Systematic review of the use, quality and effects of pelvic examination in primary care for the detection of gynaecological cancer

Title
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Background
Despite recent improvements, cancer survival rates in the United Kingdom continue to lag behind those in comparable countries (1). Relatively low survival is a feature of gynaecological cancers: cancers of the ovary; cervix; endometrium; vagina and vulva. It has been suggested that this may reflect late detection, related possibly to referral delay (2).

Urgent suspected cancer referral (USCR) guidelines have been developed as one of a number of government strategies to reduce diagnostic delay and improve patient outcomes (3, 4). Guidelines for suspected gynaecological cancer advocate pelvic examination (visualisation of the cervix +/- bimanual pelvic examination) in women presenting with symptoms suggestive of a gynaecological cancer. There is, however, limited evidence to support this. The intimate nature of pelvic examination makes teaching and learning pelvic examination challenging. Additionally the subsequent exposure required to maintain these learned skills can be limited. This may lead to reduced skills in GPs’ performance of pelvic examination.

Aim
This systematic review will gather all the current evidence on the use, quality and effects of pelvic examination in primary care in diagnosing gynaecological cancer.

Research Questions
1. Do primary care practitioners perform pelvic examination (visualisation of the cervix +/- bimanual pelvic examination) during the assessment of symptoms which are potentially indicative of gynaecological cancer?
2. What is the quality of pelvic examination performed in primary care, in terms of technical competence and interpretation of findings?
3. Is pelvic examination associated with the referral of patients with gynaecological cancer, and if so, in what way?
Objectives

To undertake a systematic literature review in order to address the three research questions; specifically:

1. to identify all relevant published literature (including both peer reviewed research and “grey literature”)
2. to conduct a narrative synthesis of the identified literature for each of the three research questions

Searches

Databases to be searched: Medline (1996 to present); EMBASE (1996 to present); CINAHL and Cochrane.

The search strategy will be based around 4 terms and their synonyms and MeSH terms:

- Pelvic examination
- Primary care
- Competency
- Gynaecological cancer

a) Pelvic examination
1. gynaecological examination/
2. pelvic exam$.tw
3. bimanual exam$.tw
4. digital exam$.tw
5. vaginal exam$.tw
6. vaginal smear$.tw
7. cervical smear$.tw
8. pap$ smear$.tw
9. cervical exam$.tw
10. intimate exam$.tw
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. ((pelvi$ or vagin$ or cervi$ or pap$ or bimanual) adj (exam$ or smear or palpation or inspect$)).tw
13. 11 or 12

b) Primary care
14. primary health care/
15. primary care.tw
16. GP.tw
17. general practice$.tw
18. family practice.tw
19. family doctor$.tw
20. general practitioner$.tw
21. nurse practitioner$.tw
22. 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21

c) Competency
23. quality.tw
24. ability.tw
25. skill$.tw
26. expertise.tw
27. capability.tw
28. competenc$.tw
29. clinical competenc$.tw
30. clinical skill$.tw
31. performance.tw
32. accuracy.tw
33. clinical expertise.tw
34. clinical performance.tw
35. clinical accuracy.tw
36. 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35
37. 13 and 22
38. 13 and 22 and 36
d) Gynaecological cancer

39. genital neoplasm, female/
40. gynaecological cancer.tw
41. gynaecological neoplasm$.tw
42. ovarian neoplasm$/
43. cervical neoplasm$/
44. uterine neoplasm$/
45. vulval neoplasm$/
46. vulval neoplasm$/
47. endometrial neoplasm$/
48. 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47
49. 38 and 48
50. 37 and 48
51. 22 and 48

The database searches will be supplemented by hand searches of:

- Conference proceedings: International Gynecological Cancer Society (IGCS) and British Gynaecological Cancer Society (BGCS)
- Reference lists of retrieved and potentially relevant papers, as well as relevant systematic reviews, other literature reviews, dissertations and these.
- Reference lists of relevant internet resources: urgent suspected cancer referral guidelines and statements for competency for pelvic examination from royal colleges and other clinical organisations with training responsibilities.

and a search of the grey literature e.g. :

- The New York Academy of Medicine
- The Joanna Briggs Institute
- Googlescholar

**Types of Study to be included**

All original research papers will be included of any design; controlled and uncontrolled quantitative studies; and qualitative studies.

Types of study: inclusion and exclusion criteria, types of participants, type of intervention and outcome will be considered separately for each research question:
1. Do primary care practitioners perform pelvic examination (visualisation of the cervix +/- bimanual pelvic examination) during the assessment of symptoms which are potentially indicative of gynaecological cancer?

**Types of study:** Studies must include patients over the age of 18 who have gynaecological cancer or symptoms which are potentially indicative of a gynaecological cancer and clinical practitioners who are general practitioners (GPs), trainee GPs and nurse practitioners (NPs). Studies examining the facilitators and barriers for performing pelvic examination will also be included.

Studies will be excluded if they are limited to patients only under the age of 18; clinicians who are not GPs, trainee GPs or NPs; pelvic examination for screening purposes; non-English language papers.

**Types of Participants:** Clinicians will be GPs, trainee GPs and NPs; Patients will be over the age of 18 and have gynaecological cancer or symptoms which are potentially indicative of gynaecological cancer.

**Type of Intervention:** diagnostic pelvic examination. There will be no Comparator.

**Outcomes:**
- Relationship between pelvic examination and symptoms of potentially indicative of a gynaecological cancer
- Barriers for pelvic examination in primary care
- Facilitators for pelvic examination in primary care

2. What is the quality of pelvic examination performed in primary care, in terms of technical competence and interpretation of findings?

**Types of study:** Studies must include clinical practitioners who are GPs, trainee GPs or NPs. Studies involving both diagnostic and screening pelvic examination will be included which examine GPs, trainee GPs and NPs skill in performing pelvic examination; skill being a combination of technique and interpretation of examination findings.

Studies will be excluded if they include clinicians who are not GPs, trainee GPs or NPs; non-English papers.

**Types of participants:** Clinicians will be GPs, trainee GPs and NPs; Patients will be females over the age of 18 or bench top simulators.

**Type of intervention:** pelvic examination: diagnostic or for screening purposes. The comparator will be any other measure of quality e.g. independently observed technique and/or interpretation of a bench top simulator; percentage of acceptable cervical smear samples; comparison of examination findings from a consented patient under general anaesthesia prior to surgery with those of an experienced examiner.
**Outcome:**

- Accuracy of technique of GPs, trainee GPs and NPs when performing pelvic examination
- Accuracy of interpretation of findings by GPs, trainee GPs and NPs when performing pelvic examination

3. **Does the use of pelvic examination in primary care influence the referral of patients with gynaecological cancer?**

**Types of studies:** Studies must include patients over the age of 18 and who have gynaecological cancer and clinicians who are GPs, trainee GPs and NPs. Studies must involve referral from primary to secondary care and involve pelvic examination. Studies will be excluded if they include only women under the age of 18; clinicians other than GPs, trainee GPs or NPs; pelvic examination for screening purposes; non-English papers.

**Types of participants:** Clinicians will be GPs, trainee GPs or NPs; Patients will be over the age of 18 and have been diagnosed with gynaecological cancer.

**Type of intervention:** pelvic examination used for diagnostic purposes. The **comparator** will be no pelvic examination or differences in usual care e.g. regional or guidelines differences or implementation of training programmes.

**Outcome:**

- The effect of pelvic examination in primary care on any of the stages involved up to diagnosis of gynaecological cancer as defined by the Arhuus statement (4)

**Study Selection**

All titles will be screened independently by two researchers against the inclusion and exclusion criteria. Following retrieval and removal of duplicates, the remaining abstracts will be assessed for eligibility by two independent researchers. Any disagreements will be resolved by discussion between the two researchers and if necessary by further discussion with a third researcher. Reasons for exclusion will be documented. Full texts will be obtained for all abstracts that meet the inclusion and exclusion criteria. They will be reviewed independently by duplicate researchers.

**Quality Appraisal**

It is expected that most of the included papers will be observational studies, although systematic reviews or randomised controlled trials may be identified. Quality assessment will be performed on
all identified papers using the Scottish Intercollegiate Guidelines Network (SIGN) methodology checklists for systematic reviews and meta-analyses, cohort studies and case-control studies. Quality appraisal will be performed by one researcher.

Data Extraction

A data extraction form will be designed and used to extract data from the included full papers. The following data will be recorded supplemented by other data as appropriate: title, author, year and journal citation; review author initials; date of data extraction; country; reasons for inclusion; paper aims/objectives; participants (e.g. age, sex, stage, other details); types of outcome measure; results; author inclusions; reviewer’s conclusions; notes. Data extraction will be replicated by a second reviewer for approximately twenty per cent of papers. The study will be reported following PRISMA reporting guidance and including PRISMA flow chart.

Data Synthesis

Data synthesis will be narrative, following the Narrative Synthesis Framework (5) with: Preliminary synthesis to provide an initial description of patterns across the included studies; Exploration of relationships within and between studies and exploration of robustness to ensure internal and external consistency and generalisability.

References
