of urgent referral
- (ii) Promotion of earlier diagnosis

No evidence was found that suggested an association between PE and the promotion of urgent referral. There was limited evidence which suggested pre-referral PE led to better patient outcomes.

Ecological triangulation

Cross-sectional themes were identified: patient, practitioner and context. The synthesis identified a complex set of mutually interdependent relationships between patient and practitioner factors and the clinical environment where consultations take place. This model is described diagrammatically (Fig. 1).

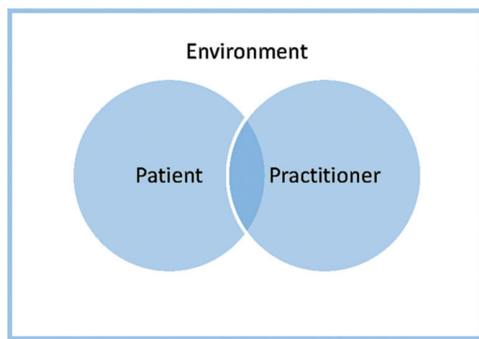


Figure 1. Ecological model of relationships between patient and practitioner factors and the clinical environment in which they were observed

Patient factors

Four authors described how patients can misattribute their symptoms (9,10,17,19). Symptoms can be misattributed to stress, menopause or previous benign symptoms e.g. bowel problems, IBS, pelvic inflammatory disease (17). Lack of symptom knowledge can lead to misattribution (9,10,19) along with lack of physical pain or disability as a result of their symptoms (10). Being too busy to make an appointment, fear about what might be found and embarrassment (9,10,19) were important factors, and embarrassment may lead to patients wishing to be examined by female rather than male practitioners (11).

Age also appears to be a factor in how patients interpret their symptoms; younger patients do not seem to view abnormal vaginal bleeding as seriously as post-menopausal women leading to patient delay (9). Additionally, Lim (19) describes a 2-month delay in presenting in women aged <25 compared with 1 month in those aged 25–29 suggesting patient knowledge of symptoms may be important.

Practitioner factors

PE was less likely to be performed if patients presented with non-alarm symptoms (9) or with vague symptoms (18). Vandborg demonstrated a clear relationship between symptom type and PE rates: rates were higher in those patients with gynaecological symptoms compared with those with abdominal symptoms (9), while van Schalkwyk (18) suggested that lack of symptom knowledge and misattribution of symptoms led to lack of pre-referral PE. Ovarian cancer symptoms were considered to be gastrointestinal symptoms (16,17). Lack of knowledge of the presentation of ovarian cancer with gastrointestinal symptoms meant irritable bowel syndrome was diagnosed even in women aged >60: cancer was not considered, and examination was not performed (17). Goff (10) stresses the importance of not labelling the symptoms experienced by patients with ovarian cancer as related to stress, depression or irritable bowel syndrome. Abnormal vaginal bleeding in younger women was attributed to hormonal or intrauterine contraception (19). Misattribution of abnormal vaginal bleeding in younger women was also observed by Vandborg (9). This effect was also seen with ovarian cancer: younger patients were more likely to have more symptoms and were more likely to be treated for another condition; diagnosis took longer for younger patients; they were more likely to be diagnosed with late-stage disease and were more likely to perceive that the attitude of their clinician was problematic (10).

Lack of examination or interpretation of examination findings as normal can lead to non-investigation of symptoms (17). Not only does misattribution of symptoms lead to non-examination but it can

also lead to referral to specialities other than gynaecology e.g. gastroenterology (9,17). Kirwan (16) demonstrated that misattribution led to less than half of patients referred to gynaecology.

Experience and clinical speciality appear to have some influence with family doctors performing fewer PEs and diagnosing less stage 1/2 ovarian cancers than their specialist colleagues (10). Male GPs, in particular those with no postgraduate qualifications, were less likely to examine older patients and patients new to the practice (20) and avoid performing PE as they perceive patients' embarrassment as a barrier to examination (11). Older GPs were more likely to perform pre-referral PE. There was an inverse relationship between age and examination practice observed in female GPs (21).

There is mixed evidence on specialists and generalists performing adequate cervical cytology (12). The special cause variation demonstrated within practices in obtaining adequate smear samples may be due to case mix, process or the individual collecting the smear, but no evidence is provided to explain these findings (20).

Contextual factors

Overarching patient and practitioner factors is the context in which the clinician practices, which, in turn, influence the opportunity the clinician has to perform PE. Milingos (15) highlights the difference in the clinical findings of the referring GP and the specialist, but these differences are not explored. Goff demonstrated significant differences between gynaecological specialists and family doctors: specialists were more likely to perform pre-referral and were more likely to diagnose early-stage disease. Specialists also exhibited fewer barriers to diagnosis as perceived by patients and were less likely to make the wrong diagnosis. Significantly more specialists performed pre-referral PE than family physicians (10).

Rurality and lack of equipment affected GPs' decisions to perform PE in Nigeria (11).

Summary

Pre-referral PE is more likely if patients present with bleeding symptoms and are not using hormonal or intrauterine contraception. Patients can misattribute their symptoms through lack of knowledge or embarrassment. Practitioners are less likely to perform pre-referral PE in patients with vague and non-alarm symptoms. Clinicians can also misattribute symptoms, especially gastrointestinal symptoms, resulting in non-examination. Lack of PE or misinterpretation of PE results can result in non-investigation of symptoms. Increased levels of experience and higher levels of knowledge lead to higher levels of pre-referral PE.

Discussion

Main findings

We found substantial gaps in the evidence on the role of PE in primary care for women with gynaecological cancer. There was limited evidence which suggested that PE reduces diagnostic delay and is associated with earlier stage diagnosis. The role of PE in primary care in this context is complex and involves patient, practitioner and contextual factors.

Evidence is limited both in number and quality of included studies with the majority of papers retrospective observational studies. The evidence suggests that pre-referral PE is not always performed when indicated and that there is no direct evidence to confirm the PE skills of referring GPs although, there appears an association between pre-referral PE and improved patient outcomes.

Strengths and limitations

Our review has been systematically conducted and is the first to examine the role of PE in diagnosing gynaecological cancer pre-referral. Crucially, it examines the role in primary care where patients usually make their initial presentation in response to their symptoms. These data provide a comprehensive summary of the available evidence as well as highlighting the gaps in knowledge. By breaking the overarching aim of the review into the three component research questions, we build a picture of the role of PE in primary care for suspected gynaecological cancer. The use of narrative synthesis and ecological triangulation identified themes between the papers adding robustness to the results.

The main limitation of the review is the relative lack of evidence and the quality of the identified evidence.

The studies were mostly observational, and while such evidence can inform clinical practice, it cannot account for all possible confounders and bias. For the second research question, there was no evidence relevant to GPs skills in taking and interpreting the findings of PE. There may be a number of confounders affecting decision to do PE and making a fast-track referral to the appropriate speciality. The use of proxies was considered but did not answer the specific research question. The studies were heterogeneous in design involving a variety of different cancer types with various methodologies.

Interpretation

The evidence that suggests PE plays a positive role in the gynaecological cancer diagnostic journey is weak.

Training programme directors, clinicians and medical educationists need to open up the discussion on the acquisition, maintenance of intimate examination skills and effective incorporation into clinical practice. We identified various patient and practitioner factors that determine the use of PE; however, we need further research into the interplay between them. We know that women's embarrassment of PE along with lack of symptom knowledge, misattribution of symptoms and difficulty in accessing primary care can act as barriers to presenting to their GP, but we need to know if these can be modified. We were not able to fully understand why GPs underperform PE despite the guideline recommendations and undergraduate training. Do GPs lack knowledge? Do they lack the skill? Is there collusion between GPs and patients to not examine? However, evidence suggests that patients' concerns regarding their symptoms are validated with examination (22). Research is required to unpick these potentially contradictory behaviours and assess the effect on patient outcomes.

General practice can be a challenging environment in which to perform PE: 10-minute consultations do not lend themselves to PE which is time-consuming; the traditional GP consultation couch, placed against a wall, finding chaperones. We do not know if graduates are competent to perform PE or how they can develop or maintain skills in practice and what the facilitators and barriers are to performing PE in primary care.

Timely diagnosis of cervical cancer, as described by Lim, relies on history taking, visualizing the cervix and a clear message to represent if symptoms persist. These requirements are common to the other gynaecological cancers (19). The foundations for history taking and examination are established in undergraduate training, but exposure to PE can be limited especially for male students (21). Interpersonal skills required for intimate examination can be difficult to teach (20), while van Schalkwyk (18) highlights the role of poor history taking. Postgraduate requirement for GPs during training in the UK is the demonstration of one PE which can be

performed either in primary care or secondary care. There are no requirements following qualification and no guidance on how skills should be maintained (23).

National and international guidelines on management of suspected gynaecological cancers are clear in their recommendation to perform PE (abdominal palpation, bimanual palpation ± visualization of the cervix) when women present with symptoms suggestive of a gynaecological cancer, but there is little evidence offered to support this recommendation (3,4,24). Pre-referral visualization of the cervix by GPs had low sensitivity and may lead to delayed diagnosis due to incorrect interpretation of examination findings (19,25). In the diagnosis of ovarian cancer, bimanual examination was found to have marked limitations when examining adnexal masses, regardless whether the clinician was a specialist or a generalist (26). These findings are not a reflection of the role that PE has in patient outcomes, but they demonstrate the complexity of its use. However, in a changing clinical environment, there is increased emphasis on the use of technology, and some clinicians advocate that physical examination is unnecessary (27).

Earlier cancer stage at diagnosis improves patient outcomes (28). While there is weak evidence suggesting an association between pre-referral PE and reduced interval to cancer diagnosis, it cannot be determined whether this is an effect of the examination or a well-informed practitioner who has considered that gynaecological cancer is a possibility: research is required to determine the extent and nature of any association.

Conclusion

We do not know if pre-referral PE leads to better outcomes for patients. PE is often not performed in primary care for women with gynaecological cancer symptoms, and evidence that it may result in earlier stage of diagnosis is weak. More research is needed.

Supplementary material

Supplementary material is available at *Family Practice* online.

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Declaration

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Conflict of interest: none.

References

1. Cancer Research UK. *Cancer Incidence Statistics*. London, UK: Cancer Research UK, 2018.
2. National Patient Safety Agency. *Delayed Diagnosis of Cancer: Thematic Review*. London, UK: National Patient Safety Agency, 2010.
3. National Institute for Health and Care Excellence. *Suspected Cancer: Recognition and Referral*. London, UK: National Institute for Health and Care Excellence, 2015.

4. Healthcare Improvement Scotland. *Scottish Referral Guidelines for Suspected Cancer*. Edinburgh, Scotland: Healthcare Improvement, 2014.
5. Bhoopatkar H, Wearn A, Vnuk A. Medical students' experience of performing female pelvic examinations: opportunities and barriers. *Aust N Z J Obstet Gynaecol* 2017; 57: 514–9.
6. Ovacom. *Information for Health Professionals*. London: Ovacom.
7. Popay J, Roberts H, Sowden A *et al*. *Guidance on the Conduct of Narrative Synthesis in Systematic Reviews: A Product From the ESRC Methods Programme*. 2006.
8. Banning J. *Ecological Triangulation: An Approach for Qualitative Meta-synthesis*. Fort Collins, CO: Colorado State University, 2003.
9. Vandborg MP, Christensen RD, Kragstrup J *et al*. Reasons for diagnostic delay in gynecological malignancies. *Int J Gynecol Cancer* 2011; 21: 967–74.
10. Goff BA, Mandel L, Muntz HG, Melancon CH. Ovarian carcinoma diagnosis. *Cancer* 2000; 89: 2068–75.
11. Anorlu RI, Ribiu KA, Abudu OO, Ola ER. Cervical cancer screening practices among general practitioners in Lagos Nigeria. *J Obstet Gynaecol* 2007; 27: 181–4.
12. Curtis P, Mintzer M, Morrell D, Resnick JC, Hendrix S, Qaqish BF. Characteristics and quality of Papanicolaou smears obtained by primary care clinicians using a single commercial laboratory. *Arch Fam Med* 1999; 8: 407–13.
13. Fiscella K, Franks P. The adequacy of Papanicolaou smears as performed by family physicians and obstetrician-gynecologists. *J Fam Pract* 1999; 48: 294–8.
14. Jansen JJ, Grol RP, Van Der Vleuten CP *et al*. Effect of a short skills training course on competence and performance in general practice. *Med Educ* 2000; 34: 66–71.
15. Milingos DS, Harry VN, Cruickshank ME. The clinically suspicious cervix—how often is it cancer? *J Low Genit Tract Dis* 2010; 14: 196–9.
16. Kirwan JM, Tincello DG, Herod JJ, Frost O, Kingston RE. Effect of delays in primary care referral on survival of women with epithelial ovarian cancer: retrospective audit. *BMJ* 2002; 324: 148–51.
17. Evans J, Ziebland S, McPherson A. Minimizing delays in ovarian cancer diagnosis: an expansion of Andersen's model of 'total patient delay'. *Fam Pract* 2007; 24: 48–55.
18. van Schalkwyk SL, Maree JE, Wright SC. Cervical cancer: the route from signs and symptoms to treatment in South Africa. *Reprod Health Matters* 2008; 16: 9–17.
19. Lim AW, Ramirez AJ, Hamilton W *et al*. Delays in diagnosis of young females with symptomatic cervical cancer in England: an interview-based study. *Br J Gen Pract* 2014; 64: e602–10.
20. Harrison WN, Mohammed MA, Wall MK, Marshall TP. Analysis of inadequate cervical smears using Shewhart control charts. *BMC Public Health* 2004; 4: 25.
21. Reid SE, Simpson JM, Britt HC. Pap smears in general practice: a secondary analysis of the Australian Morbidity and Treatment Survey 1990 to 1991. *Aust N Z J Public Health* 1997; 21: 257–64.
22. Kravitz RL, Callahan EJ. Patients' perceptions of omitted examinations and tests: a qualitative analysis. *J Gen Intern Med* 2000; 15: 38–45.
23. Royal College of General Practitioners. Clinical Examination and Procedural Skills. www.rcgp.org.uk/training-exams/training/mrcgp-workplace-based-assessment-wpba/ceps-tool-for-mrcgp-workplace-based-assessment.aspx (accessed on 31 January 2018).
24. Cancer Australia. Vaginal Bleeding in Pre- Peri- and Post-Menopausal Women. canceraustralia.gov.au/system/tdf/publications/abnormal-vaginal-bleeding-pre-peri-and-post-menopausal-women-diagnostic-guide-general-practitioners/pdf/ncgc_a3_menopause_chart_june_2012_final.pdf?file=1&type=node&id=2789 (accessed on 31 January 2018).
25. Lim AW, Hamilton W, Hollingworth A, Stapley S, Sasieni P. Performance characteristics of visualising the cervix in symptomatic young females: a review of primary care records in females with and without cervical cancer. *Br J Gen Pract* 2016; 66: e189–92.
26. Padilla LA, Radosevich DM, Milad MP. Accuracy of the pelvic examination in detecting adnexal masses. *Obstet Gynecol* 2000; 96: 593–8.
27. Spence D. Bad Medicine: clinical examination. *Br J Gen Pract* 2017; 67: 31.
28. The King's Fund. *How to Improve Cancer Survival: Explaining England's Relatively Poor Rates*. London, UK: King's Fund, 2011.
29. Macleod U, Mitchell ED, Burgess C, MacDonald S, Ramirez AJ. Risk factors for delayed presentation and referral of symptomatic cancer: evidence for common cancers. *Br J Cancer* 2009; 1010 (suppl 2): S92–101.
30. Yu CK, Chiu C, McCormack M, Olaitan A. Delayed diagnosis of cervical cancer in young women. *J Obstet Gynaecol* 2005; 25: 367–70.