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Establishing the sensitivity and specificity of the gynaecological cancer distress screen

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Abstract

Objective: Nuanced distress screening tools can help cancer care services manage specific cancer groups' concerns more efficiently. This study examines the sensitivity and specificity of a tool specifically for women with gynaecological cancers (called the Gynaecological Cancer Distress Screen or DT-Gyn).

Methods: This paper presents cross-sectional data from individuals recently treated for gynaecological cancer recruited through Australian cancer care services, partner organisations, and support/advocacy services. Receiver operating characteristics analyses were used to evaluate the diagnostic accuracy of the DT-Gyn against criterion measures for anxiety (GAD-7), depression (patient health questionnaire), and distress (IES-R and K10).

Results: Overall, 373 individuals aged 19–91 provided complete data for the study. Using the recognised distress thermometer (DT) cut-off of 4, 47% of participants were classified as distressed, while a cut-off of 5 suggested that 40% had clinically relevant distress. The DT-Gyn showed good discriminant ability across all measures

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(IES-R: area under the curve (AUC) = 0.86, 95% CI = 0.82–0.90; GAD-7: AUC = 0.89, 95% CI = 0.85–0.93; K10: AUC = 0.88, 95% CI = 0.85–0.92; PHQ-9: AUC = 0.85, 95% CI = 0.81–0.89) and the Youden Index suggested an optimum DT cut-point of 5.

Conclusions: This study established the psychometric properties of the DT-Gyn, a tool designed to identify and manage the common sources of distress in women with gynaecological cancers. We suggest a DT cut point ≥ 5 is optimal in detecting 'clinically relevant' distress, anxiety, and depression in this population.

KEYWORDS

cancer, distress thermometer, gynaecological cancer, oncology, psycho-oncology, psychological support, routine screening, sensitivity, specificity

1 | INTRODUCTION

Psychological distress is a common experience for women with gynaecological cancer, with prevalence estimates ranging from 30% to 85%.^{1,2} For these women, distress is associated with poor treatment compliance,³ increased health service utilisation but reduced adherence to surveillance screening,⁴ impaired quality of life,⁵ and mortality.⁶ Prompt identification and management of distress can reduce emotional suffering for patients and their families or caregivers,⁷ reduce the potentially adverse effects of illness adjustment, and decrease healthcare expenditure and service utilisation.⁸

Screening for distress can facilitate appropriate and timely supportive cancer care⁹ and improve patient outcomes.¹⁰ Of course, there are trade-offs when choosing a screening tool, with a one-size-fits-all approach having limited utility given the number of cancer-specific sources of distress.⁷ Thus, understanding the contextual factors that increase susceptibility to distress will enable cancer service providers to manage women's concerns more efficiently. This is particularly important given that 24%–41% of cancer patients experience psychological symptoms, but most do not disclose them to their cancer care team,¹¹ and for women with gynaecological cancers specifically, holding back concerns is even more common.¹²

Possibly the limited disclosure by women with gynaecological cancer is because of the sensitive nature of many of their concerns (e.g., changes in sexual function and appearance of genitalia,¹³ pain, decreased sexual desire and intimacy,¹⁴ and alterations to perceived body image¹⁵). Adapted screening measures are needed to facilitate robust communication between patients and their cancer care team, identify concerns not easily detected by generic tools, and enable the enactment of appropriate and timely referral pathways.¹⁶

As such, a nuanced distress screening tool specifically for women with gynaecological cancer was developed.¹⁷ However, while this tool, the Gynaecological Cancer Distress Screen or DT-Gyn, has undergone an extensive process to establish face and content validity, sensitivity and specificity have yet to be determined. The present study establishes the initial psychometric properties and has two primary aims to: (1) assess the sensitivity and specificity of the

DT-Gyn in women with gynaecological cancer compared with four gold standard measures for anxiety, depression, and distress; and (2) establish the clinical cut-point scores appropriate for the intended population.

2 | METHODS

This paper presents data from 373 individuals previously treated for gynaecological cancer recruited through Australian gynaecological cancer services (Gold Coast University Hospital, Queensland, Hunter New England Centre for Gynaecological Cancer, New South Wales, Mater Hospital, Queensland), partner organisations (The Wesley Hospital Choices Cancer Support Centre [Choices], Icon Cancer Centre), and gynaecological cancer support/advocacy services (Cancer Council Queensland, Ovarian Cancer Australia, Australia New Zealand Gynaecological Oncology Group, sTEAL STRONG, Queensland Centre for Gynaecological Cancer). Inclusion criteria included being aged 18 and over, being diagnosed with gynaecological cancer in the past 12-month, and the ability to speak and read Grade 8 English, while those with medical contraindications preventing participation were excluded from this study. Women awaiting confirmation of results or who were considered suspected of having a gynaecological cancer (diagnosis pending) were deemed ineligible for participation.

Ethical approval was obtained from relevant Human Research and Ethics Committees (HREC/2018/QGC/48488; GU Ref No: 2019/151) prior to participant recruitment. All participating women provided informed consent and participated in the study without being provided incentive to do so.

2.1 | Participants and procedure

Experienced cancer nurses at each site identified eligible participants at their outpatient appointments and determined if there were clinical, cognitive, or psychiatric conditions, or other reasons, preventing

informed consent. A total of 321 individuals completed the written questionnaire (90% response rate). However, 5 participants did not provide data on key variables (DT-Gyn or Impact of Event Scale-Revised [IES-R]) and were not included in this analysis.

For the community sample, partner organisations and supportive advocacy services were asked to promote the study through flyers, posters, and online platforms (e.g., Facebook). Potential participants were then able to use a QR code or weblink to access the online survey via the REDCap virtual platform. The survey commenced with an extended information sheet and referral list; implied consent was assumed if individuals completed the survey. Overall, 75 women completed the survey, but almost one-quarter ($n = 18$) of the participants were excluded because of missing data.

2.2 | Measurement

A structured survey collected data on socio-demographic characteristics and cancer histories (e.g., age, ethnicity, marital status, education, employment status, cancer diagnosis, treatment received, and previous cancer diagnosis), as well as distress, post-traumatic stress, anxiety, and depressive symptoms.

2.2.1 | Distress thermometer

The distress thermometer (DT) is widely used to screen for global psychological distress in cancer patients, and while this instrument has been widely validated in a variety of cancer populations, one of its limitations is that it does not account for problems or concerns associated with specific cancer types.¹⁸ For this reason, the DT-Gyn was developed.¹⁷ This instrument was adapted from the National Comprehensive Cancer Network (NCCN) DT¹⁹ and retained the single-item 11-point DT (higher scores denoting higher distress) and 11 of the original problem items. An additional 14 gynaecological cancer specific problem items and three open-ended follow-up questions (other sources of distress not currently listed, confirmation of the key sources of distress being experienced, and whether help for experienced distress is sought) were added (tool is provided in Appendix 1). Information about the process of DT-Gyn development have been discussed in detail previously.¹⁷

2.2.2 | Anxiety scale

The GAD-7 is a 7-item instrument to assess generalised anxiety disorder (GAD). Raw scores are summed to form a scale between 0 and 21, with higher scores indicating greater anxiety levels.²⁰ Initial scale development suggested scores ≥ 10 were consistent with potentially significant generalised anxiety (sensitivity 89%, specificity 82%, ICC = 0.83)²⁰ as well as other anxiety disorders (e.g., post-traumatic stress disorder [PTSD], panic disorders and social anxiety disorder²¹) and its associated functional disability.²²

2.2.3 | Patient health questionnaire

The Patient Health Questionnaire (PHQ-9) is a 9-item instrument used to screen for the presence and severity of depressive symptoms.²³ The instrument is scored by summing 8 of the 9 items, with higher scores denoting greater symptom severity and a cut-point ≥ 10 suggestive of depression. Validation of this instrument has shown sensitivity between 74% and 88% and a specificity of 88% and 91% in detecting major depression.²³

2.2.4 | Psychological distress measures

Two measures of distress were included in this study, the IES-R and Kessler's Psychological distress scale (K10). The IES-R is a 22-item measure that comprises three subscales (intrusion, avoidance and hyperarousal) which are summed to form a measure for current subjective distress (ranging from 0 to 88), with a cut-point of >33 denoting symptoms consistent with post-traumatic distress.²⁴ The instrument has demonstrated excellent internal reliability for the total scale score ($\alpha = 0.94\text{--}0.95$).²⁵ The K10 includes 10-items related to psychological distress,²⁶ with lower scores (≤ 19) indicating low levels of distress, scores between 20 and 24 indicating moderate distress, and scores ≥ 25 indicating high levels of distress.²⁶

2.3 | Statistical considerations

2.3.1 | Sample size

Sample size calculations were informed by DT validation studies.^{27,28} We assumed the ratio of those with clinically relevant distress (cases, DT ≥ 4) to those without (controls <4) in our sample would be 40:60, with an estimated tool sensitivity and specificity of 85% and 80%, respectively. To ensure a sensitivity $\geq 85\%$ (95% confidence interval [CI] = 0.79–0.91) and a specificity $\geq 80\%$ (95% CI = 0.74–0.81) with one-sided $\alpha = 0.025$, we required 137 cases. Thus, a total sample of 343 women (137 cases/206 controls) was needed to achieve adequate power for this analysis. To account for missing data and non-response (10%), a final sample of 377 women was required.

2.3.2 | Statistical analysis

Statistical analyses were performed using SPSS (Statistical Package for the Social Sciences) version 23²⁹ and STATA 13.³⁰ Descriptive data are expressed as counts and percentages, mean and standard deviation (SD) or median and interquartile range (IQR), and bivariate statistics were performed using chi-square (χ^2) tests, ANOVA, Pearson correlation coefficients or their non-parametric equivalents. Statistical significance was set at $\alpha = 0.05$.

Nonparametric estimation of the receiver operating characteristics (ROC) analysis with 95% Bamber confidence intervals

(95% CI)³¹ were used to determine the optimal cut-off for the DT-Gyn against the criterion measures for anxiety (GAD-7), depression (PHQ-9), and distress (IES-R and K10). ROC curves estimated the sensitivity (true-positive rate) and specificity (true-negative rate) for each DT value (0–10) relative to the established cut-off score of the GAD-7 (≥ 10), PHQ-9 (≥ 10), IES-R (≥ 33), and K10 (≥ 25). Optimal DT thresholds were determined using the area under the curve (AUC), which quantified the ability of the instrument to discriminate between participants with and without 'clinically relevant distress'. For this study, diagnostic accuracy was defined as acceptable ($AUC \leq 0.70$), good ($AUC \leq 0.80$), and excellent ($AUC \leq 0.90$).³²

In addition to the ROC analyses, the percentage correctly classified, and the positive and negative likelihood ratios, were determined. To further evaluate performance at a given cut-point, the Youden index was calculated. The Youden index has a maximum value of 1 (a perfect test) and a minimum of 0 (denoting a test with no diagnostic value), with the optimum being when both the sensitivity and specificity are equal to 1.³³

3 | RESULTS

3.1 | Participant characteristics

Table 1 presents the characteristics of participating individuals by study site. The average age was 57 years ($SD = 14$), with those recruited at the Mater and from the community being younger than Gold Coast University and John Hunter Hospital participants ($F(3,374) = 8.886, p < 0.01$). First Nations Australians comprised a small proportion of the sample and were primarily recruited from Mater and John Hunter Hospitals ($\chi^2(3) = 8.524, p = 0.04$). In contrast, the proportion of participants born outside Australia varied from 36% at the Mater Hospital, to 8% of the community sample ($\chi^2(3) = 24.546, p < 0.01$). Around three-quarters of participants reported a household income of \$80,000AUD or less (29.6%, < \$20,000; 34.9%, \$20,000 to \$59,999; 15.3%, \$60,000 to \$79,999), 58% were married or living with their partner, and one-third (34.5%) were retired. No differences were noted between these groups.

When examining cancer histories, some differences were noted between sites. Three-quarters of community participants reported having had ovarian cancer (75.4%), almost half of John Hunter Hospital participants reported having uterine/endometrial cancer (45.6%), and most Gold Coast and Mater Hospital participants reported cancer of the ovary (34.4% and 28.3% respectively), uterus/endometrium (35.2% and 34.2% respectively), or cervix (24.6% and 25.0% respectively) ($\chi^2(9) = 74.569, p < 0.01$). Results are further detailed in Table 1.

3.2 | Distress

Non-parametric descriptive statistics and correlations using Spearman's rho are outlined in Table 2. The median DT score for

individuals in this study was 3 [IQR = 5.0], and using the recognised DT cut-off of 4, 46.6% of participants were classified as distressed ($n = 174$), and when using a cut-off of 5, 39.9% of participants were classified as distressed ($n = 149$). The median score for the IES-R was 16.0 [IRQ = 31.0], GAD-7 was 4.0 [IQR = 9.0], K10 was 15.0 [IQR = 11.0], and PHQ-9 was 5.5 [IQR = 9]. These values corresponded with 28% of participants reporting an IES-R score ≥ 33 (probable PTSD), 23% reported a GAD-7 ≥ 10 (GAD), 21% had a K10 score ≥ 25 (high psychological distress), and 30% reported a PHQ-9 score ≥ 10 , suggestive of major depression. Moderate-strong positive correlations were noted between the DT and measures for anxiety (GAD-7; $r_s = 0.72, 95\% CI = 0.55, 0.83, p < 0.01$), depression (PHQ-9; $r_s = 0.64, 95\% CI = 0.45, 0.78, p < 0.01$), and distress (IES-R; $r_s = 0.69, 95\% CI = 0.51, 0.81, p < 0.01$; K10, $r_s = 0.81, 95\% CI = 0.69, 0.89, p < 0.01$).

3.3 | Diagnostic accuracy of the DT

The ROC analysis summary statistics, graphical representations, and Youden Index are detailed in Table 3, Figure 1, and Table S1 (in Online Supplemental Materials). The area under the ROC curve showed good discriminative ability across all criterion measures (IES-R: $AUC = 0.86, 95\% CI = 0.82, 0.90$; GAD-7: $AUC = 0.89, 95\% CI = 0.85, 0.93$; K10: $AUC = 0.88, 95\% CI = 0.85, 0.92$; PHQ-9: $AUC = 0.85, 95\% CI = 0.81, 0.89$) and the Youden Index suggested an optimum DT cut-point of 5 for the IES-R, K10, and PHQ-9 and for 6 for the GAD-7 (see Table 3).

With consideration to the Youden Index, a DT cut-point ≥ 5 was recommended rather than a DT cut-point ≥ 6 , as it maximised sensitivity and specificity against the GAD-7. At this cut-point provided 80% sensitivity (95% CI = 70%, 88%) and 78% specificity (95% CI = 80%, 89%), with around 85% of women correctly classified as having GAD symptoms. For the IES-R, a cut-point ≥ 5 provided 85% sensitivity (95% CI = 77%, 92%) and 77% specificity (95% CI = 71%, 82%), with ~80% of women correctly classified as having symptoms consistent with PTSD symptoms. The optimum cut-point for the K10 was ≥ 5 , which provided 92% sensitivity (95% CI = 84%, 97%) and 73% specificity (95% CI = 67%, 78%), with 77% of women correctly classified as having psychological distress. Finally, for the PHQ-9 at a cut-point ≥ 5 which provided 82% sensitivity (95% CI = 74%, 89%), and 78% specificity (95% CI = 72%, 82%), with around 79% of women correctly classified as having symptoms of clinical depression.

4 | DISCUSSION

This study examined the sensitivity and specificity of the DT-Gyn, a nuanced tool designed to accurately identify and manage distress in women with gynaecological cancer. The DT-Gyn showed good sensitivity and specificity across all gold-standard measures of psychological distress ($AUC = 0.85-0.89$, sensitivity = 85–92, specificity = 73–78). Other studies in gynaecological cancer patients have

TABLE 1 Characteristics of the sample.^a

	GCUH n (%) or M (SD)	Mater n (%) or M (SD)	JHH n (%) or M (SD)	Community n (%) or M (SD)	Total n (%) or M (SD)
Mean age (SD)	59.2 (13.6)	54.5 (14.8)	62.0 (12.9)	51.4 (13.3)	57.1 (14.2)**
First nations Australian					
No	120 (100)	114 (95.8)	73 (94.8)	57 (100)	364 (97.6)*
Yes	0 (0.0)	5 (4.2)	4 (5.2)	0	9 (2.4)
Country of birth					
Australia	75 (62.0)	77 (64.2)	68 (86.1)	35 (92.1)	255 (71.2)**
Elsewhere	46 (38.0)	43 (35.8)	11 (13.9)	3 (7.9)	103 (28.8)
Annual household income (AUD)					
Less than \$20,000	28 (31.8)	31 (33.0)	20 (29.4)	10 (19.6)	89 (29.6)
\$20,000 to \$59,999	32 (36.4)	30 (31.9)	29 (42.6)	14 (27.5)	105 (34.9)
\$60,000 to \$79,999	11 (12.5)	13 (13.8)	8 (11.8)	14 (27.5)	46 (15.3)
\$80,000 to \$99,999	8 (9.1)	9 (9.6)	5 (7.4)	2 (3.9)	24 (8.0)
More than \$100,000	9 (10.2)	11 (11.7)	6 (8.8)	11 (21.6)	37 (12.3)
Marital status					
Married/de facto	72 (60.5)	67 (55.8)	41 (53.2)	36 (63.2)	216 (57.9)
Separated/divorced	19 (16.0)	25 (20.8)	14 (18.2)	10 (17.5)	68 (18.2)
Widowed	12 (10.1)	8 (6.7)	14 (18.2)	1 (1.8)	35 (9.4)
Single	16 (13.4)	20 (16.7)	8 (10.4)	10 (17.5)	54 (14.5)
Educational attainment					
Primary education	1 (0.8)	7 (5.8)	2 (2.6)	0	10 (2.7)**
Secondary education	59 (48.8)	54 (45.0)	37 (47.4)	11 (19.3)	161 (42.8)
Certificate/diploma	37 (30.6)	38 (31.7)	23 (29.5)	16 (28.1)	114 (30.3)
Bachelor's degree	23 (19.0)	21 (17.5)	16 (20.5)	20 (35.1)	80 (21.3)
Postgraduate degree	1 (0.8)	0	0	10 (17.5)	11 (2.9)
Employment status					
Employed full-time	27 (22.5)	23 (19.3)	11 (13.9)	11 (20.8)	72 (19.4)
Employed part-time	19 (15.8)	23 (19.3)	13 (16.5)	15 (28.3)	70 (18.9)
Home duties	12 (10.0)	13 (10.9)	9 (11.4)	2 (3.8)	36 (9.7)
Student	0 (0.0)	3 (2.5)	1 (1.3)	1 (1.9)	5 (1.3)
Retired	46 (38.3)	38 (31.9)	34 (43.0)	10 (18.9)	128 (34.5)
Unable to work	16 (13.3)	19 (16.0)	11 (13.9)	14 (26.4)	60 (16.2)
Cancer type					
Ovary	42 (34.4)	34 (28.3)	11 (13.9)	43 (75.4)	130 (34.4)**
Uterus/Endometrial/Uterine	43 (35.2)	41 (34.2)	36 (45.6)	5 (8.8)	125 (33.1)
Cervix	30 (24.6)	30 (25.0)	13 (16.5)	6 (10.5)	79 (20.9)
Other ^b	7 (5.7)	15 (12.5)	19 (24.1)	3 (5.3)	44 (11.6)
Cancer stage					
Stage I	50 (41.0)	66 (55.5)	49 (65.3)	21 (36.8)	186 (49.9)**
Stage II	26 (21.3)	22 (18.5)	9 (12.0)	5 (8.8)	62 (16.6)

(Continues)

TABLE 1 (Continued)

	GCUH n (%) or M (SD)	Mater n (%) or M (SD)	JHH n (%) or M (SD)	Community n (%) or M (SD)	Total n (%) or M (SD)
Stage III	22 (18.0)	26 (21.8)	14 (18.7)	19 (33.3)	81 (21.7)
Stage IV	24 (19.7)	5 (4.2)	3 (4.0)	12 (21.1)	44 (11.8)
Cancer recurrence					
No	102 (83.6)	108 (90.0)	69 (87.3)	29 (56.9)	308 (82.8)**
Yes	20 (16.4)	12 (10.0)	10 (12.7)	22 (43.1)	64 (17.2)
Mean months since diagnosis (SD)	22.0 (20.7)	24.9 (17.5)	31.1 (38.4)	0	25.4 (25.5)

Abbreviations: AUD, Australian dollars; GCUH, Gold Coast University hospital; JHH, John Hunter hospital.

^an's might differ because of missing values.

^b'Other cancers' comprised individuals with cancer of the vulva (8.7%, $n = 33$), vagina (0.5%, $n = 2$), fallopian tube (2.1%, $n = 8$) and other genital area (0.3%, $n = 1$).

* $p < 0.05$; ** $p < 0.01$.

TABLE 2 Dispersion, correlations and 95% confidence intervals^a between the DT-Gyn and validated instruments.

	n	Md [IQR]	DT-Gyn r_s (95% CI)	IES r_s (95% CI)	GAD r_s (95% CI)	K10 r_s (95% CI)	PHQ r_s (95% CI)
DT-Gyn score	373	3.0 [5.0]	--				
IES-R total score	375	16.0 [31.0]	0.69 (0.51, 0.81)**	--			
GAD-7 total score	373	4.0 [9.0]	0.72 (0.55, 0.83)**	0.73 (0.58, 0.84)**	--		
K10 total score	371	15.0 [11.0]	0.81 (0.69, 0.89)**	0.74 (0.59, 0.85)**	0.77 (0.63, 0.86)**	--	
PHQ-9 total score	374	5.5 [9]	0.64 (0.45, 0.78)**	0.56 (0.34, 0.72)**	0.64 (0.45, 0.78)**	0.81 (0.68, 0.88)**	--

Abbreviations: DT-Gyn, gynaecological cancer distress screen; GAD-7, generalised anxiety disorder scale; IES-R, impact of event scale—Revised; K10, Kessler's psychological wellbeing scale; PHQ-9, patient health questionnaire.

^aEstimation is based on Fisher's r -to- z transformation and Fieller, Hartley, and Pearson standard errors.

**Spearman Rho for rank order correlation is significant at the 0.01 level (2-tailed).

TABLE 3 Summary validation measures for the DT-Gyn including the Youden index.

Measure ^a	Sensitivity 95% CI	Specificity 95% CI	Youden index	Distribution	Optimum cut-point for the DT ^b
IES-R	0.85 (0.77, 0.92)	0.77 (0.71, 0.82)	0.63	0.27	≥ 5
GAD-7	0.80 (0.70, 0.88)	0.85 (0.80, 0.89)	0.65	0.25	≥ 6
K10	0.92 (0.84, 97)	0.73 (0.67, 0.78)	0.65	0.27	≥ 5
PHQ-9	0.82 (0.74, 0.89)	0.78 (0.72, 0.82)	0.60	0.29	≥ 5

Abbreviations: DT, distress thermometer; GAD-7, generalised anxiety disorder scale; IES-R, impact of event scale-revised; K10, Kessler's psychological wellbeing scale; PHQ-9, patient health questionnaire.

^aCaseness was defined as ≥ 33 for Impact of Event Scale—Revised, ≥ 10 on the anxiety (GAD-7) and depression (PHQ-9) scales, and a score of ≥ 20 for the K10.

^bThe optimal cut-off for the DT is given by the maximum value of the Youden index which measures the vertical distance from the line of equality to the ROC curve.

recommended cut-points ranging from 2 to 7.^{34,35} The heterogeneity of cancer populations (age, cancer type, symptom burden and its impact on interpersonal functioning^{13,14}) partially explains differences in defined 'clinically relevant distress', though the NCCN identifies DT scores ≥ 4 as significant.¹⁹ Moreover, while a lower DT

cut point will increase sensitivity, the trade-off needs to be commensurate with the potential benefits. At a cut-point of three, our study provided little certainty about the probability of 'clinically-relevant distress' among those with a positive DT score (positive likelihood ratio ~ 1.8 ³⁶). In contrast, using a DT cut-point ≥ 5 , almost

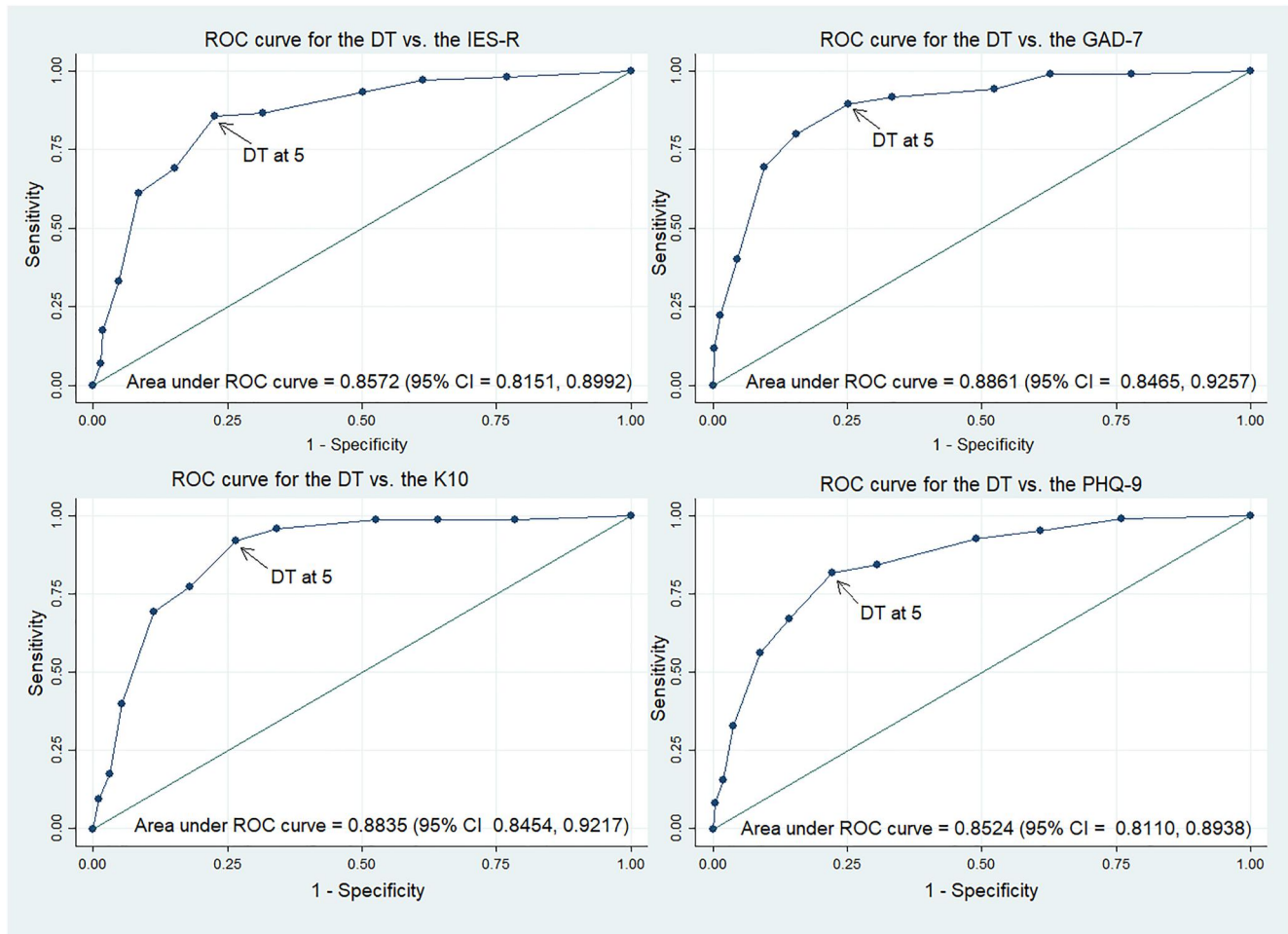


FIGURE 1 ROC curves for the Distress Thermometer criterion measures for anxiety (GAD-7), depression (PHQ-9), and distress (IES-R and K10). DT, distress thermometer; GAD-7, generalised anxiety disorder scale; IES-R, impact of event scale—Revised; K10, Kessler's psychological wellbeing scale; PHQ-9, patient health questionnaire; ROC, receiver operating characteristics.

80% of women in this study were correctly classified and, given a positive result, had a 3.5-fold increased probability of having clinically relevant distress.³⁶

Results from this study are consistent with other research in gynaecological cancer populations. Around 40% of women reported a DT score ≥ 5 compared with 35% of women in a US study.³⁷ Using a cut-point of 5 and a clinical pathway model for universal distress screening, the American study found a 15% increase in multidisciplinary service referrals and a 32% increase in social work referrals alone. Given the sources of distress reported by many women in this study and the request for informational and practical supports, it can be anticipated that implementing comprehensive distress screening programs would result in similar resource/infrastructure requirements.

Of course, the increased service requirements associated with routine distress screening must be balanced against the significant economic and psychosocial costs associated with unrecognised and untreated distress. According to the Australian Bureau of Statistics, around 15% of Australian adults report high or very high levels of psychological distress using the K10, which has a considerable economic impact on individuals, families and the broader community.³⁸

In cancer populations, distress is associated with reduced treatment adherence, dissatisfaction with clinical care, and decreased survival,³⁹ and targeted and timely distress management is likely to reduce its potential negative consequences. Thus, while comprehensive screening programs can identify distress in women with cancer, understanding the contextual factors that increase susceptibility can help cancer care teams and service providers to manage women's concerns more efficiently. For example, the prevalence and severity of distress frequently differ by cancer type, socioeconomic status, and life stage^{1,37,40} and during periods of uncertainty along the cancer journey.⁴⁰ Clinicians and other health professionals in this arena need to be cognisant of the characteristics that increase vulnerability to distress to tailor supportive care pathways to meet the needs of specific sub-populations.^{1,40}

4.1 | Study limitations

Several limitations need to be highlighted. First, the study must be considered within the context in which it occurred, that is, the global

COVID-19 pandemic. COVID-19 has profoundly affected individuals, families, and the wider community, and the impact posed by lockdowns, physical distancing, and potential social isolation cannot be underestimated. While the effects of COVID-19 on health and well-being are well documented, sensitivity analysis in this study did not find significant differences in distress levels by study site over time (see Figure S1 in Online Supplemental Materials for further details).

COVID-19 also impacted research progression, with restrictions delaying or preventing study completion. Like many other studies, there was difficulty recruiting participants as many eligible women switched to telehealth consultations and access to hospitals was only restricted to essential personnel. Consequently, this study was paused for 6 months between March and September 2020. Though the temporary pause did not influence recruitment targets, the delays at participating sites extended recruitment from 4 to 7 months (ending in April 2021) when funding was exhausted.

Next, around one-quarter (24%, $n = 18$) of the community sample did not provide complete data for this analysis. This might reflect sensitive nature of many questions or survey burden and might provide insight into the utility of the tool as an online instrument. Finally, women in this study were treated as a homogeneous group. While this was appropriate for statistical purposes, it is important to acknowledge the heterogeneity of women with cancer and the particular vulnerabilities affecting specific patient subgroups and further research exploring differences across stage (early vs. advanced), cancer type, and age are needed.¹ Despite this, anecdotal evidence suggested that participants and research staff perceived the tool positively and welcomed enhanced cancer care opportunities.

4.2 | Clinical implications

Despite the brevity and simple structure of the DT-Gyn and other distress screening tools, the implementation of routine distress screening remains ad hoc.⁴¹ Implementing comprehensive distress screening is operationally complex and screening naïve services need to consider how to best integrate distress screening programs into their setting and ensure adequate systems of care to treat distressed patients.⁴² It is not enough to simply identify distress in these populations, and while not all distressed patients will accept referral, psycho-oncology infrastructure is needed. This is particularly important as identifying patients with clinically relevant distress is likely to increase the demand for supportive cancer care.⁸

As such, implementation of low intensity models is recommended, where access is the central guiding value and where intervention depth and focus can be guided by the level of distress and the nature of women's concerns.⁴³ Using the tiered approach, low intensity interventions emphasising self-management, symptom control, and behaviour change can be delivered by a range of different health professionals involved in the woman's care (for example including specialist cancer nurses and allied health), while for those who report high distress and complex problems, more specialised or

intensive interventions can be provided by trained specialist health professionals or multi-disciplinary team.⁴³

Reducing contextual barriers (poor health literacy, anticipated resistance in patients, lack of training for staff, and having sufficient time to devote to patients' identified concerns⁸) associated with screening non-adherence is also necessary. According to the NCCN, distress screening education needs to include the following components: (1) The prevalence of distress in women with gynaecological cancer and its potential impact on clinical care⁴⁰; (2) Using a systematic approach to identify patient distress; (3) Potential sources of distress reported by gynaecological cancer patients and the strategies for improving supportive cancer care,⁴⁰ and; (4) Guidance in developing topic-elicitors that promote therapeutic communication with patients about their distress and the importance of managing their psychosocial concerns.⁸

4.3 | Conclusion

This study established the sensitivity and specificity of the DT-Gyn in women with gynaecological cancer. It suggests a DT cut point ≥ 5 is optimal in detecting 'clinically relevant' distress, anxiety, and depression in this population. Moreover, the information generated through the 'cancer-specific problem list' can enhance disclosure, thus providing a significant opportunity to improve the supportive care for women with gynaecological cancer.

AUTHOR CONTRIBUTIONS

Concept and design of the study: Charrlotte Seib, Emma Harbeck, Debra Anderson, Suzanne Chambers. Data collection: Janine Porter-Steele, Jasotha Sanmugarajah, Lewis Perrin, Catherine Shannon, Nimithri Cabraal, Bronwyn Jennings, Geoffrey Otton, Catherine Adams, Anne Mellon. Data analysis and interpretation: Charrlotte Seib, Emma Harbeck, Suzanne Chambers. Writing manuscript: Charrlotte Seib, Emma Harbeck. Critical revision of findings: Caroline Nehill. Critical review final manuscript and approval: Charrlotte Seib, Emma Harbeck, Debra Anderson, Janine Porter-Steele, Caroline Nehill, Jasotha Sanmugarajah, Lewis Perrin, Catherine Shannon, Nimithri Cabraal, Bronwyn Jennings, Geoffrey Otton, Catherine Adams, Anne Mellon, Suzanne Chambers.

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CONFLICT OF INTEREST STATEMENT

Caroline Nehill is employed at Cancer Australia, who funded this project. All other authors declare that they have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that supports the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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