Knowledge of Potential Harms and Benefits of Tamoxifen among Women Considering Breast Cancer Preventive Therapy

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ABSTRACT

Tamoxifen reduces breast cancer incidence in women at increased risk, but may cause side effects. We examined women's knowledge of tamoxifen's potential harms and benefits, and the extent to which knowledge reflects subjective judgments of awareness and decision quality. After a hospital appointment, 408 (55.7%) women at increased risk of breast cancer completed a survey assessing objective knowledge about the potential benefit (risk reduction) and harms (endometrial cancer, thromboembolic events, and menopausal side effects) of tamoxifen, and subjective tamoxifen knowledge and decisional quality. Two hundred fifty-eight (63.2%) completed a 3-month follow-up survey. Sixteen percent (15.7%) of participants recognized the potential benefit and three major harms of using tamoxifen. These women were more likely to have degree-level education [vs. below degree level; OR, 2.24; 95% confidence interval (CI), 1.11–4.55] and good numeracy (vs. poor numeracy; OR, 5.91; 95% CI, 1.33–26.19). Tamoxifen uptake was higher in women who recognized all harms and benefits (vs. not recognizing; OR, 2.47; 95% CI, 0.94–6.54). Sixty-six percent (65.8%) of tamoxifen users were unaware of its potential benefit and harms. Most (87.1%) women reported feeling informed about tamoxifen, and subjective decisional quality was high [Mean (SD), 17.03 (1.87), out of 18]. Knowledge regarding the potential harms and benefit of tamoxifen is low in women considering prevention therapy, and they may need additional support to make informed decisions about tamoxifen preventive therapy.

Background

Breast cancer affects of 54,000 women in the United Kingdom (UK) each year. Women with first- and second-degree relatives with breast cancer are at increased risk of developing the disease (2). Breast cancer risk can be calculated using established models (3). The National Institute of Health and Care Excellence (NICE) considers women with a lifetime risk of breast cancer of 17% to 30% to be at moderate risk, and those exceeding this level to be at high risk (4). Women within these categories are eligible for early mammographic screening and have the option of using medications for preventive therapy.

Tamoxifen can reduce breast cancer risk among this population by at least 30% (5, 6). However, tamoxifen users may experience adverse effects of the medication. For example, tamoxifen increases the risk of gynecological and vasomotor symptoms, thromboembolic events, and endometrial cancer (5, 7–9). The majority of side effects start within 12 months of initiation, but can occur throughout treatment (7, 8).

There is widespread reluctance to use preventive therapy among patients, with fewer than one in seven eligible women initiating therapy after it has been offered (10–12). Lack of information on chemoprevention has been reported by patients as one barrier to initiation (13, 14). Healthcare professionals in primary and secondary care have expressed concern about their ability to discuss the harms and benefits with patients (15). A national survey of UK general practitioners (GP) indicated just over half were aware tamoxifen could reduce breast cancer risk in healthy women, and only 42% felt comfortable discussing its harms and benefits (16). Women may feel dissatisfied with the support they receive from healthcare professionals and could leave appointments without a clear understanding of the potential harms and benefits of chemoprevention.

Supporting women to make an informed decision should be a goal of a clinical appointment, as outlined in shared decision-making frameworks both in the UK (17) and in the United States (18). Assessing objective patient knowledge is one approach to evaluating the quality of decisions occurring in this setting. However, it is also important to consider subjective methods, such as the extent to which people feel informed and satisfied with their involvement in the decision-making

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process (19, 20). Subjective knowledge assessments may reflect perceived adequacy of the information provided (20), but are often only weakly associated with objective knowledge (21). To date, no studies have included subjective assessments of decision quality in women considering preventive therapy, indicating that aspects of informed decision-making have not been fully considered. In women making breast cancer treatment decisions, clinician communication style (22, 23) and receipt of a decision support tool (24) were related to subjective decision quality, and ethnic minority groups were more likely to report lower quality decision-making experiences (25).

In this study, we assessed objective knowledge about the potential harms and benefits of tamoxifen in women at increased risk of breast cancer, and also women's subjective assessments of their knowledge and the quality of their decision about chemoprevention. We examined the socio-demographic, health-service, and psychologic factors associated with objective knowledge about tamoxifen, and the extent to which knowledge was related to tamoxifen uptake and subjective decisional quality.

Materials and Methods

Ethics

Ethical approval was awarded by the National Research Ethics Service Committee North West—Preston (14/NW/1408). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Context

Recruitment took place between September 2015 and December 2016 in hospital outpatient clinic settings. At the time these data were collected, tamoxifen was included within the 2013 NICE clinical guideline CG164 for the management and care of women with a family history of breast cancer (26). However, at this point tamoxifen was not licensed for this indication by the Medicines and Healthcare products Regulatory Agency (MHRA), meaning that clinicians wishing to prescribe the drug would have to do so "off-label."

Women who present to primary care due to concerns about their breast cancer risk are referred to secondary care if their GP believes they are likely to meet NICE criteria for moderate or high breast cancer risk (4). During the secondary care appointment, women are asked about the age and onset of cancers within their family to produce a pedigree. This information is used to assess their risk as "population level," "moderate," or "high" according to NICE thresholds (4). This phrasing is used with patients, unless they specifically ask for a percentage risk estimate. If a numerical risk estimate is requested, they will be told the following risk estimates: population (<17% lifetime risk), moderate (17%–29% lifetime risk), and high (≥ 30% lifetime risk). The topic of tamoxifen will be discussed with women who are at moderate or high risk. Women who are interested in using tamoxifen for primary prevention will generally be required to book a GP appointment, where the GP will consider prescribing the drug, in consultation with a secondary clinician. However, in some circumstances, the prescription could be initiated in secondary care by a clinical geneticist, oncologist, or surgeon, and subsequently continued in primary care by a GP.

Four types of clinic in secondary and tertiary care were used to identify women at increased risk of breast cancer: family history clinics ($n = 12$), breast clinics ($n = 4$), clinical genetics centers ($n = 3$), and a family history clinic with genetics support ($n = 1$). Most of the clinics were located in major cities across England.

Participants

Following their appointment, women were approached by a research nurse or a healthcare professional to discuss the study. Women were eligible if they were aged 18 years or older, spoke English, had discussed preventive therapy with a healthcare professional, were assessed within their clinical appointment as having a "moderately high" or "high" risk of breast cancer according to NICE guidelines (4), and had no known contraindications for tamoxifen use. The study protocol did not require healthcare professionals to change any aspect of the discussion they would typically have with patients, including how tamoxifen was presented during the consultation. Women provided verbal consent to their details being passed on to the research team, and then consent was implied following the return of the written questionnaire. Women were excluded if they could not read English, had a previous diagnosis of breast cancer, or the research nurse or healthcare professional felt they did not have the mental capacity to consent.

Measures

Women were invited to complete a baseline survey containing measures of knowledge, healthcare professional satisfaction, and information provision. Women returning baseline questionnaires were sent a follow-up questionnaire at 3 months containing a measure of subjective decisional quality and an item assessing their decision about uptake of tamoxifen for preventive therapy. Length of follow-up was decided on the basis that this was a reasonable amount of time to consider the harms and benefits of tamoxifen and speak with a GP about obtaining a prescription. A reminder postcard was sent to participants who did not respond to either the baseline or 3-month questionnaire within 2 weeks. A reminder questionnaire was sent to participants who did not return either the baseline or 3-month questionnaire within 2 weeks of the reminder postcard. The full baseline survey and follow-up survey are available here: https://osf.io/mqz9y/.

Objective knowledge about tamoxifen

The items assessing objective knowledge were adapted from a six-item questionnaire used previously (27). Knowledge was

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assessed by listing three potential harms of using tamoxifen for preventive therapy (endometrial cancer, menopausal symptoms, blood clotting) and one potential benefit (breast cancer). For each potential harm and benefit, women were asked "Who is more likely to experience the following. . .?" Responses were: "Women who take tamoxifen," "Women who do not take tamoxifen," "Both groups are equally likely," and "Unsure." The correct response for the three potential harms was "Women who take tamoxifen," and the correct response for the potential benefit was "Women who do not take tamoxifen." All other responses were marked as incorrect. Women who correctly answered all three potential harms and the potential benefit of using tamoxifen were classified as having good knowledge in the main analysis. Women who had missing data on any of the four items were excluded from the analysis ($n = 25$). The Kuder–Richardson reliability coefficient (KR-20) for this four-item scale was 0.65.

Subjective knowledge about tamoxifen

A single item assessed participants' current perceived knowledge about tamoxifen following their appointment in secondary care: "How informed do you feel about tamoxifen and its use by women at increased risk of breast cancer?" Responses were: "Not very informed at all" (=1), "Quite uninformed" (=2), "Quite well informed" (=3), and "Very well informed" (=4). We wanted to examine the group of women who reported feeling strongly uninformed; therefore, participants who responded "Not very informed at all" were coded as being uninformed. All other responses were coded as informed in the analysis.

Healthcare professional satisfaction

The validated genetic counseling satisfaction scale was used (28). This six-item scale assesses patient satisfaction with the appointment and healthcare professional. In this context, participants assessed their satisfaction with their appointment in secondary care and the healthcare professional they saw during that visit (e.g., family history physician, genetics counselor, clinical geneticist, surgeon, nurse specialist). Example items include: "The clinician considered any stress I was facing," "The clinician was concerned about my wellbeing," and "The appointment was helpful to me." Each item was scored on a 4-point scale ["strongly disagree" (=1) to "strongly agree" (=4)]. Items were summed to create a scale score ranging from 6 to 24, with higher scores indicating stronger healthcare professional satisfaction. Cronbach's alpha for the total scale was 0.93.

Information provision

A single item assessed whether women reported receiving information about preventive therapy during their appointment: "During your hospital appointment, did the clinician give you a leaflet about tamoxifen?" ("Yes," "No," and "Unsure"). No and unsure responses were combined, with missing data for this item also included in this category.

Subjective decision quality

The brief measure of subjective decision quality for breast cancer treatment was adapted for the preventive therapy setting and used in the 3-month follow-up questionnaire (20). This scale assesses six dimensions of subjective decision quality: "How 'right for you' was your decision about tamoxifen" (fit) ["not at all right for me" (=1); "neither right or wrong" (=2); "completely right for me" (=3)]; "How much information did you have for your decision about tamoxifen" (adequacy of information) ["not enough information" (=1); "enough information" (=2); "too much information" (=3)]; "How much time did you have for your decision about tamoxifen" (adequacy of time) ["not enough time" (=1); "just right" (=2); "too much time" (=3)]; "How much involvement did you have in your decision about tamoxifen" (adequacy of involvement) ["not enough involvement" (=1); "just right" (=2); "too much involvement" (=3)]; "How much regret do you have with regard to your decision about tamoxifen?" (regret) ["no regret" (=1); "some regret" (=2); a lot of regret (=3)]; "How satisfied are you with the decision you made about tamoxifen" (satisfaction) ["not at all satisfied" (=1); "somewhat satisfied" (=2); "totally satisfied" (=3)]. Each item included a "still deciding" response (=4). As the quality of decisions cannot be assessed in people who have not finalized their decision, we restricted our analysis of this outcome to the subsample of women who reported that they had made a decision (56.8%, 146/257). Responses were recoded in line with the original guidelines (20). A single-scale score was calculated (ranging from 6 to 18), with higher scores indicating higher subjective decision quality. Cronbach's alpha for the total scale was 0.75.

Preventive therapy decision

Women were asked to indicate which of seven statements applied to them with regard to their decision about using tamoxifen for preventive therapy. The options were: "I decided immediately that I did not want to take tamoxifen," "After some thought, I decided that I did not want to take tamoxifen," "I am still deciding if I want to take tamoxifen," "I met with my GP to talk about tamoxifen, and I decided against it," "I met with my GP to talk about tamoxifen, but they would not prescribe it," "I have a prescription for tamoxifen from my GP," and "I am currently taking tamoxifen." Women were classified as initiating tamoxifen if they reported having a prescription for tamoxifen from their GP or were currently taking tamoxifen (11).

Analysis

The analysis plan was preregistered (DOI 10.17605/OSF.IO/YE6D2). To establish potential bias among the sample retained at follow-up, women responding to the baseline questionnaire only were compared with respondents to the 3-month questionnaire with regard to objective and perceived knowledge about tamoxifen, healthcare professional satisfaction, and information provision. *T* tests and Pearson χ^2 test were used where appropriate. Differences in socio-demographic and

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clinical factors between responders and nonresponders to the baseline questionnaire have previously been reported, and no differences were observed (11).

Measures were described using percentages [with 95% confidence intervals (CI)] and means (with SD). A multivariable logistic regression model was used to identify factors associated with good objective knowledge of tamoxifen, defined as recognizing all three major potential harms and the potential benefit. This model was adjusted for participant characteristics, information provision, healthcare professional satisfaction, and subjective knowledge about tamoxifen. In a sensitivity analysis, the proportion of women who correctly identified the benefit and at least two out of the three potential harms associated with tamoxifen were classified as having good knowledge about tamoxifen.

To identify the factors associated with higher subjective decisional quality, we used a multivariable linear regression model adjusted for the same factors previously described as well as objective knowledge about tamoxifen. Multivariable logistic regression was used to examine factors associated with preventive therapy uptake (yes vs. no). *The likelihood of having missing data for each of the measures is likely to be associated with individual factors (e.g., education level) or the variable itself (e.g., avoidance of knowledge assessments). As such, the missing data would be missing at random or missing not at random.* Missing data were deleted listwise when examining descriptive data and univariable associations, and pairwise when multivariable analyses were used. A value of $P \leq 0.05$ was considered to be statistically significant. The analysis was completed in SPSS version 21.0.

Results

Sample

In total, 732 women were invited to complete a survey; 408 women (55.7%; 95% CI, 52.1–59.4) returned the baseline survey and 258 (63.2%; 95% CI, 58.4–67.9) women provided uptake data at least 3 months after their appointment.

Participant characteristics, clinical information, and descriptions of the measures are presented in **Tables 1** and **2**. The mean age of baseline respondents was 45.3 years (SD ± 7.82). The majority of women had children, were married or cohabiting, had attained less than a degree level of education, correctly answered the numeracy item, were white, had good or excellent health, and were employed. The sample included more women who were classified as having a "moderately high" risk of breast cancer than a "high" risk of breast cancer. Patient satisfaction with healthcare professionals was high (mean = 19.30, SD ± 3.77 out of 24).

There were no differences between women who provided baseline data only and those who were retained at 3-month follow-up with regards to objective knowledge, healthcare professional satisfaction, and information provision (Supplementary Table S1). A higher proportion of women who provided baseline and 3-month data felt informed about tamoxifen following their appointment in secondary care (91.0%; 95% CI, 86.8–94.2) compared with women who provided baseline data only (80.3%; 95% CI, 72.9–86.4).

Table 1. Description of demographic and clinical data.

Mean (± SD) for continuous variables; % (95% CI) for categorical variables		
Baseline (*n* = 408)		***n***
Age, mean ± SD	45.30 ± 7.82	408
Children		
Yes	77.0 (72.6–81.0)	314
No	23.0 (19.0–27.4)	94
White ethnic group		
White	95.5 (93.0–97.3)	384
Other	4.5 (2.7–7.0)	18
Missing, *n*	6	
Education level		
Degree or above	44.2 (39.3–49.3)	176
Below degree level	55.8 (50.7–60.7)	222
Missing, *n*	10	
Health status		
Poor	4.0 (2.3–6.4)	16
Fair	19.5 (15.7–23.7)	78
Good	60.0 (55.0–64.8)	240
Excellent	16.5 (13.0–20.5)	66
Missing, *n*	8	
Risk level		
Moderate	59.6 (54.6–64.4)	243
High	39.0 (34.2–43.9)	159
Unclear	1.5 (0.5–3.2)	6
SES		
Low (most deprived)	29.9 (25.5–34.7)	120
Middle	32.7 (28.1–37.5)	131
High (least deprived)	37.4 (32.7–42.3)	150
Missing, *n*	7	
Employment		
Full-time	85.3 (81.5–88.6)	348
All other employments	14.7 (11.4–18.5)	60
Marital status		
Married or cohabiting	74.3 (69.7–78.5)	298
Unmarried	25.7 (21.5–30.3)	103
Missing, *n*	7	
Numeracy		
Good numeracy	81.8 (77.6–85.5)	323
Poor numeracy	18.2 (14.5–22.4)	72
Missing, *n*	13	

Abbreviation: SES, socio-economic status.

Knowledge about tamoxifen harms and benefits and information provision

The majority of women reported feeling informed about tamoxifen and its use by women at increased risk of breast cancer following their appointment in secondary care (87.1%; 95% CI, 83.4–90.2). However, in the objective assessment, only 15.7% (95% CI, 12.2–19.7) of women correctly identified the potential benefit (breast cancer risk reduction) and all three potential harms (endometrial cancer, menopausal symptoms, blood clotting) of using tamoxifen. Overall, 60.9% (95% CI, 55.8–65.7) of women were aware tamoxifen could reduce breast cancer risk. Half of the sample were aware women taking

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Table 2. Description of tamoxifen knowledge and psychologic data.

Baseline ($n = 408$)	Mean (± SD) for continuous variables; % (95% CI) for categorical variables	*n*
Received a leaflet about tamoxifen		
Yes	71.1 (66.4–75.4)	290
No	25.7 (21.6–30.3)	105
Unsure	3.2 (1.7–5.4)	13
Knowledge		
Potential benefit and harms of using tamoxifen[a]		
Yes	15.7 (12.2–19.7)	60
No	84.3 (80.3–87.8)	323
Missing, *n*	25	
Tamoxifen can reduce breast cancer risk		
Yes	60.9 (55.8–65.7)	238
No	39.1 (34.3–44.2)	153
Missing, *n*	17	
Tamoxifen can increase risk of menopausal symptoms		
Yes	50.1 (45.1–55.2)	197
No	49.9 (44.8–54.9)	196
Missing, *n*	15	
Tamoxifen can increase risk of blood clotting		
Yes	49.7 (44.7–54.8)	193
No	50.3 (45.2–55.3)	195
Missing, *n*	20	
Tamoxifen can increase risk of endometrial cancer		
Yes	27.3 (22.9–32.0)	107
No	72.7 (68.0–77.1)	285
Missing, *n*	16	
Satisfaction with healthcare professional, mean ± SD	19.30 (3.77)	375
Missing, *n*	33	
Felt informed about tamoxifen		
Yes	87.1 (83.4–90.2)	351
No	12.9 (9.8–16.6)	52
Missing, *n*	5	
Three month follow-up ($n = 258$)		
Subjective decisional quality, mean ± SD	17.03 ± 1.87	146
"Still deciding," *n*	111	
Missing, *n*	1	

[a]This variable included the potential benefit of tamoxifen (a reduction in breast cancer risk) and three potential harms of tamoxifen (increased risk of menopausal symptoms, blood clotting, and endometrial cancer).

tamoxifen were more likely to experience menopausal symptoms (50.1%; 95% CI, 45.1–55.2) and blood clotting (49.7%; 95% CI, 44.7–54.8), and 27.3% (95% CI, 22.9–32.0) had knowledge about the increased risk of endometrial cancer associated with tamoxifen. A fifth (18.2%; 95% CI, 14.5–22.4) of women recognized all three potential harms associated with taking tamoxifen.

In a multivariable analysis, women with a higher level of education (OR, 2.24; 95% CI, 1.11–4.55; $P = 0.025$) and with higher numeracy levels (OR, 5.91; 95% CI, 1.33–26.19; $P = 0.019$) were more likely to have good knowledge about the potential benefits and harms of tamoxifen (**Table 3**).

A registered sensitivity analyses changing the threshold for "good knowledge," and an exploratory analysis reclassifying those with missing data as having incorrect knowledge, did not affect these estimates (Supplementary Tables S2 and S3; Supplementary Appendix).

In total, 71.1% (95% CI, 66.4–75.4) of women stated their healthcare professional gave them a leaflet about tamoxifen during their appointment, with 28.9% (95% CI, 24.6–33.6) of women reporting that they did not receive or were unsure whether they received a leaflet. A higher proportion of women who received a leaflet about tamoxifen had good knowledge on its harms and benefits (17.9%), compared with those who did not receive a leaflet or were unsure (10.1%). In the multivariable analysis (**Table 3**), this difference was not statistically significant (OR, 1.54; 95% CI, 0.66–3.59; $P = 0.313$).

Subjective decisional quality

Among women who were followed-up at 3 months ($n = 258$), 257 completed the decisional quality scale. Of this group, 111 (43.2%; 95% CI, 37.1–49.5) stated they were still deciding about tamoxifen (on ≥ 1 item) and 146 (56.8%; 95% CI, 50.5–62.9) had made their decision regarding tamoxifen. We conducted an exploratory analysis to examine the factors associated with women reporting they were still deciding about tamoxifen on one or more items on the subjective decision quality scale (Supplementary Table S4). In the multivariable analysis, women who felt more informed about tamoxifen were less likely to be still deciding about tamoxifen at 3 months (OR, 0.88; 95% CI, 0.81–0.96; $P = 0.003$).

Overall, among women who reported making a decision, there was a high level of decisional quality about tamoxifen, with a mean ± SD score of 17.03 ± 1.87 out of a possible 18. Most women reported having no regret about their decision (92.5%; 95% CI, 88.2–96.8; 135/146), having the right amount of involvement in their decision (93.8%; 95% CI, 89.9–97.7; 137/146), felt enough information was provided (90.4%; 95% CI, 85.6–95.2; 132/146), and had the right amount of time to make a decision (95.9%; 95% CI, 92.7–99.1; 140/146). Endorsement was lower for whether the decision was "completely right for me" (78.1%; 95% CI, 71.4–84.8; 114/146), and for feeling totally satisfied with their decision (77.4%; 95% CI, 70.6–84.2; 113/146).

In a multivariable model including women who had reached a decision about tamoxifen initiation ($n = 128$), those who felt more informed about tamoxifen after their appointment in secondary care (vs. less informed; $\beta = 0.22$, $P = 0.018$) and who were from more disadvantaged socioeconomic backgrounds (vs. least deprived; $\beta = 0.27$, $P = 0.015$) reported higher decisional quality (**Table 4**; $n = 18$ missing data).

Factors associated with uptake of tamoxifen

Responses to the uptake items included: "I decided immediately that I did not want to take tamoxifen" (20.5%; 95% CI, 15.8–26.0; 53/258), "After some thought, I decided that I did not want to take tamoxifen" (29.8%; 95% CI, 24.3–35.8; 77/258), "I am still deciding if I want to take tamoxifen" (30.6%; 95% CI, 25.1–36.6; 79/258), "I met with my GP to talk about

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Table 3. Knowledge about the potential harms and benefits of tamoxifen by participant characteristics and univariable and multivariable logistic regression model ($n = 317$).

		Univariable		Multivariable	
Good knowledge[a] (%; *N*)		**OR (95% CI)**	***P* value**	**OR (95% CI)**	***P* value**
Age					
≤ 35 years	10.3 (4)	0.66 (0.20–2.11)	0.479	0.54 (0.11–2.61)	0.443
36–49 years	16.9 (41)	1.16 (0.61–2.21)	0.644	0.71 (0.31–1.62)	0.417
≥ 50 years	14.9 (15)	Ref.		Ref.	
Children					
Yes	16.2 (48)	1.21 (0.61–2.40)	0.585	1.38 (0.54–3.56)	0.504
No	13.8 (12)	Ref.		Ref.	
Ethnic group[b]					
White	15.1 (55)	—	—	—	—
Other	28.6 (4)	—	—	—	—
Education level					
Degree or above	22.2 (38)	2.40 (1.36–4.25)	**0.003**	2.24 (1.11–4.55)	**0.025**
Below degree level	10.6 (22)	Ref.		Ref.	
Health status					
Poor[b]	20.0 (3)	—		—	
Fair	6.8 (5)	0.36 (0.12–1.13)	0.079	0.39 (0.11–1.41)	0.149
Good	18.3 (42)	1.12 (0.53–2.39)	0.764	1.13 (0.48–2.65)	0.777
Excellent	16.7 (10)	Ref.		Ref.	
Risk level					
Moderate	18.9 (43)	1.82 (0.99–3.33)	0.052	1.96 (0.95–4.04)	0.069
High	11.3 (17)	Ref.		Ref.	
Unclear[b]	0.0 (0)	—		—	
SES					
Low (most deprived)	14.3 (16)	0.83 (0.42–1.67)	0.606	0.97 (0.43–2.22)	0.945
Middle	15.0 (19)	0.88 (0.45–1.71)	0.704	0.87 (0.39–1.93)	0.734
High (least deprived)	16.7 (23)	Ref.		Ref.	
Employment					
Full-time	16.1 (53)	Ref.		Ref.	
All other employments	13.0 (7)	0.78 (0.33–1.81)	0.556	1.07 (0.42–2.74)	0.894
Marital status					
Married or cohabiting	16.3 (46)	1.16 (0.60–2.21)	0.662	0.99 (0.43–2.29)	0.985
Unmarried	14.4 (14)	Ref.		Ref.	
Numeracy					
Good numeracy	19.0 (58)	7.72 (1.84–32.43)	**0.005**	5.91 (1.33–26.19)	**0.019**
Poor numeracy	2.9 (2)	Ref.		Ref.	
Received leaflet					
Yes	17.9 (49)	1.94 (0.97–3.89)	0.062	1.54 (0.66–3.59)	0.313
No/unsure	10.1 (11)	Ref.		Ref.	
Satisfaction with HCP					
Mean ± SD	19.34 ± 3.55	1.00 (0.93–1.09)	0.922	0.98 (0.90–1.07)	0.664
Informed about tamoxifen					
Yes	17.4 (58)	4.85 (1.15–20.55)	**0.032**	5.36 (0.67–42.66)	0.113
No	4.2 (2)	Ref.		Ref.	

Note: Bold *P*-values indicate that this finding reaches statistical significance $P < 0.05$.
Abbreviation: SES, socio-economic status.
[a]This variable included the potential benefit of tamoxifen (a reduction in breast cancer risk) and three potential harms of tamoxifen (increased risk of menopausal symptoms, blood clotting, and endometrial cancer).
[b]Category not included in univariable and multivariable analyses due to insufficient cases.

tamoxifen, and I decided against it" (3.5%; 95% CI, 1.6–6.5; 9/258), "I met with my GP to talk about tamoxifen, but they will not prescribe it" (0%, 0/258), "I have a prescription for tamoxifen from my GP" (2.7%; 95% CI, 1.1–5.5; 7/258), and "I am currently taking tamoxifen" (12.0%; 95% CI, 8.3–16.6; 31/258). Two women did not provide a yes response to any item. Uptake of tamoxifen at 3-month follow-up was 14.7% (95% CI, 10.6–19.7, 38/258) when combining responses from women with a prescription and who reported currently using tamoxifen.

A higher proportion of women with good objective knowledge about the potential benefits and harms of using tamoxifen initiated chemoprevention (27.9%; 95% CI, 15.3–43.7; 12/43), compared with those with poor knowledge (12.2%; 95% CI, 8.00–17.5; 25/205; **Table 5**). There were no statistically significant associations in the multivariable model (**Table 5**). Despite greater knowledge among women using tamoxifen compared with nonusers, levels were not optimal: 65.8% (95% CI, 48.6–80.4; 25/38) of this group failed to

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Table 4. Subjective decisional quality by participant characteristics and univariable and multivariable linear regression model ($n = 128$).

		Univariable			Multivariable		
Decisional quality (mean ± SD)		**B (SE)**	**β**	***P* value**	**B (SE)**	**β**	***P* value**
Age							
≤ 35 years	16.41 ± 2.15	−0.26 (0.56)	−0.04	0.652	0.17 (0.74)	0.03	0.816
36–49 years	17.24 ± 1.51	0.58 (0.39)	0.14	0.139	0.50 (0.48)	0.12	0.294
≥ 50 years	16.67 ± 2.59	Ref.	—	—	Ref.	—	—
Children							
Yes	17.13 ± 1.58	0.48 (0.37)	0.11	0.205	0.24 (0.52)	0.05	0.644
No	16.66 ± 2.66	Ref.	—	—	Ref.	—	—
Ethnic group							
White	17.04 ± 1.89	0.20 (0.78)	0.02	0.796	0.73 (0.97)	0.07	0.451
Other	16.83 ± 1.33	Ref.	—	—	Ref.	—	—
Education level							
Degree or above	17.08 ± 1.86	0.11 (0.31)	0.03	0.728	−0.21 (0.41)	-0.05	0.604
Below degree level	16.97 ± 1.90	Ref.	—	—	Ref.	—	—
Health status							
Poor	17.17 ± 0.98	0.13 (0.83)	0.01	0.871	0.18 (1.12)	0.02	0.876
Fair	16.19 ± 2.65	−0.84 (0.49)	−0.17	0.091	−1.13 (0.58)	-0.23	0.054
Good	17.28 ± 1.65	0.25 (0.39)	0.07	0.526	0.04 (0.46)	0.01	0.936
Excellent	17.03 ± 1.66	Ref.	—	—	Ref.	—	—
Risk level							
Moderate	17.15 ± 1.41	0.38 (0.33)	0.10	0.248	0.25 (0.38)	0.06	0.515
High	16.77 ± 2.57	Ref.	—	—	Ref.	—	—
Unclear[a]	—	—			—		—
SES							
Low (most deprived)	17.36 ± 1.11	0.40 (0.41)	0.09	0.333	1.25 (0.51)	0.27	**0.015**
Middle	16.84 ± 2.28	−0.12 (0.36)	−0.03	0.731	0.08 (0.42)	0.02	0.855
High (least deprived)	16.97 ± 1.84	Ref.	—	—	Ref.	—	—
Employment							
Full-time	17.10 ± 1.90	0.48 (0.44)	0.09	0.281	0.60 (0.53)	0.11	0.258
All other	16.62 ± 1.66	Ref.	—	—	Ref.	—	—
Marital status							
Married or cohabiting	17.13 ± 1.57	0.53 (0.38)	0.12	0.169	0.41 (0.51)	0.09	0.418
Unmarried	16.60 ± 2.75	Ref.	—	—	Ref.	—	-
Numeracy							
Good numeracy	17.07 ± 1.80	0.37 (0.43)	0.07	0.389	0.42 (0.49)	0.08	0.393
Poor numeracy	16.70 ± 2.29	Ref.	—	—	Ref.	—	—
Received leaflet							
Yes	17.13 ± 1.37	0.34 (0.34)	0.08	0.323	0.21 (0.42)	0.05	0.620
No/unsure	16.79 ± 2.75	Ref.	—	—	Ref.	—	—
Satisfaction with HCP							
Mean ± SD	-	0.02 (0.04)	0.03	0.729	−0.02 (0.05)	−0.04	0.642
Informed about tamoxifen							
Yes	17.13 ± 1.77	1.88 (0.67)	0.23	**0.005**	1.78 (0.74)	0.22	**0.018**
No	15.25 ± 2.76	Ref.	—	—	Ref.		—
Knowledge—harms and benefits							
Yes	17.33 ± 1.41	0.37 (0.41)	0.08	0.365	0.23 (0.48)	0.04	0.640
No	16.97 ± 1.99	Ref.	—	—	Ref.		

Note: Bold *P*-values indicate that this finding reaches statistical significance $P < 0.05$.
Abbreviation: SES, socio-economic status.
[a]Category not included in univariable and multivariable analyses due to insufficient cases.

recognize the major potential benefit and three major potential harms of the drug.

Discussion

In this multicenter survey of healthy women considering breast cancer primary prevention, only one in six women recognized the potential benefits and harms of tamoxifen, i.e., that it can reduce breast cancer risk, but may cause thromboembolic events, endometrial cancer, and menopausal side-effects. A third of women in this sample did not recognize any of these harms. Knowledge was particularly poor among women with lower levels of education and numeracy. Knowledge was higher among women who reported tamoxifen use at follow-up, but even among this group two thirds failed to recognize the key benefit and all three harms. Women's

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Table 5. Uptake of tamoxifen by participant characteristics and univariable and multivariable logistic regression model ($n = 187$).

Uptake of tamoxifen (*N*; %)		Univariable		Multivariable	
		OR (95% CI)	*P* value	OR (95% CI)	*P* value
Age					
≤ 35 years[a]	1 (3.8)	—		—	—
36–49 years	29 (17.3)	1.46 (0.63–3.39)	0.378	1.31 (0.46–3.76)	0.617
≥ 50 years	8 (12.5)	Ref.		Ref.	
Children					
Yes	36 (17.6)	5.43 (1.26–23.34)	**0.023**	3.71 (0.73–18.80)	0.113
No	2 (3.8)	Ref.		Ref.	
Ethnic group[a]					
White	37 (15)	—	—	—	—
Other	1 (11.1)	Ref.		Ref.	
Education level					
Degree or above	20 (17.2)	1.41 (0.71–2.82)	0.327	1.54 (0.61–3.89)	0.360
Below degree level	18 (12.9)	Ref.		Ref.	
Health status					
Poor[a]	0	—	—	—	—
Fair	5 (10.6)	0.68 (0.20–2.32)	0.538	0.81 (0.19–3.56)	0.783
Good	25 (16.6)	1.13 (0.46–2.82)	0.787	1.28 (0.43–3.84)	0.661
Excellent	7 (14.9)	Ref.		Ref.	
Risk level					
Moderate	24 (15.1)	1.05 (0.52–2.15)	0.885	0.75 (0.32–1.77)	0.510
High	14 (14.4)	Ref.		Ref.	
Unclear[a]	0	—		—	—
SES					
Low (most deprived)	7 (11.9)	0.78 (0.30–2.03)	0.613	1.57 (0.54–4.58)	0.412
Middle	14 (16.3)	1.13 (0.52–2.47)	0.759	1.66 (0.64–4.27)	0.296
High (least deprived)	16 (14.7)	Ref.		Ref.	
Employment					
Full-time	32 (14.5)	Ref.		Ref.	
All other employments	6 (16.2)	1.14 (0.44–2.96)	0.783	1.88 (0.62–5.68)	0.265
Marital status					
Married or cohabiting	33 (16.7)	2.16 (0.80–5.81)	0.127	1.64 (0.47–5.70)	0.435
Unmarried	5 (8.5)	Ref.		Ref.	
Numeracy					
Good numeracy	32 (15.3)	1.37 (0.50–3.76)	0.536	1.21 (0.35–4.23)	0.765
Poor numeracy	5 (11.6)	Ref.		Ref.	
Received leaflet about tamoxifen					
Yes	28 (14.9)	1.05 (0.48–2.29)	0.903	0.62 (0.24–1.58)	0.314
No/unsure	10 (14.3)	Ref.		Ref.	
Satisfaction with HCP					
Mean ± SD	19.54 ± 3.34	1.02 (0.93–1.12)	0.689	1.06 (0.94–1.20)	0.349
Felt informed about tamoxifen[a]					
Yes	38 (16.3)	—	—	—	—
No	0 (0.0)	Ref.		Ref.	
Knowledge—harms and benefits					
Yes	12 (27.9)	2.79 (1.27–6.12)	**0.011**	2.47 (0.94–6.54)	0.067
No	25 (12.2)	Ref.		Ref.	

Note: Bold *P*-values indicate that this finding reaches statistical significance $P < 0.05$.
Abbreviation: SES, socio-economic status.
[a]Category not included in univariable and multivariable analyses due to insufficient cases.

decisions regarding breast cancer preventive therapy appear to be based on incomplete information, and this may be a particular problem for those with low literacy and numeracy skills.

The finding of poor knowledge among users of tamoxifen may be problematic from a safety perspective. A lower level of awareness of these potential harms may hinder recognition of an adverse event and delay or prevent help-seeking behavior. Healthcare professionals counseling women who are initiating tamoxifen for primary prevention should promote awareness of these signs and symptoms during the counseling process. This should be presented using absolute risk information so patients are aware these harms are possible, but can accurately gauge the likelihood of experiencing them. If GPs are to initiate tamoxifen prescriptions, or continue those that have been started in secondary care, they are likely to require information and support. A recent national survey of GPs indicated nearly 60% felt uncomfortable discussing the harms and benefits of

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tamoxifen for primary prevention (16), although this study was conducted prior to it being licensed for this indication, in November 2018. Low knowledge among women initiating preventive therapy may also have detrimental effects on long-term adherence to the medication (29), which has been shown to be problematic in this context (8, 30).

As part of their discussion about tamoxifen, a substantial minority of women did not report receiving written information during their appointment. Clinical centers should make efforts to improve dissemination to ensure all women considering preventive therapy are provided with written informational support. However, improvements may be needed to the information currently being provided, as receipt of information may not substantially affect women's knowledge of tamoxifen's harms and benefits. This may be because the information was overly complex, which is supported by the observation that women with lower levels of education and numeracy had poorer knowledge. NICE decision tools are freely available (4). Although these aids frame numerical information using evidence-based approaches (31), they are lengthy documents that contain complex terminology. These aids should be user-tested with the appropriate groups to ensure comprehension and usability (32, 33). Alternative risk communication tools, such as interactive websites and "gist-based information," have been shown to be acceptable to patients (33–35), and can improve breast cancer risk perceptions, knowledge, and interest in using chemoprevention (36, 37). Developing similar tools for use in the context of breast cancer prevention in the UK could be a useful next step.

The data presented here highlight a gap between participants' perceived and actual levels of knowledge about tamoxifen. The low levels of objective knowledge reported were not reflected in women's judgments about their own awareness, with nearly all respondents indicating that they felt quite or very informed about tamoxifen after their appointment in secondary care. Weak associations between subjective and objective knowledge measures have previously been reported (21). Furthermore, objective knowledge did not affect subjective decisional quality, with average scores for this construct being notably high. The high levels of subjective decisional quality suggest that most women felt supported and involved in their decision about chemoprevention, and were satisfied with their choice. Although there are no "correct" responses to subjective decision quality scales (20), our data indicate women may be unaware of gaps in their knowledge, and as a result believe their decisions to be of high quality. Healthcare professionals should be aware that subjective assessments of knowledge and decisional quality may not reflect their own interpretations of a high quality decision in the preventive therapy setting. Clinicians may also need to go beyond simple checks of comprehension, and instead use techniques such as the "teach back" method to verify understanding in verbal consultations (38, 39). This involves the patient reporting back to the communicator their interpretation of the message conveyed, with misunderstandings addressed and clarified. Such measures could enhance the quality of informed decision-making about tamoxifen chemoprevention for women at increased risk of developing breast cancer, even if uptake did not increase.

This study had limitations. Although response rates were high, and there were few differences among responders and nonresponders, those who did not complete the questionnaires may have scored differently on the assessments. The proportion of women using tamoxifen was small, and therefore the CIs for estimates involving this outcome were wide. These data were collected prior to the NICE 2017 updated guidelines recommending anastrozole for postmenopausal women, and therefore our findings may not be generalizable to women considering this drug. The reliability of the subjective decision scale was below levels previously reported (20), and may have affected the associations reported. The study relied on self-reported uptake data, and therefore estimates may not be as reliable as more objective assessments. The proportion of women self-reporting use of tamoxifen at 3 months is likely to be falsely elevated due to a higher likelihood of drop-out among those less interested in the topic (e.g., nonusers). In this study, women were followed up at 3 months to investigate their decision about tamoxifen as this was decided to be a reasonable amount of time to consider the harms and benefits, and speak with a GP. However, data from the subjective decisional quality scale indicated approximately half of the sample were still considering whether to use tamoxifen. A longer follow-up may have affected the proportion of women currently using tamoxifen, and their responses to the decision quality scale. Furthermore, their decision to use breast cancer chemoprevention may have been influenced by discussions in primary care. Tamoxifen's off-license status has previously been identified as a barrier to GP prescribing for breast cancer prevention (16), and the data presented here were collected before this became a licensed indication by the MHRA in 2018.

In conclusion, the majority of women at increased risk of breast cancer considering the use of tamoxifen for primary prevention reported low levels of knowledge in relation to its major potential benefit and harms. Knowledge was particularly poor among women with lower levels of education and numeracy, which has the potential to exacerbate socioeconomic inequalities. Although information leaflets and support tools are available and appear to be provided to the majority of women faced with this decision, they do not appear to be effective at supporting adequate understanding of the potential harms and benefits. Objective knowledge was not associated with women's subjective assessments of tamoxifen knowledge or decisional quality. Healthcare professionals should therefore be cautious about assuming an informed decision about breast cancer prevention has been made, and techniques such as the "teach back" method could

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be usefully employed. There is also scope for developing and testing decision aids about primary prevention of breast cancer using different formats and "gist" versus "verbatim" detail.

Disclosure of Potential Conflicts of Interest

R.J. Thorneloe reports personal fees from Novartis outside the submitted work. K.E. Lloyd reports grants from Economic and Social Research Council during the conduct of the study. S.G. Smith reports grants from Cancer Research UK and grants from Yorkshire Cancer Research during the conduct of the study; personal fees from Leeds University Testing Organisation outside the submitted work. No potential conflicts of interest were disclosed by the other authors.

Availability of Data and Material

Participants did not provide explicit consent for their data to be shared in public repositories. Therefore, data may not be made publicly available due to ethical restrictions. We can share the anonymized version of the data to individual qualified researchers upon request. Data requests may be sent to the corresponding author of this article.

Authors' Contributions

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Acquisition of data (provided animals, acquired and managed patients, provided facilities, etc.): L. Side, S.G. Smith
Analysis and interpretation of data (e.g., statistical analysis, biostatistics, computational analysis): R.J. Thorneloe, L.H. Hall, F.M. Walter, K.E. Lloyd, S.G. Smith
Writing, review, and/or revision of the manuscript: R.J. Thorneloe, L.H. Hall, F.M. Walter, L. Side, K.E. Lloyd, S.G. Smith
Administrative, technical, or material support (i.e., reporting or organizing data, constructing databases): R.J. Thorneloe, L.H. Hall, S.G. Smith
Study supervision: S.G. Smith

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