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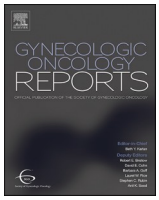

Feasibility of assessing symptoms associated with ovarian cancer using an electronic medical intake questionnaire

Eric D. Helm [a,*], Cam Nguyen [a], Stephen Rotholz [a], Saketh R. Guntupalli [a], Barbara A. Goff [b], Benjamin G. Bitler [a,c], Kian Behbakht [a,c]

[a] University of Colorado, Division of Gynecologic Oncology, Department of Obstetrics and Gynecology
[b] University of Washington, Department of Obstetrics and Gynecology
[c] University of Colorado, Division of Reproductive Sciences, Department of Obstetrics and Gynecology

A B S T R A C T

Objective: Symptoms occur in up to 75% of patients with early-stage ovarian cancer; as such, using a symptom inventory (SI) to stratify which patients should receive screening for ovarian cancer is an attractive approach to mitigate false-positives. We report on the feasibility and results of a prospective four-question SI that assessed the following symptoms: abdominal pain, bloating, early satiety, and urinary complaints. Frequency and duration of symptoms were not assessed.
Methods: A SI was added to the standard pre-appointment check-in process via the electronic medical record's (EMR) patient portal for all annual or new patient visits in a generalist obstetrics and gynecology faculty practice in patients over 40 years of age. IRB exemption was granted. Data were extracted from the EMR, compiled in REDCap, and analyzed in R.
Results: A total of 589 individual patients were included in the final analysis. The median age of the participants was 50 years (range: 40–86). 27.8 % of patients experienced at least one symptom in the prior year, and the most commonly reported symptom was urinary urgency/frequency (14.9 %). Patients with a history of medical comorbidities such as depression, uterine fibroids, endometriosis, and irritable bowel syndrome were more likely to screen positive on the SI. No cancers have been diagnosed to date.
Conclusions: Implementing a SI using the EMR is feasible but is influenced by the presence of pre-existing diagnoses. The effectiveness of an EMR-based SI pre-screen as a selection criterion for early detection requires further study and assessment of frequency and duration of symptoms should be considered.

1. Introduction

Advancements in the clinical management of ovarian cancer have resulted in an overall decreased incidence of disease and prolonged survival (Seer, n.d; Somasegar et al., 2024). However, ovarian cancer continues to have the highest incidence-fatality rate of any gynecologic malignancy (Torre et al., 2018), predominantly because the disease has often already metastasized at the time of diagnosis. Despite efforts to use biomarker assays such as cancer antigen 125 (CA125) and Human epididymis protein 4 (HE4) in combination with ultrasonography, a screening tool for ovarian cancer that is sensitive and specific enough to be feasible on a wide scale has not been developed (Goff et al., 2007; Buys, 2011; Jacobs et al., 2016). Ovarian cancer is relatively rare, with a 1.1 % lifetime risk, and thus screening tests require a specificity of greater than 90 % to prevent a large number of false positives that can lead to harm (Jacobs et al., 2016; Van Gorp et al., 2011; Urban et al., 2018; Urban et al., 2017; Menon et al., 2009; Moore et al., 2011). In the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Randomized Controlled Trial, for example, 15 % of patients who underwent surgery for a false positive screen result suffered a major surgical complication such as infection, cardiovascular event, or bowel injury (Buys, 2011). The UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS) showed that using CA125 and ultrasonography as a screening tool did increase the number of cancers diagnosed at early stage, but did not improve overall survival (Jacobs et al., 2016). These studies suggest that there is limited to no role of screening in low risk women. Currently the diagnosis of ovarian cancer is made when a clinician has a high index of suspicion in a symptomatic patient (Burke et al., 2023).

Ovarian cancer symptoms are vague and non-specific but are nevertheless present. Studies have consistently shown that 75–90 % of patients with early stage ovarian cancer have symptoms prior to diagnosis; bloating (B), Eating problems (E), abdominal pain (A), trouble with urination (T) are the most common symptoms identified (Smith

* Corresponding author at: Department of Obstetrics and Gynecology, University of Colorado School of Medicine, 12631 East 17th, Avenue, Room 4007, B198-6, Aurora, CO, 80045, United States.
E-mail address: Eric.Helm@CUAnschutz.edu (E.D. Helm).

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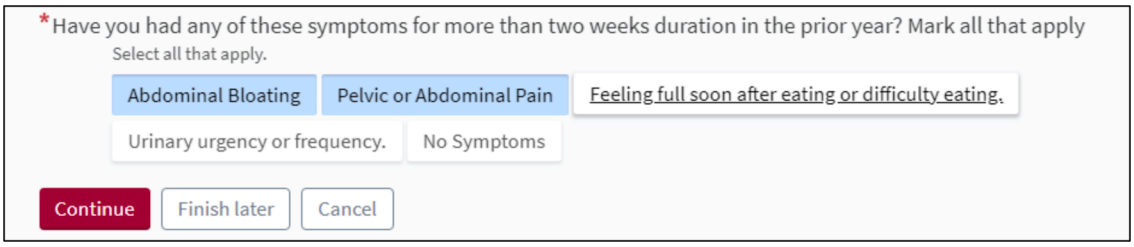

Fig. 1. Gynecologic oncology symptoms questionnaire in patient portal to be completed prior to a gynecologic preventive care visit.

and Anderson, 1985; Goff, 2004; Goff, 2022; Chan et al., 2022). We have described these symptoms with the BEAT acronym. One survey of patients with ovarian cancer showed that over a third of patients eventually diagnosed with advanced ovarian cancer were initially diagnosed with depression, irritable bowel syndrome, or told that they had "nothing wrong" (Goff et al., 2000). In response to such work, a validated symptom inventory that has a 56.7 % and 79.5 % sensitivity for early and late-stage ovarian cancer, respectively, and an approximately 90 % specificity was proposed (Goff et al., 2007).

Symptom inventories (SI) have been piloted in clinics to assess feasibility of implementation of questionnaires for ovarian cancer symptoms (Wickline et al., 2022; Goff et al., 2012). However, using a SI as a screening modality has not been piloted in an electronic format in an average-risk population. Because the patient portal administered through Electronic Medical Records (EMR) has been used successfully to improve screening rates for colorectal and lung cancers in other populations (Dharod et al., 2019; Goshgarian et al., 2022), we chose to use the patient-facing portal to administer a symptom survey for ovarian cancer.

The goals of this study were to assess the uptake and feasibility of an electronically administered SI for patients presenting for an annual or new patient visit in a generalist obstetrics and gynecology (OBGYN) faculty practice and to explore the output of such a survey when administered as part of routine care.

2. Methods

2.1. Questionnaire Design and Setup

Beginning February 2021, a new gynecologic oncology symptoms questionnaire was introduced to the standard intake forms assigned to patients via the patient portal associated with the EMR. The questionnaire triggered for patients $\geq$ 40 years of age who were scheduled for an annual or a new patient visit in a generalist OBGYN faculty practice. Age $\geq$ 40 years was used as a cut-off given the low incidence of ovarian cancer in younger populations and a rise in incidence observed in diagnosis at age 40 (Roett and Evans, 2009; ,UK, n.d). The questionnaire inquired if the patient had any of the following symptoms for more than two weeks duration in the prior year: abdominal bloating, pelvic or abdominal pain, feeling full soon after eating or difficulty eating, or urinary urgency or frequency (Fig. 1). The survey did not ask the duration or frequency of symptoms. In September 2021, a fifth response "No symptoms" was added. Internal Review Board approval was obtained for this study under Exempt status (COMIRB 22–1086).

2.2. Study population

To study the feasibility of survey implementation and uptake by patients, all instances of the questionnaire assigned between February 2021 and July 2023 were included for analysis. To study the results of the symptom inventory, unique patients who completed the questionnaire between September 2021 and July 2023 were included for analysis. Because the survey did not include a "No symptoms" option until September 2021, the data collected prior to this was excluded from

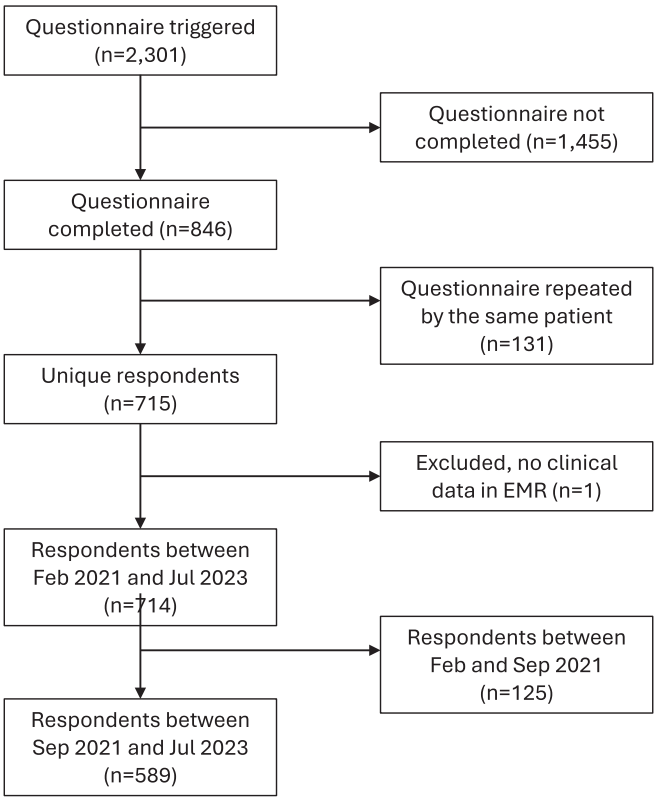

Fig. 2. Flow diagram of study population.

analyses evaluating the prevalence of symptoms and association between symptoms and medical history. Since the questionnaire can be triggered multiple times, if a patient responded to the survey more than once during the study period, the first patient encounter was selected for analysis. One patient who completed the questionnaire for a new patient visit but did not attend the appointment nor have any clinical information available in the EMR was excluded.

2.3. Data Collection and analysis

Responses to the symptoms questionnaire and patient demographics data were obtained from Health Data Compass, which is our institution's data warehouse that integrates patient data from the EMR and provider billing data. Additional data on medical history, interventions or workups performed and their results were manually abstracted from EMR. All workup performed within three months of the preventive care visit, or the date of the questionnaire if the visit was not completed, was included.

Descriptive statistics were used to summarize the data. Continuous variables were reported as medians and ranges, while categorical variables were presented as frequencies and proportions. Comparisons between groups were made using Wilcoxon rank sum test for continuous

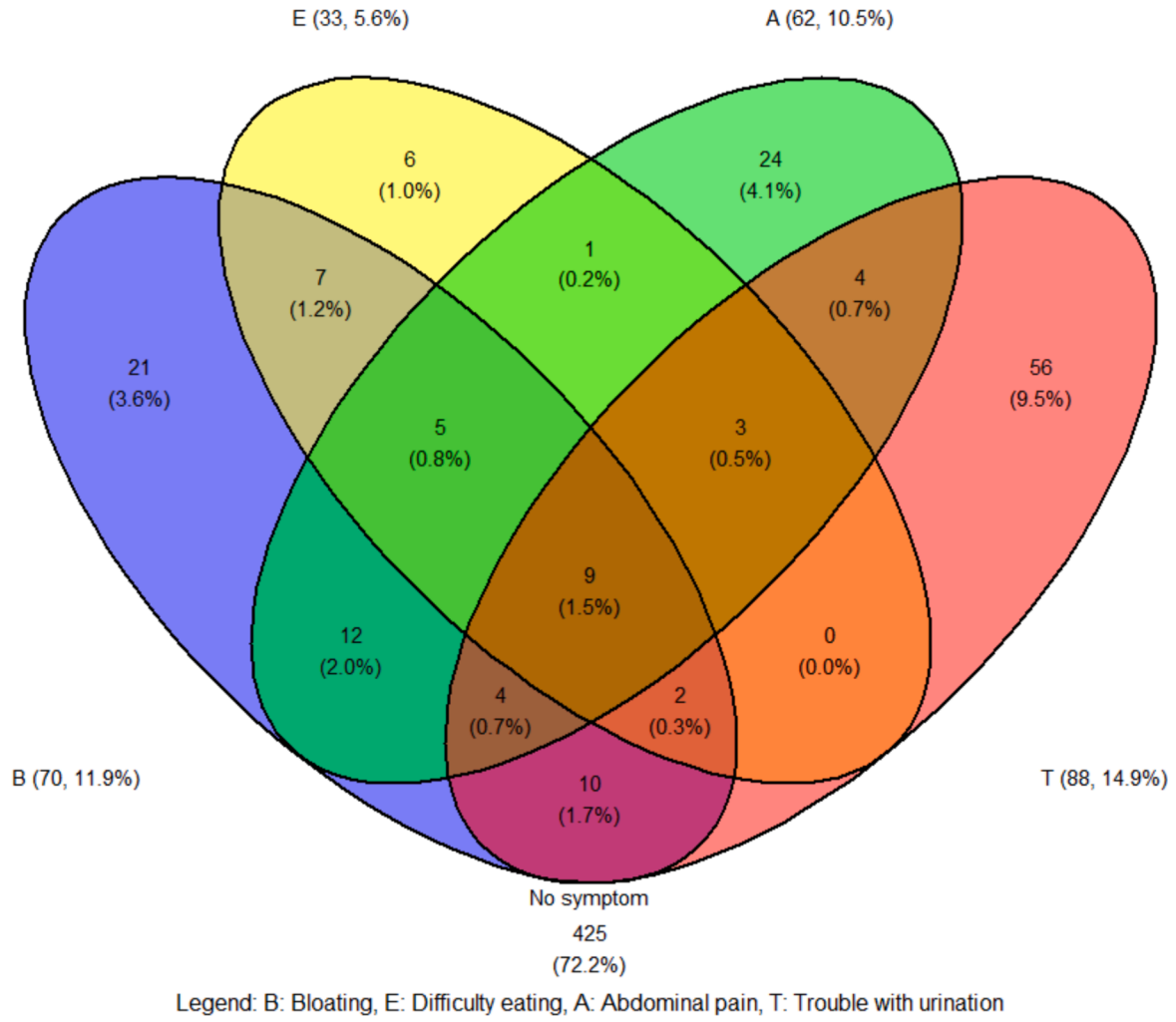

Fig. 3. Distribution of the combinations of symptoms reported by patients presenting for a preventive care visit between September 2021 and July 2023.

variables and Fisher's exact tests for categorical variables. We evaluated the association between the presence of one or more symptoms and prior/concurrent medical conditions through multiple pairwise comparisons. Given the exploratory nature of the study, no adjustments were made for multiple comparisons. All statistical analyses were performed using R Statistical Software, v4.2.3. Visualization of the distribution of symptoms reported was made using the package ggvenn (Yan, n.d).

3. Results

3.1. Feasibility and uptake

During the study period, the survey was expected to have been triggered 2,301 times, and 846 surveys were completed (Fig. 2). However, it is not known how many patients saw or opened the survey as it was not a requirement to complete prior to their visit. This reflects a

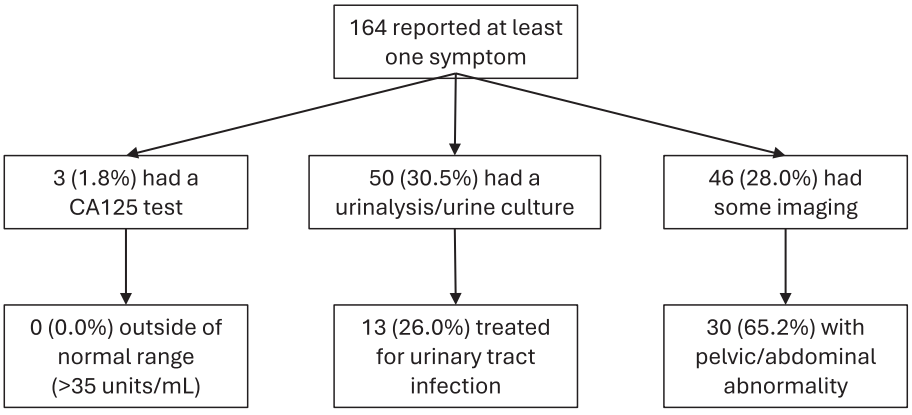

Fig. 4. Workup performed within three months of preventive care visit for patients who reported at least one symptom between September 2021 and July 2023 and their findings. Workup not mutually exclusive; patients may have more than one test performed.

Table 1
Characteristics of individual patients who responded to the symptoms questionnaire between September 2021 and July 2023 and comparison between those reporting no symptom and those reporting at least one symptom.

	Total (N = 589)		No symptom (N = 425)		1 + symptom (N = 164)		
	N	%	N	%	N	%	p-value
Age (median, range)	50	40–86	50	40–86	51	40–79	0.436
Race							0.286
White	425	72.2	309	72.7	116	70.7	
Black/African American	54	9.2	37	8.7	17	10.4	
Asian/Pacific Islander	35	5.9	26	6.1	9	5.5	
American Indian/Alaska Native	4	0.7	2	0.5	2	1.2	
More than one race	10	1.7	4	0.9	6	3.7	
Other	55	9.3	42	9.9	13	7.9	
Not reported	6	1.0	5	1.2	1	0.6	
Personal cancer history	141	23.9	102	24.0	39	23.8	>0.999
Medical history[a]							
Depression	168	28.5	106	24.9	62	37.8	**0.002**
Endometriosis	30	5.1	16	3.8	14	8.5	**0.034**
Adenomyosis	26	4.4	15	3.5	11	6.7	0.116
Uterine fibroids	138	23.4	86	20.2	52	31.7	**0.005**
Ovarian cyst/PCOS	115	19.5	70	16.5	45	27.4	**0.004**
GERD	173	29.4	109	25.6	64	39.0	**0.002**
IBS	35	5.9	16	3.8	19	11.6	**<0.001**
Chronic pelvic pain	19	3.2	5	1.2	14	8.5	**<0.001**
Workup							**<0.001**
None	422	71.6	334	78.6	88	53.7	
CA125/UA/Imaging/Other	167	28.4	91	21.4	76	46.3	

(PCOS: polycystic ovary syndrome; GERD: gastroesophageal reflux disease; IBS: irritable bowel syndrome; UA: urinalysis).
[a] Medical history is not mutually exclusive; percentages do not add to 100%.

minimum response rate of 36.8 %. The 846 surveys were completed by a total of 715 individual patients between February 2021 and July 2023; one patient was excluded from subsequent analyses due to no clinical data in the EMR. The median age of the participants was 50 years (range: 40–86), and the majority were White (72.0 %), followed by Black and Other (9.1 % each), and Asian/Pacific Islander (6.4 %) (data not shown), which reflects the patient diversity at the study site.

3.2. Symptom prevalence

Of the 589 patients included in this portion of the analysis, 164 (27.8 %) reported experiencing at least one symptom associated with ovarian cancer in the prior year (Fig. 3). The most reported symptom was urinary urgency or frequency (n = 88, 14.9 %) and the least reported symptom was early satiety or difficulty eating (n = 33, 5.6 %). Among those 164 reporting symptom(s), most reported only one symptom (n = 107, 65.2 %) and 9 patients (5.5 %) reported experiencing all four symptoms.

3.3. Medical Workup

Of the 164 patients who reported symptoms between September 2021 and July 2023, 76 (46.3 %) underwent some workup within three months of their visit (Fig. 4).

Three patients had a CA125 test ordered by their provider. All CA125 lab tests were less than 35 U/mL. Fifty (30.5 %) patients with a positive SI (reporting any symptom) had a urinalysis and/or urine culture ordered within three months of their preventive care visit. Thirteen of these patients were ultimately treated for a urinary tract infection.

Forty-six (28.0 %) patients with a positive SI had an imaging study ordered. Among these 46 patients, 30 (65.2 %) had an abnormal finding. The most common gynecologic abnormalities were uterine fibroids or polyp (n = 16), ovarian cyst (n = 8), and adenomyosis (n = 2) (abnormalities not mutually exclusive). No ovarian cancers have been diagnosed to date, although prospective follow-up continues.

3.4. Medical history

Women who reported at least one symptom were more likely than women with no symptoms to have a history of depression (37.8 % vs 24.9 %, p = 0.002), endometriosis (8.5 % vs 3.8 %, p = 0.034), uterine fibroids (31.7 % vs 20.2 %, p = 0.005), ovarian cyst or PCOS (27.4 % vs 16.5 %, p = 0.004), gastroesophageal reflux disease (GERD) (39.0 % vs 25.6 %, p = 0.002), irritable bowel syndrome (IBS) (11.6 % vs 3.8 %, p < 0.001) and chronic pelvic pain (8.5 % vs 1.2 %, p < 0.001) (Table 1).

We wanted focus on patients that reported all 4 symptoms and for this reason, chose to include respondants from the entire study period. From February 2021 to July 2023, 14 patients reported experiencing all four symptoms in the prior year. Most had existing diagnoses and/or findings on imaging that may explain their symptoms (Table 2).

4. Discussion

We present an analysis of a patient-facing electronic symptom inventory questionnaire piloted to patients presenting for an annual or

Table 2
Fourteen patients reported experiencing all four symptoms between February 2021 and July 2023. Most had existing conditions and/or findings on imaging that may explain their symptoms. (GERD: gastroesophageal reflux disease; IBS: irritable bowel syndrome; UTI: urinary tract infection).

Patient	Age	Race	Medical History					Imaging findings	UTI
			Endometriosis	Fibroids	Ovarian cyst	GERD	IBS		
1	40	Asian/Pacific Islander	+			+	+	Cystocele	
2	40	White				+		Negative	
3	41	Black/African American		+	+				
4	44	Other				+	+		
5	45	White		+		+			
6	46	White			+			Adenomyosis	+
7	50	White			+				
8	51	Other						Uterine polyp	
9	51	White			+			Negative	
10	52	White		+				Fibroid, ovarian cyst	
11	52	White	+		+			Negative	
12	63	White							
13	64	White	+					Negative	
14	76	White			+	+	+	Ovarian cysts	+

new patient visit in a generalist OBGYN faculty practice. The survey had a minimum response rate of 36.8 %, which could possibly be higher as we do not know how many patients opened the questionnaire. The response rate is consistent with other published EMR surveys (Dharod et al., 2019; Goshgarian et al., 2022; Krist et al., 2017; Meltzer et al., 2024).

In our pilot study, 27.8 % of patients reported a positive response on the SI. This stands in contrast to prior work in which a validated SI showed a positive response rate of 4 % among patients presenting to a primary care clinic (Goff et al., 2012). Our survey may have had a higher positive screening rate for a variety of reasons. We considered if age and its related menopausal status influenced the frequency of the positive survey for each of the symptoms since patients with comorobidites that arise among menstruating patients such as fibroids, endometriosis, and PCOS might be more likely to screen positive. However, in an analysis of responses by age greater than or less than 63 (the average age of ovarian cancer diagnosis), no significant differences in screening positivity was found among any of the four symptoms (data not shown). We do recognize that we are uncertain how many patients saw the questionnaire; if those who did not respond to the survey were all asymptomatic, then the positive SI percentage would be substantially lower. Additionally, our study includes urinary urgency or frequency as a symptom, which was not included in previously validated surveys. Urinary symptoms were the most commonly reported in this survey, and if the 56 patients who exclusively reported a urinary symptom were removed from the analysis, the positive response rate decreases from 27.8 % to 18.3 %. Furthermore, the prior study showing a 4 % positive response rate was a randomized-controlled trial in which all patients who enrolled at a primary care clinic responded to the survey. Our survey inherently includes a response bias by which patients who do not have any symptoms may be less likely to respond. Finally, for the symptom index to be considered positive in the study by Goff et al., the frequency of symptoms needed to be more than 14 days per month and the duration of symptoms needed to be less than one year. Our survey questions inquired if patients had experienced symptoms for at least two weeks in the prior year, and did not include currently experiencing the symptoms, the duration and frequency modifying questions that were implemented as a cutoff value in prior work. Our EMR-based survey was initially designed with simplicity in mind for patients to complete on their smart devices and thus did not include specifying questions regarding the number of times per month experienced the symptom. Future work could focus on both the feasibility and the positive response rate if more follow-up questions are built into the screening tool to create stricter criteria for a positive screen.

The benefit of an electronic survey administered prior to an appointment is the opportunity to establish an agenda in a healthcare environment with increasing demands and metrics yet with decreasing patient interaction time. Additionally, an electronic survey built into the EMR, once established, requires little upkeep and can have further workflows (such as follow up screenings or automatic referrals) built into the system based on the survey results. Whereas surveys administered by front desk or medical assistant/nursing staff require clinical time, effort, and attention to detail at each patient visit, an electronic survey is automatic and does not distract from the other important work of healthcare staff. Furthermore, such an electronic survey can be assigned to patients who meet specific demographic criteria regardless of whether they are presenting to primary or specialist care and does not require a patient to be engaged in gynecologic care. This potentially eliminates a barrier to screening.

Concerns with electronic screenings include barriers such as literacy, language spoken, electronic literacy, access to internet or smart phones and patient preference to interact with a human rather than an electronic application. Our study is limited in that socioeconomic status, literacy level, language spoken and patient communication preferences could not be analyzed; future feasibility studies should focus on factors that contribute to response rate and the best way to reach different populations for screening.

Medical histories of patients who responded with symptoms to the survey more commonly included depression, ovarian cyst/PCOS, uterine fibroids, endometriosis, IBS, GERD, and chronic pelvic pain. These more common medical histories confound screening efforts for ovarian cancer. Creating symptom-based screening algorithms that account for these confounding medical histories is needed and require prospective study. Requiring a duration of symptoms less than a year may help eliminate the false positives screens in women with these chronic conditions.

5. Conclusion

This study describes the feasibility of implementing a patient-facing symptom inventory for ovarian cancer through the electronic medical record to patients presenting for an annual or new patient visits in a generalist OBGYN faculty practice. This study demonstrates that such a survey is feasible and sustainable. However, this study also demonstrates that further workflows would need to be implemented to operationalize an ovarian cancer screening algorithm based on symptoms. Additionally, with 27.8 % of patients screening positive, and most with co-existing contributing medical diagnoses, this study highlights the challenges of using a simplified symptom inventory in a screening algorithm.

CRediT authorship contribution statement

Eric D. Helm: Writing – review & editing, Writing - Original Draft, Project administration, Methodology. **Cam Nguyen:** Writing – review & editing, Writing – original draft, Project administration, Formal analysis. **Stephen Rotholz:** Writing – review & editing, Methodology, Conceptualization. **Saketh R. Guntupalli:** Writing – review & editing, Supervision, Conceptualization. **Barbara A. Goff:** Writing – review & editing, Supervision, Investigation, Conceptualization. **Benjamin G. Bitler:** Writing – review & editing, Methodology, Conceptualization. **Kian Behbakht:** Writing – review & editing, Project administration, Methodology, Investigation, Conceptualization.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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