TORFP: SEER 2016-07 Contract No. HHSN261201300020I Order No. HHSN26100014 Iowa: Elizabeth Chrischilles, Ph.D.

DELIVERABLE: Final Task Order Report

("ONWARD Study")

Contract No. HHSN2612013000201 Task Order No. HHSN26100014 NCI Control No: NO1PC - 2013 - 00020 Iowa: Elizabeth Chrischilles, PhD Submission Date: November 1, 2018

Contents

A. (Dbjectives of the study	3
B. F	Progress to date	4
I	Work completed, organized by task	4
I	I. Any work not completed that was proposed, organized by task	6
C. [Description of the sampling methodology and descriptive statistics for final sample	7
D. [Detailed findings of the Patient Generated Health Data Collection pilot	8
I	. Sampling frame and subject recruitment	8
I	I. Subject enrollment	10
I	II. Data collection and analysis	12
ľ	V. Survey #1 results	12
١	/. Survey #2 Results	19
E. C	Description of any problems encountered and resolution	30
F. C	Data collection instruments	30
G. F	easibility Assessment Report	30
L	. Evaluation of methods used to contact and recruit patients	30
I	I. Evaluation of methods used to collect PGHD from participants. Includes:	30
	a. Evaluation of potential efficacy of the PGHD approach and recommendations for the role of PGHD in future cancer surveillance research	30
	b. Assessment of utility of the specified data collection method as a tool for longitudinal data collection	31
	c. Information about burden the data collection method poses to patients	31
	d. Information about the extent of patient engagement with the study	31
	e. Information about the ease and usability of the data collection tool or process from the patier perspective	nt's 34
	f. Analysis of usefulness to patients of the data summaries provided to them	40
	g. Info about the quality of data collected	40
	h. Assessment of potential for interoperability of the data collection platform with informatics- based registry systems	42
	i. Information about what would be required to replicate the approach in larger studies, includin any technical documentation or info needed to replicate procedures	ıg 43
	i. Decentralized approach	44
	ii. Centralized approach	44
	j. Recommendations for standard operating procedures for the selected approach	45
I	II. A detailed workload requirements report to include:	45

a. A cost breakdown per participant	45
b. Breakdown of costs to 1) identify participants, 2) contact participants, 3) recruit participants, 4 re-contact participants, 5) collect data from participants) 47
Appendix 1. Detailed study recruitment and enrollment procedures	50
I. Invitation mailings	50
II. Enrollment and online survey procedures	50
III. Number of invitation mailings	51
IV. Subject queries	52
V. Nonresponse assessment	52
Appendix 2. Assessment of differences in completion of study procedures by patient and invitation mailing characteristics	53
Appendix 3. Survey screenshots	56
Appendix 4. ONWARD PHR screenshots	87

A. Objectives of the study

The purpose of this pilot study was to explore options for collecting patient generated health data (PGHD) as an enhancement to NCI's mission of providing national cancer statistics to reduce the burden of cancer within the U.S. population. PGHD can be used to improve the quality of care, to extend research beyond the clinical encounter, to support behavioral interventions, and to add depth to surveillance activities. Patient portals could be used to collect data at multiple points over time, and give value back to patients by providing them with a summary of their own contributed data for management of their own care.

- 1. To assess the feasibility of PGHD methods to serve as a complement to traditionally collected registry data, focusing on patients' personal experiences in adhering to cancer treatment as a starting point for this evaluation;
- 2. To investigate the feasibility of collecting PGHD at a minimum of two points in time, for a longitudinal view of patients' personal experiences in adhering to cancer treatment regimens;
- 3. To provide value back to patients by offering reports or journaling capabilities as a record of personal experiences during treatment;
- 4. To generate knowledge on best practices, costs, and benefits for utilizing PGHD methodologies in the context of cancer treatment surveillance.

B. Progress to date

I. Work completed, organized by task

Task 1: Submit a full Project Plan within 45 days of Task Order Award in accordance with C.2 Reporting Requirements of this Task Order.

Summary and Evaluation: Submitted on 11/03/2016.

Task 2: Obtain Institutional Review Board (IRB) clearance to proceed with the Task Order. Determine in coordination with the COR or designee whether an NIH clinical exemption can be granted from the Office of Management and Budget (OMB) to conduct the work without having to negotiate a full OMB clearance process. If a clinical exemption is not granted, work with the COR to submit a formal application to OMB for clearance under the Paperwork Reduction Act.

<u>Summary and Evaluation</u>: We received IRB full approval of the full project on 12/8/2016; this includes a waiver of documentation of consent. An NIH clinical exemption has been granted and we understand that we will not need to negotiate a full OMB clearance process.

Task 3: Define the sampling frame and selection procedures to conduct a full pilot study of the proposed PGHD methodology in a representative population. Sampling should be limited to participants that 1) are ages 50 years and older, 2) have been diagnosed with breast, prostate, or colorectal cancer, and 3) received their diagnosis no more than 10 years prior to study start date.

Summary and Evaluation: The sampling frame was restricted to first primary cancers diagnosed in 2015 for each of the three study cancer types. (See **Table 1**).

Task 4: Coordinate with the COR or designee to identify technical requirements for data collection methodology.

<u>Summary and Evaluation</u>: The Iowa PHR platform was configured for the ONWARD study. The study website is <u>http://www.onwardstudy.org/</u>.

We confirmed with NCI that a primary interest was to assess means of collecting current medication adherence from patients. We planned to collect information on patient comorbidities, current medications (both cancer and non-cancer medications) and patient-reported outcomes (PROs) for all three cancer types.

On the 4/10/17 call, we discussed with NCI our approach to repeating measures for symptoms and/or medication adherence. Thereafter, NCI recommended that we collect symptom and adherence information at both the baseline and follow up time points. We discussed internally and will proceed accordingly with that suggestion.

The baseline and follow up surveys - 'Survey #1' and 'Survey #2', respectively - were developed and programmed in the online tool. Patients were sent individualized credentials to log in to the study website that allowed them to provide consent and take Survey #1. Three months later they were invited by email or postal mail to take Survey #2. System use logs were generated for users.

Task 5: Conduct the pilot study following the sampling procedures and utilizing the proposed PGHD collection methodology.

<u>Summary and Evaluation</u>: The study protocol was approved by the University of Iowa IRB. Study materials were ordered and the online tool was configured. REDCap was used for case tracking. Patient resources suggested by NCI at <u>https://smokefree.gov/springboard</u> were incorporated into the online tool. We developed RSS feeds specific to cancer type and provided cancer type-specific news content to subjects as well (per <u>https://medlineplus.gov/rss.html</u>). However, these feeds were subsequently removed from the online tool when it was discovered that these resources were taken offline by NIH.

Data collection instruments were developed by the research team and feedback was obtained from NIH. Data dictionaries of these instruments, including all items, variable names, and data sources when applicable, were provided to NIH as deliverables on 06/18/2018. Screenshots of these instruments were also provided.

Study invitations were mailed to 2358 persons, and 46 of these were returned to the research team as undeliverable. A total of 395 subjects were enrolled and completed Survey #1. 91.4% of enrollees who completed Survey #1 also completed Survey #2, and an additional 1.3% started but did not complete Survey #2.

Task 6: Work with the COR or designee to assemble an analytic database of de-identified process, context, and outcome measures.

Summary and Evaluation: A summary of the analysis plan was presented on the 9/22/17 webinar. Thereafter, in summer 2018, we consulted with NCI on the measures and supporting documentation needed.

Task 7: Participate in monthly management meetings by telephone conference call and/or webinar with the NCI and other SEER Contractors to discuss progress over the duration of the project. Document in the Monthly Progress Call Reports in accordance with C.2 Reporting Requirements of this Task Order.

Summary and Evaluation: We have participated in the following conference calls and/or webinars:

- Monthly Progress Call (1) on October 11, 2016
- Webinar with other contractors on November 21, 2016 (Monthly Progress Call (2))
- Monthly Progress Call (3) on December 12, 2016
- Monthly Progress Call (4) on January 9, 2017
- Monthly Progress Call (5) on February 13, 2017
- Webinar with other contractors on March 27, 2017 (Monthly Progress Call (6))
- Monthly Progress Call (7) on April 10, 2017
- Monthly Progress Call (8) on May 8, 2017
- Webinar with other contractors on June 26, 2017 (Monthly Progress Call (9))
- Monthly Progress Call (10) on July 10, 2017
- Monthly Progress Call (11) on August 14, 2017
- Webinar with other contractors on September 22, 2017 (Monthly Progress Call (12))

We have also participated in several additional calls convened to provide NCI with updates on project status, though formal Progress Call Reports were not submitted.

Task 8: Conduct and provide with the Final Task Order Report, an assessment of feasibility for utilizing the proposed methodology to collect PGHD in surveillance-related programs in the future.

<u>Summary and Evaluation</u>: With the submission of the current report, this Task is completed. See below for details.

Task 9: Submit a Final Task Order Report in accordance with C.2 Reporting Requirements of this Task Order.

Summary and Evaluation: With the submission of the current report, this Task is completed.

II. Any work not completed that was proposed, organized by task

None. All work is completed.

C. Description of the sampling methodology and descriptive statistics for final sample

The Iowa Cancer Registry contained 3,610 cases of first primary breast, prostate, or colorectal cancer diagnoses in 2015 among adults ages 50+. Of these, all minority (N = 167) and colorectal (N = 717) cancer cases, and a random sample of non-Hispanic Whites with prostate or breast cancer (N = 1479) were selected from SEER*DMS by the Iowa Cancer Registry for a total of 2363 cases (*Table 1*). The cases were then securely provided to the study team for mailing preparation.

	Minorit	y Status	RUCC*	[•] Category		
Cancer type and age group	White, Non-	Non-White				Total by
at diagnosis	Hispanic	or Hispanic	Metro	Nonmetro	Total	cancer type
Female breast - 50-64	383	29	243	169	412	0
Female breast - 65+	391	19	209	201	410	022
Prostate - 50-64	363	49	221	191	412	074
Prostate - 65+	375	37	209	203	412	- 824
Colorectal - 50-64 (Male)	171	17	89	99	188	
Colorectal - 50-64 (Female)	118	8	55	71	126	
Colorectal - 65+ (Male)	191	7	96	102	198	- /1/
Colorectal - 65+ (Female)	204	1	106	99	205	_
Total	2196	167	1228	1135	2363	2363

Table 1. Cas	es selected for s	tudv recruitment	t - diaanosis v	vear 2015.	restricted to	first	primarv	, cases

*Rural-Urban Continuum Code

D. Detailed findings of the Patient Generated Health Data Collection

pilot

Methods and findings of the pilot, titled **ON**line **W**ay for patients to **A**ugment **R**egistry **D**ata (ONWARD), are described below.

I. Sampling frame and subject recruitment

Sampled cases (N = 2363) were mailed study invitation packets. The packets contained (1) a cover letter on Iowa Cancer Registry (ICR) letterhead and signed by the ICR medical director and project coordinator, (2) a study brochure, (3) a 'reply card', and (4) a prepaid business reply envelope. The cover letter included unique credentials that recipients could use to log in to the study website and review the informed consent document. The study brochure described the purpose of the study and highlighted the process of enrolling. The reply card was provided as an additional means for patients to ask questions about the study. The prepaid envelope was included as a way to return the reply card to the study team. Materials contained information for patients to contact the research team with any questions. See Appendix I for recruitment and enrollment details.

Address lists of patients were cleansed against US Postal Service records using an on-campus service. Five cases were excluded due to insufficient address information. Ultimately, the research team mailed invitations to 2358 persons, of which 2312 were delivered (not returned to the research team by the USPS) (*see Table 2*).

	Female	Female					
	breast,	breast,	Prostate,	Prostate,	Colorectal,	Colorectal,	
	50-64	65+	50-64	65+	50-64	65+	All
Age, mean in years	56.9	71.4	59	69.5	58.1	71.6	62.7
Full Sample, No.	412	410	412	412	314	403	2363
Invitations Mailed, No.	411	410	410	412	312	403	2358
	408	395	408	401	309	391	2312
Invitations Delivered, No. (%)	(17.6)	(17.1)	(17.7)	(17.3)	(13.4)	(16.9)	(100)

Table 2. Mailed and delivered invitations by cancer type and age group

Figure 1 shows the completion rate for selected recruitment activities by cancer type and age group, among the full sample of selected patients: (1) ever logged in to the online tool, (2) provided consent, (3) started Survey #1, and (4) completed Survey #1. Patients aged 50-64 at diagnosis completed each activity at higher rates than younger patients. (See Appendix 2 for additional comparisons of completion of study procedures.)



Figure 1. Selected recruitment events by cancer type and age group at diagnosis (N = 2312)

II. Subject enrollment

Overall, 17.1% of patients for whom invitations were delivered completed Survey #1 (N = 395). Survey #1 completion ranged from a high of 23.3% among younger breast cancer patients, to a low of 9.0% among older colorectal cancer patients. Within each cancer type, persons age 50-64 at diagnosis were significantly more likely to complete Survey #1 than their older age group counterparts (*Table 3*). Slightly more metro (vs nonmetro) area-residing breast and prostate cancer patients completed Survey #1, while the trend was reversed for colorectal cancer patients (*Table 3*).

Table 3. Survey #1 completion rates by age group and rurality among cases with delivered invitations(N = 2312)

	No. (%)	_	No. (%)	_	No. (%)		No. (%)		
Characteristic	Breast	P value*	Prostate	P value*	Colorectal	P value*	Overall	P value*	
Age Group									
50-64	95 (23.3)	40,0001	90 (22.1)	0.0245	61 (19.7)	-0.0001	246 (21.9)	-0.0001	
65+	49 (12.4)	- <0.0001	65 (16.2)	0.0345	35 (9.0)	<0.0001	149 (12.6)	<0.0001	
Rurality									
Metro	86 (19.4)	0 2270	85 (20.0)	0 5000	40 (12.0)	0.2010	211 (17.6)	0 5 2 2 7	
Nonmetro	58 (16.2)	0.2379	70 (18.2)	0.5008	56 (15.3)	0.2016	184 (16.6)	0.5327	
Total	144 (17.9)		155 (19.2)		96 (13.7)		395 (17.1)		

*Chi-square

Table 4 compares respondent with non-respondent characteristics. Respondents and nonrespondents had similar stage distribution and treatment characteristics. Older people and those of nonwhite race were significantly less likely to respond.

Table 4. Comparison o	f demographic	characteristics of re	espondents vs nonres	pondents

					_				
	Br	east	Pro	state	Colo	orectal		41I	
		Non-		Non-		Non-		Non-	
	Respondents								
	(N = 144)	(N = 677)	(N = 155)	(N = 667)	(N = 96)	(N = 619)	(N = 395)	(N = 1963)	P value*
Age at Diagnosis									
45-54	31 (21.5)	88 (13.0)	16 (10.3)	44 (6.6)	17 (17.7)	73 (11.8)	64 (16.2)	205 (10.4)	
55-64	64 (44.4)	228 (33.7)	74 (47.7)	276 (41.4)	44 (45.8)	178 (28.8)	182 (46.1)	682 (34.7)	<0.0001
65-74	35 (24.3)	210 (31.0)	57 (36.8)	243 (36.4)	25 (26.0)	152 (24.6)	117 (29.6)	605 (30.8)	<0.0001
75+	14 (9.7)	151 (22.3)	8 (5.2)	104 (15.6)	10 (10.4)	216 (34.9)	32 (8.1)	471 (24.0)	-
Rurality									
Metro	86 (59.7)	365 (53.9)	85 (54.8)	344 (51.6)	40 (41.7)	306 (49.4)	211 (53.4)	1015 (51.7)	0 5 2 4 5
Nonmetro	58 (40.3)	312 (46.1)	70 (45.2)	323 (48.4)	56 (58.3)	313 (50.6)	184 (46.6)	948 (48.3)	0.5345
White Race	141 (97.9)	641 (94.7)	152 (98.1)	602 (90.3)	94 (97.9)	605 (97.3)	387 (98.0)	1845 (94.0)	0.0013
AJCC Stage									
0	1 (0.7)	5 (0.7)	0	0	1 (1.0)	24 (3.9)	2 (0.5)	29 (1.5)	_
Ι	100 (69.4)	399 (58.9)	25 (16.1)	75 (11.2)	22 (22.9)	176 (28.4)	147 (37.2)	650 (33.1)	
II	28 (19.4)	190 (28.1)	79 (51.0)	357 (53.5)	21 (21.9)	182 (29.4)	128 (32.4)	729 (37.1)	- 0 1052
III	10 (6.9)	52 (7.7)	22 (14.2)	75 (11.2)	37 (38.5)	170 (27.5)	69 (17.5)	297 (15.1)	0.1055
IV	2 (1.4)	14 (2.1)	7 (4.5)	59 (8.9)	9 (9.4)	49 (7.9)	18 (4.6)	122 (6.2)	_
Unknown	3 (2.1)	17 (2.5)	22 (14.2)	101 (15.1)	6 (6.3)	18 (2.9)	31 (7.9)	136 (6.9)	
Surgery	139 (96.5)	644 (95.1)	88 (56.8)	313 (46.9)	90 (93.8)	588 (95.0)	317 (80.3)	1545 (78.7)	0.4204
Radiation	95 (66.0)	415 (61.3)	36 (23.2)	172 (25.8)	20 (20.8)	80 (12.9)	151 (38.2)	667 (34.0)	0.1055
Chemotherapy	52 (36.1)	220 (32.5)	2 (1.3)	12 (1.8)	55 (57.3)	239 (38.6)	109 (27.6)	471 (24.0)	0.1294

*Chi-square

III. Data collection and analysis

After login and consent, participants completed surveys specific to their type of cancer (*Appendix 3. Survey screenshots*). Upon completion of the survey, the PHR home screen was presented and participants were free to use a variety of self-guided features (*Appendix 4. ONWARD PHR screenshots*). An invitation to the second survey was mailed to respondents three months after survey #1 completion.

Statistical analyses were carried out using SAS version 9.4 (SAS Institute, Cary, NC). Registry items, Survey #1 responses, and Survey #2 responses were compared by cancer type using Pearson chi-square for proportions and ANOVA for mean values (with the exception of **Tables 20-23** and **Table 26**, which were compared using Student T-tests).

IV. Survey #1 results

Demographic characteristics by cancer type are summarized in **Table 5.** Age distribution varied among cancer types (P=0.0047) with breast cancer participants being the youngest, although mean age only varied from a low of 64.4 years (breast cancer) to 66.1 years (prostate cancer). Metro/nonmetro residence also varied by cancer type (P=0.0207), as breast cancer patients tended toward metro area residence while colorectal cancer patients tended to reside in nonmetro areas. Lastly, the level of education varied by cancer type (0=0.0018), with lower education level observed among colorectal cancer patients. There were no significant differences among cancer types in health literacy, marital status, race, or employment status.

	Breast	Prostate	Colorectal		Total
	(N = 144)	(N = 155)	(N = 96)	P value	(N = 395)
Age Group ^a					
45 - 54, No. (%)	12 (8.4)	5 (3.2)	8 (8.4)		25 (6.4)
55 - 64, No. (%)	67 (46.9)	58 (37.4)	37 (39.0)	0.0047	162 (41.2)
65 - 74, No. (%)	43 (30.1)	81 (52.3)	38 (40.0)	0.0047	162 (41.2)
75+, No. (%)	21 (14.7)	11 (7.1)	12 (12.6)		44 (11.2)
Mean Age (SD)	64.4 (8.4)	66.1 (6.5)	65.6 (8.4)	0.1697	65.4 (7.7)
Rurality					
Metro, No. (%)	86 (59.7)	85 (54.8)	40 (41.7)	0.0207	211 (53.4)
Nonmetro, No. (%)	58 (40.3)	70 (45.2)	56 (58.3)	0.0207	184 (46.6)
Health Literacy Level ^b					
Low (score ≤12), No. (%)	23 (16.0)	35 (22.6)	23 (24.0)		81 (20.5)
Medium (13 or 14), No. (%)	37 (25.7)	47 (30.3)	28 (29.2)	0.2660	112 (28.4)
High (score =15), No. (%)	84 (58.3)	73 (47.1)	45 (46.9)		202 (51.1)
Marital Status ^c					
Married, No. (%)	101 (71.6)	133 (85.8)	77 (81.1)		311 (79.5)
Divorced/Separated, No. (%)	18 (12.8)	12 (7.7)	6 (6.3)	_	36 (9.2)
Living with Partner, No. (%)	6 (4.3)	5 (3.2)	3 (3.2)	0.1095	14 (3.6)
Never Married, No. (%)	5 (3.6)	3 (1.9)	3 (3.2)	_	11 (2.8)
Widowed, No. (%)	11 (7.8)	2 (1.3)	6 (6.3)		19 (4.9)
Highest Level of Education ^d					
High School, GED, or Less, No. (%)	30 (21.1)	37 (23.9)	38 (40.0)	0.0018	105 (26.8)

Table 5. Sociodemographic characteristics of survey #1 respondents

TORFP: SEER 2016-07 Contract No. HHSN261201300020I Order No. HHSN26100014 Iowa: Elizabeth Chrischilles, Ph.D.

	Breast	Prostate	Colorectal		Total
	(N = 144)	(N = 155)	(N = 96)	P value	(N = 395)
Some College or 2-year Degree, No. (%)	54 (38.0)	35 (22.6)	31 (32.6)		120 (30.6)
College Graduate or More, No. (%)	58 (40.8)	83 (53.5)	26 (27.4)	_	167 (42.6)
Female ^e , No. (%)	143 (100.0)	0 (0.0)	42 (44.7)	-	185 (47.4)
Employed ^f , No. (%)	84 (58.7)	87 (56.5)	57 (60.6)	0.8067	228 (58.3)
White Race, No. (%)	141 (97.9)	152 (98.1)	94 (97.9)	0.9948	387 (98.0)

^a2 missing; ^bHealth Literacy Level scored and categorized according to <u>Hawley et al</u>. ^c4 missing; ^d3 missing; ^e5 missing; ^f4 missing

A comparison of clinical characteristics by cancer type is presented in **Table 6**. The majority of patients were surveyed within three years of their cancer diagnosis. Stage at diagnosis varied across cancer types (P<0.0001), with breast at lower stages (Stage I), colorectal at higher stages (Stage III), and many prostate cancer participants at Stage II. Breast and colorectal cancer patients had more surgical and chemotherapy treatment than prostate cancer patients and breast cancer patients were much more likely to receive radiation therapy. In addition, breast cancer participants endorsed more depression (P=0.0008) and upper extremity swelling (P=0.0009), and prostate cancer participants had less upper extremity disability (QuickDASH) scores (P=0.0041). Obesity rates were high overall but not different among cancer groups. On average, participants had 1.2 comorbid diagnoses in addition to their cancer. Few patients had a weighted Charlson-Katz comorbidity score greater than 0.

The PROMIS Global-10 instrument was collected at both surveys. Both physical and mental health scores were on average within normal limits (T-score >50) for patients with breast and prostate cancer. Physical health was slightly better among patients with prostate cancer but still within 0.5 SD of the general population mean of 50.

	Breast	Prostate	Colorectal		Total
	(N = 144)	(N = 155)	(N = 96)	P value	(N = 395)
AJCC Stage					
0, No. (%)	1 (0.7)	0 (0.0)	1 (1.0)		2 (0.5)
I, No. (%)	100 (69.4)	25 (16.1)	22 (22.9)		147 (37.2)
II, No. (%)	28 (19.4)	79 (51.0)	21 (21.9)	<0.0001	128 (32.4)
III, No. (%)	10 (6.9)	22 (14.2)	37 (38.5)	<0.0001	69 (17.5)
IV, No. (%)	2 (1.4)	7 (4.5)	9 (9.4)		18 (4.6)
Unknown, No. (%)	3 (2.1)	22 (14.2)	6 (6.3)		31 (7.9)
Time Since Diagnosis ^a					
2 to <3 years, No. (%)	91 (63.6)	89 (58.6)	60 (62.5)	- 0.6471	240 (61.4)
3 to 3.5 years, No. (%)	52 (36.4)	63 (41.5)	36 (37.5)	0.0471	151 (38.6)
Surgery, No. (%)	139 (96.5)	88 (56.8)	90 (93.8)	<0.0001	317 (80.3)
Radiation, No. (%)	95 (66.0)	36 (23.2)	20 (20.8)	<0.0001	151 (38.2)
Chemotherapy, No. (%)	52 (36.1)	2 (1.3)	55 (57.3)	<0.0001	109 (27.6)
Comorbidities					
Heart Attack, No. (%)	5 (3.5)	10 (6.5)	6 (6.3)	0.4545	21 (5.3)
Heart Failure, No. (%)	4 (2.8)	6 (3.9)	5 (5.3)	0.6227	15 (3.8)
Kidney Problems, No. (%)	4 (2.8)	12 (7.8)	5 (5.2)	0.1602	21 (5.3)
Cirrhosis, No. (%)	1 (0.7)	1 (0.7)	3 (3.1)	0.1745	5 (1.3)
Cerebrovascular Event, No. (%)	6 (4.2)	7 (4.5)	8 (8.3)	0.3149	21 (5.3)
Ulcer, No. (%)	3 (2.1)	7 (4.5)	3 (3.1)	0.5027	13 (3.3)
Depression, No. (%)	44 (30.6)	24 (15.5)	13 (13.5)	0.0008	81 (20.5)

Table 6. Clinical characteristics of survey #1 respondents

	Breast	Prostate	Colorectal		Total
	(N = 144)	(N = 155)	(N = 96)	P value	(N = 395)
Other Cancer Diagnosis, No. (%)	15 (10.4)	11 (7.1)	15 (15.6)	0.0985	41 (10.4)
Diabetes, No. (%)	21 (14.6)	22 (14.3)	16 (16.7)	0.8648	59 (15.0)
Arthritis, No. (%)	61 (42.7)	64 (40.3)	41 (43.6)	0.9330	166 (42.4)
Chronic Pulmonary Disease, No. (%)	10 (6.9)	11 (7.1)	7 (7.3)	0.9947	28 (7.1)
Comorbidities, mean (SD)	1.2 (1.2)	1.1 (1.2)	1.3 (1.3)	0.6394	1.2 (1.2)
Katz-Charlson Score >0 ^b , No. (%)	6 (4.2)	7 (4.5)	7 (7.3)	0.5145	20 (5.1)
QuickDASH Upper Extremity Disability Score ^c , mean (SD)	15.2 (15.3)	10.0 (13.7)	15.4 (17.5)	0.0041	13.2 (15.5)
Edema					
Upper Extremity Swelling, No. (%)	21 (14.6)	6 (3.9)	4 (4.2)	0.0009	31 (7.9)
Upper Extremity Heaviness, No. (%)	23 (16.0)	15 (9.7)	8 (8.3)	0.1208	46 (11.7)
Lower Extremity Swelling, No. (%)	30 (20.8)	25 (16.1)	19 (19.8)	0.5548	74 (18.7)
Lower Extremity Heaviness, No. (%)	19 (13.2)	20 (12.9)	16 (17.0)	0.6233	55 (14.0)
BMI at Diagnosis ^d					
Overweight (25.0-29.9) , No. (%)	83 (58.5)	86 (56.6)	51 (55.4)	0 9027	220 (57.0)
Obese (Over 30.0) , No. (%)	59 (41.6)	66 (43.4)	41 (44.6)	0.8957	166 (43.0)
BMI at Present ^e					
Underweight (Under 18.5) , No. (%)	2 (1.4)	1 (0.7)	0 (0.0)		3 (0.8)
Normal (18.5-24.9) , No. (%)	36 (25.4)	18 (11.9)	17 (18.7)	0.0795	71 (18.5)
Overweight (25.0-29.9) , No. (%)	44 (31.0)	64 (42.4)	35 (38.5)	0.0785	143 (37.2)
Obese (Over 30.0) , No. (%)	60 (42.3)	68 (45.0)	39 (42.9)		167 (43.5)
PROMIS Physical Health Score ^f , mean (SD)	50.7 (8.5)	52.6 (8.2)	50.0 (8.9)	0.0361	51.3 (8.5)
PROMIS Mental Health Score, mean (SD)	51.3 (8.7)	53.1 (8.6)	52.2 (8.8)	0.1940	52.2 (8.7)

^aTime since diagnosis was calculated from age at diagnosis (registry) and age at baseline (reported) and 4 were missing; ^bCharlson Comorbidity scored according to <u>Katz et al</u>.; ^cParticipants who left 2 or more answers blank were excluded (N = 394) per <u>Angst et al.</u>; ^d9 missing; ^e11 missing; ^fPROMIS Global Scores Global-10 (Patient-Reported Outcome Measurement Information System (<u>http://www.healthmeasures.net/</u>) and 3 missing; ^g4 missing

Symptom inventory information by cancer type is displayed in **Table 7**. Overall, fatigue and cancer worries were of highest prevalence, and the profile of symptoms varied among cancer types. Overall, prostate cancer participants reported fewer of these symptoms than the other cancer types, with the exception of bladder and sexual problems, for which prostate cancer participants reported higher rates. Breast cancer patients reported the most lymphedema and the most distress, depression, or anxiety.

Table 7. Sympton	n inventory re	ported at survey	' #1
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	_	No. (%)			No. (%)
" <u>After your cancer diagnosis</u> did you	Breast	Prostate	Colorectal		Total
experience any of the following?"	(N = 144)	(N = 155)	(N = 96)	P value	(N = 395)
Fatigue ^a	97 (67.8)	50 (32.3)	61 (63.5)	<0.0001	208 (52.8)
Pain ^f	45 (31.9)	21 (13.7)	29 (30.9)	0.0004	95 (24.5)
Neuropathy or Nerve Problems ^b	57 (39.9)	19 (12.3)	48 (50.5)	<0.0001	124 (31.6)
Cardiomyopathy ^b	3 (2.1)	3 (2.0)	5 (5.2)	0.2571	11 (2.8)
Trouble Thinking or Concentrating ^b	50 (35.2)	16 (10.3)	29 (30.2)	<0.0001	95 (24.2)
Lymphedema ^f	16 (11.3)	2 (1.3)	1 (1.1)	<0.0001	19 (4.9)
Decreased Range of Motion ^a	26 (18.2)	15 (9.7)	15 (15.6)	0.0993	56 (14.2)
Rotator Cuff Problems ^f	8 (5.6)	16 (10.6)	10 (10.5)	0.2537	34 (8.8)

		No. (%)		No. (%)	
" <u>After your cancer diagnosis</u> did you	Breast	Prostate	Colorectal	_	Total
experience any of the following?"	(N = 144)	(N = 155)	(N = 96)	P value	(N = 395)
Bladder Problems ^c	9 (6.3)	54 (35.1)	16 (16.8)	<0.0001	79 (20.2)
Frozen Shoulder ^d	1 (0.7)	1 (0.7)	3 (3.2)	0.1727	5 (1.3)
Other Shoulder Problems ^c	9 (6.3)	7 (4.6)	6 (6.3)	0.7612	22 (5.6)
Sexual Problems ^g	18 (12.9)	93 (60.8)	21 (22.3)	<0.0001	132 (34.1)
Distress, Depression, or Anxiety ^e	60 (42.0)	29 (18.8)	26 (28.3)	<0.0001	115 (29.6)
Cancer Worries ^a	78 (54.2)	68 (43.9)	43 (45.3)	0.1705	189 (48.0)
Relationship or Body Image Worries ^b	33 (23.1)	30 (19.4)	12 (12.6)	0.1323	75 (19.1)

°1 missing; °2 missing; °3 missing; °4 missing; °6 missing; °7 missing; 88 missing

People who reported a symptom were asked three follow up questions about therapy, whether they told a doctor, and whether or not they still had the symptom. These responses are tabulated in **Table 8** for the ten symptoms reported by more than 10% of respondents.

Patients were most likely to report getting therapy for pain (42.1%), decreased range of motion (40.0%), bladder problems (43.6%), and distress, depression or anxiety (33.9%). Patients were least likely to tell a doctor about their perceived cognitive problems, cancer worries, and relationship or body image worries. The majority of symptoms were persistent in spite of telling a doctor or getting therapy, ranging from 59% (fatigue, pain) to almost 90% (nerve/neuropathy, sexual) still symptomatic. Among participants who said that they have neuropathy or nerve pain, colorectal cancer participants were more likely to have told a doctor. Among participants with decreased range of motion (RoM), breast cancer participants were significantly less likely to still have the problem than the other two cancer types. Among participants who had sexual problems, colorectal cancer participants were less likely to have told a doctor. Among participants about cancer, prostate cancer participants were significantly less likely to still have these worries. Lastly, among participants who said they had worries about relationships or body image, breast cancer participants were less likely to tell a doctor.

Table 8. Symptom* inventory with secondary questions about actions taken and results

*Symptoms endorsed by >10% of respondents

		No. (%)			No. (%)
Symptom	Breast	Prostate	Colorectal	_	Total
Secondary guestion	(N = 144)	(N = 155)	(N = 96)	P value	(N = 395)
Fatigue ^a	97 (67.8)	50 (32.3)	61 (63.5)	<0.0001	208 (52.8)
Underwent Therapy	8 (8.3)	3 (6.0)	10 (16.4)	0.1422	21 (10.1)
Told a Doctor	74 (76.3)	35 (70.0)	52 (86.7)	0.0994	161 (77.8)
Still have Fatigue	56 (58.3)	28 (56.0)	38 (62.3)	0.7878	122 (58.9)
Pain ^e	45 (31.9)	21 (13.7)	29 (30.9)	0.0004	95 (24.5)
Underwent Therapy	16 (35.6)	9 (42.9)	15 (51.7)	0.3872	40 (42.1)
Told a Doctor	45 (100.0)	19 (90.5)	28 (96.6)	0.1189	92 (96.8)
Still have Pain	25 (55.6)	12 (57.1)	19 (65.3)	0.6841	54 (59.0)
Neuropathy or Nerve Problems ^b	57 (39.9)	19 (12.3)	48 (50.5)	<0.0001	124 (31.6)
Underwent Therapy	14 (25.0)	6 (31.6)	12 (25.0)	0.8347	32 (26.0)
Told a Doctor	51 (89.5)	15 (79.0)	48 (100.0)	0.0111	114 (91.9)
Still have Neuropathy	46 (80.7)	16 (84.2)	45 (93.8)	0.1472	107 (86.3)
Trouble Thinking or Concentrating ^b	50 (35.2)	16 (10.3)	29 (30.2)	<0.0001	95 (24.2)
Underwent Therapy	5 (10.0)	2 (12.5)	3 (10.3)	0.9599	10 (10.5)
Told a Doctor	31 (62.0)	9 (56.3)	21 (72.4)	0.4974	61 (64.2)
Still have Trouble Thinking	38 (76.0)	12 (75.0)	21 (72.4)	0.9391	71 (74.7)
Decreased Range of Motion (RoM) ^a	26 (18.2)	15 (9.7)	15 (15.6)	0.0993	56 (14.2)
Underwent Therapy	12 (46.2)	5 (35.7)	5 (33.3)	0.6719	22 (40.0)
Told a Doctor	24 (92.3)	10 (66.7)	11 (73.3)	0.1001	45 (80.4)
Still have Decreased RoM	13 (50.0)	13 (86.7)	13 (86.7)	0.0119	39 (69.6)
Bladder Problems ^c	9 (6.3)	54 (35.1)	16 (16.8)	<0.0001	79 (20.2)
Underwent Therapy	2 (22.2)	23 (43.4)	9 (56.3)	0.2573	34 (43.6)
Told a Doctor	7 (77.8)	51 (96.2)	15 (93.8)	0.1127	73 (93.6)
Still have Bladder Problems	8 (88.9)	40 (76.9)	12 (75.0)	0.6912	60 (77.9)
Sexual Problems ^f	18 (12.9)	93 (60.8)	21 (22.3)	<0.0001	132 (34.1)
Underwent Therapy	1 (5.6)	19 (20.4)	3 (15.0)	0.2994	23 (17.6)
Told a Doctor	12 (66.7)	78 (83.9)	10 (50.0)	0.0031	100 (76.3)
Still have Sexual Problems	16 (88.9)	82 (89.1)	18 (90.0)	0.9923	116 (89.2)
Distress, Depression, or Anxiety ^d	60 (42.0)	29 (18.8)	26 (28.3)	<0.0001	115 (29.6)
Underwent Therapy	16 (26.7)	12 (41.4)	11 (42.3)	0.2294	39 (33.9)
Told a Doctor	40 (66.7)	20 (69.0)	19 (73.1)	0.8403	79 (68.7)
Still have Distress	43 (72.9)	21 (75.0)	19 (73.1)	0.9772	83 (73.5)
Cancer Worries ^a	78 (54.2)	68 (43.9)	43 (45.3)	0.1705	189 (48.0)
Underwent Therapy	10 (12.8)	6 (8.8)	5 (11.6)	0.7398	21 (11.1)
Told a Doctor	46 (59.0)	42 (62.7)	19 (44.2)	0.1433	107 (56.9)
Still have Worries about Cancer	60 (77.9)	35 (51.5)	35 (81.4)	0.0004	130 (69.2)
Relationship or Body Image Worries ^b	33 (23.1)	30 (19.4)	12 (12.6)	0.1323	75 (19.1)
Underwent Therapy	3 (9.1)	1 (3.3)	2 (16.7)	0.3386	6 (8.0)
Told a Doctor	9 (27.3)	15 (50.0)	8 (66.7)	0.0354	32 (42.7)
Still have Relationship Worries	25 (75.8)	23 (76.7)	11 (91.7)	0.4852	59 (78.7)

^a1 missing; ^b2 missing; ^c3 missing; ^d6 missing; ^e7 missing; ^f8 missing

A summary of care coordination during follow-up items is represented in **Table 9**. A greater proportion of breast cancer patients said that they were "cancer-free". There were no differences between cancer types in receiving coordinated care, treatment summaries, or follow-up care instructions. In addition, participants varied on factors that they considered when they selected the surgeon to perform their cancer surgery. Breast cancer patients were more likely to take surgeon reputation into account, while colorectal cancer patients were more likely to be referred by another physician.

		No. (%)			No. (%)
	Breast	Prostate	Colorectal	_	Total
	(N = 144)	(N = 155)	(N = 96)	P value	(N = 395)
"Has a doctor told you that your cancer has come back?" ^a	4 (2.8)	14 (9.2)	9 (9.5)	0.0525	27 (6.9)
"To the best of your knowledge, are you now cancer-free?" ^b	138 (95.8)	124 (81.6)	80 (83.3)	0.0005	342 (87.2)
"Was there one health professional who COORDINATED your					
cancer care?"					
Yes	114 (79.2)	125 (81.2)	76 (79.2)	_	315 (80.0)
No	20 (13.9)	20 (13.0)	11 (11.5)	0.8518	41 (12.9)
Don't Know	10 (6.9)	9 (5.8)	9 (9.4)	_	28 (7.1)
Did you receive a "written or computer print-out summary of					
the cancer treatments that you received?"d					
Yes	75 (52.5)	78 (50.7)	56 (59.6)	_	209 (53.5)
No	48 (33.6)	42 (27.3)	23 (24.5)	0.2209	113 (28.9)
Don't Know	20 (14.0)	34 (22.1)	15 (16.0)	_	69 (17.7)
Did you receive "written or computer print-out instructions					
about routine cancer check-ups after completing your					
cancer treatments?" ^e					
Yes	120 (83.9)	125 (81.7)	80 (85.1)	_	325 (83.3)
No	12 (8.4)	19 (12.4)	9 (9.6)	0.7500	40 (10.3)
Don't Know	11 (7.7)	9 (5.9)	5 (5.3)		25 (6.4)
"How certain were you about which doctor was in charge of					
your follow-up care?" ^c					
Very Certain	123 (85.4)	129 (83.2)	77 (81.1)	_	329 (83.5)
Somewhat Certain	16 (11.1)	12 (7.7)	11 (11.6)	- 0 2402	39 (9.9)
Neither Certain nor Uncertain	3 (2.1)	4 (2.6)	4 (4.2)	0.5405	11 (2.8)
Treatment Not Complete	2 (1.4)	10 (6.5)	3 (3.2)		15 (3.8)
Factors Influencing Surgeon Choice					
Referred by Another Doctor	79 (54.9)	67 (43.2)	64 (66.7)	0.0013	210 (53.2)
Surgeon Reputation	46 (31.9)	27 (17.4)	18 (18.8)	0.0061	91 (23.0)
Family/Friend Recommendation	16 (11.1)	7 (4.5)	6 (6.3)	0.0823	29 (7.3)
Only Surgeon in Health Care Plan	6 (4.2)	6 (3.9)	8 (8.3)	0.2423	20 (5.1)
Medical Institution of Choice	28 (19.4)	18 (11.6)	13 (13.5)	0.1497	59 (14.9)
Near Home	20 (13.9)	15 (9.7)	4 (4.2)	0.0467	39 (9.9)
Other	8 (5.6)	6 (3.9)	7 (7.3)	0.4956	21 (5.3)

Table 9. Care coordination experience among survey #1 respondents

^a6 missing; ^b3 missing; ^c1 missing; ^d4 missing; ^e5 missing

Survey items referring to all medications the participants were taking are summarized in **Table 10**, and responses overall were comparable across cancer type. Overall, patients were taking an average of 4.1 medications regularly. The mean medication burden score was comparable to a sample of multi-morbid patients at Mayo clinic where the mean (SD) score was 5.5 (10.1) (Eton et al, Qual Life Res 2017;26:489-503).

Table 10. Medication burden summary, survey #1

	Breast	Prostate	Colorectal		Total
	(N = 144)	(N = 155)	(N = 96)	P value	(N = 395)
Medications Taken Regularly, mean (SD)	4.5 (3.4)	3.7 (3.0)	4.1 (3.7)	0.1212	4.1 (3.4)
Medication Burden Score ^a , mean (SD)	5.3 (13.4)	5.4 (14.1)	6.2 (16.5)	0.8859	5.6 (14.5)
"How much of a problem has it been for you to"	, ,				· · ·
Organize Medications ^a					
Not at all, No. (%)	127 (88.2)	140 (90.9)	88 (92.6)		355 (90.3)
A little bit, No. (%)	11 (7.6)	11 (7.1)	4 (4.2)	-	26 (6.6)
Somewhat, No. (%)	4 (2.8)	2 (1.3)	1 (1.1)	0.8464	7 (1.8)
Quite a bit, No. (%)	1 (0.7)	0 (0.0)	1 (1.1)	-	2 (0.5)
Very Much, No. (%)	1 (0.7)	1 (0.7)	1 (1.1)	-	3 (0.8)
Take More than One Medication Per Day ^b					
Not at all, No. (%)	126 (87.5)	141 (91.0)	87 (91.6)	_	354 (89.9)
A little bit, No. (%)	10 (6.9)	6 (3.9)	1 (1.1)	_	17 (4.3)
Somewhat, No. (%)	3 (2.1)	1 (0.7)	1 (1.1)	0.2281	5 (1.3)
Quite a bit, No. (%)	2 (1.4)	3 (1.9)	5 (5.3)	_	10 (2.5)
Very Much, No. (%)	3 (2.1)	4 (2.6)	1 (1.1)		8 (2.0)
Take Medications Several Times Each Day ^c					
Not at all, No. (%)	120 (83.9)	137 (89.0)	82 (87.2)	_	339 (86.7)
A little bit, No. (%)	11 (7.7)	11 (7.1)	6 (6.4)		28 (7.2)
Somewhat, No. (%)	8 (5.6)	4 (2.6)	1 (1.1)	0.3011	13 (3.3)
Quite a bit, No. (%)	3 (2.1)	0 (0.0)	3 (3.2)	_	6 (1.5)
Very Much, No. (%)	1 (0.7)	2 (1.3)	2 (2.1)		5 (1.3)
Refill Medications ^d					
Not at all, No. (%)	126 (88.1)	133 (86.4)	81 (87.1)	_	340 (87.2)
A little bit, No. (%)	9 (6.3)	11 (7.1)	5 (5.4)		25 (6.4)
Somewhat, No. (%)	2 (1.4)	3 (2.0)	2 (2.2)	0.8723	7 (1.8)
Quite a bit, No. (%)	3 (2.1)	1 (0.7)	3 (3.2)	_	7 (1.8)
Very Much, No. (%)	3 (2.1)	6 (3.9)	2 (2.2)		11 (2.8)
Adjust your Medications ^e					
Not at all, No. (%)	128 (88.9)	141 (92.2)	84 (88.4)	_	353 (90.1)
A little bit, No. (%)	9 (6.3)	7 (4.6)	6 (6.3)	_	22 (5.6)
Somewhat, No. (%)	5 (3.5)	1 (0.7)	3 (3.2)	0.6699	9 (2.3)
Quite a bit, No. (%)	1 (0.7)	2 (1.3)	0 (0.0)	_	3 (0.8)
Very Much, No. (%)	1 (0.7)	2 (1.3)	2 (2.1)		5 (1.3)
Take Medications as Directed ^a					
Not at all, No. (%)	130 (90.3)	131 (85.1)	82 (86.3)	_	343 (87.3)
A little bit, No. (%)	7 (4.9)	8 (5.2)	4 (4.2)	_	19 (4.8)
Somewhat, No. (%)	3 (2.1)	3 (2.0)	1 (1.1)	0.5382	7 (1.80
Quite a bit, No. (%)	0 (0.0)	1 (0.7)	2 (2.1)	_	3 (0.8)
Very Much, No. (%)	4 (2.8)	11 (7.1)	6 (6.3)		21 (5.3)
Plan Activities around Medication Schedule ^a					
Not at all, No. (%)	128 (88.9)	137 (89.0)	79 (83.2)	_	344 (87.5)
A little bit, No. (%)	9 (6.3)	11 (7.1)	12 (12.6)	_	32 (8.1)
Somewhat, No. (%)	5 (3.5)	3 (2.0)	2 (2.1)	0.7963	10 (2.5)
Quite a bit, No. (%)	1 (0.7)	2 (1.3)	1 (1.1)	_	4 (1.0)
Very Much, No. (%)	1 (0.7)	1 (0.7)	1 (1.1)		3 (0.8)

^aCalculated using the 7 items in the table above and transformed, per Eton et al. with 2 missing. Possible scores ranged from 0 to 100; ^b1 missing; ^c4 missing; ^d5 missing; ^e3 missing

Cancer medications are summarized for baseline respondents by cancer type in **Table 11**. The majority of cancer medications were taken by breast cancer participants, and most of the responses reflected a lack of difficulty taking these medications.

		No. (%)			No. (%)
	Breast	Prostate	Colorectal		Total
	(N = 144)	(N = 155)	(N = 96)	P value	(N = 395)
In-Clinic Chemotherapy Now ^a	2 (1.4)	2 (1.3)	7 (7.3)	0.0088	11 (2.8)
Cancer Medications by Mouth Now ^a	102 (70.8)	7 (4.6)	3 (3.1)	<0.0001	112 (28.4)
Cancer Medications by Mouth Ever ^b	14 (33.3)	1 (0.7)	18 (19.8)	<0.0001	33 (11.8)
"How often do you" ^c					
Forget to Take Medications ^d					
None of the time	83 (82.2)	7 (100.0)	2 (100.0)		92 (83.6)
Some of the time	17 (16.8)	0 (0.0)	0 (0.0)	0.7509	17 (15.5)
All of the time	1 (1.0)	0 (0.0)	0 (0.0)		1 (0.9)
Decide not to Take Medications					
None of the time	96 (94.1)	7 (100.0)	2 (66.7)	_	105 (93.8)
Some of the time	5 (4.9)	0 (0.0)	1 (33.3)	0.2712	6 (5.4)
All of the time	1 (1.0)	0 (0.0)	0 (0.0)		1 (0.9)
"In the past 7 days"a					
I took all doses	91 (90.1)	7 (100.0)	1 (33.3)		99 (89.2)
I missed or skipped 1 dose	7 (6.9)	0 (0.0)	1 (33.3)	0.0012	8 (7.2)
I missed or skipped 2 doses	2 (2.0)	0 (0.0)	0 (0.0)	0.0013	2 (1.8)
I missed or skipped 3 doses	1 (1.0)	0 (0.0)	1 (33.3)	_	2 (1.8)

Table 11. Cancer medications summary, survey #1

^a1 missing; ^bOnly asked to those who answered "No" to cancer medications now and 4 were missing; ^cOnly asked to those who answered "Yes" to cancer medications now; ^d2 missing

V. Survey #2 Results

As shown in **Table 12**, 91% of patients who completed Survey #1 also completed Survey #2. An additional 1.3% of subjects started but did not complete Survey #2. No statistically significant differences in completion rates were found across cancer type or age group. In survey #2, we introduced new items and also repeated some quality of life and symptom items.

Table 12.	Survey #	#2 status among	g subjects v	who comple	eted Survey	y #1 (N = 395)
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		$N = \langle 0/ \rangle$			NI	- (0/)		$\mathbf{N} = (0/)$
		NO. (%)		_	NC	D. (%)	_	NO. (%)
		Cancer Type			Age	Group		
	Breast	Prostate	Colorectal		50-64	65+		
	(N=144)	(N=155)	(N=96)	P value	(N=246)	(N=149)	P value	Total
Submitted	130 (90.3)	143 (92.3)	88 (91.7)		224 (91.1)	137 (91.9)		361 (91.4)
Started	4 (2.8)	0 (0.0)	1 (1.0)	0.3196	4 (1.6)	1 (0.7)	0.7128	5 (1.3)
Not started	10 (6.9)	12 (7.7)	7 (7.3)		18 (7.3)	11 (7.4)		29 (7.3)

A question about household income was added at survey #2 (*Table 13*). Household income varied significantly by cancer type with prostate cancer patients reporting the highest income.

Table 13. Demographics summary, survey #2

		No. (%)			No. (%)
	Breast	Prostate	Colorectal	_	Total
	(N = 130)	(N = 143)	(N = 88)	P value	(N = 361)
Race					
White	128 (98.5)	142 (99.3)	87 (98.9)		357 (98.9)
Native American	2 (1.5)	0 (0.0)	1 (1.1)	0.4629	3 (0.8)
Black	0 (0.0)	1 (0.7)	0 (0.0)	_	1 (0.3)
Hispanic/Latino ^a	1 (0.8)	1 (0.7)	1 (1.2)	0.9362	3 (0.9)
Marital Status Now ^b					
Married	89 (69.0)	120 (83.9)	71 (80.7)		280 (77.8)
Divorced/Separated	19 (14.7)	11 (7.7)	6 (6.8)		36 (10.0)
Living with Partner	5 (3.9)	3 (2.1)	2 (2.3)	0.1926	10 (2.8)
Never Married	4 (3.1)	4 (2.8)	3 (3.4)		11 (3.1)
Widowed	12 (9.3)	5 (3.5)	6 (6.8)		23 (6.4)
Live Alone ^c	23 (17.8)	16 (11.2)	12 (13.8)	0.2908	51 (14.2)
Employment Status ^c					
Employed for Wages	58 (44.6)	53 (37.1)	23 (26.1)		134 (37.1)
Self-employed	10 (7.7)	13 (9.1)	12 (13.6)		35 (9.7)
Out of work and looking for work	2 (1.5)	0 (0.0)	0 (0.0)		2 (0.6)
Out of work but not currently looking	2 (1.5)	0 (0.0)	1 (1.1)	0.0690	3 (0.8)
Homemaker	3 (2.3)	0 (0.0)	1 (1.1)		4 (1.1)
Retired	51 (39.2)	74 (51.8)	45 (51.1)		170 (47.1)
Unable to work	3 (2.3)	3 (2.1)	5 (5.7)		11 (3.1)
Annual Household Income ^d					
Less than \$20,000	15 (11.6)	4 (2.8)	13 (15.1)	_	32 (8.9)
\$20,001 - \$35,000	12 (9.3)	7 (4.9)	16 (18.6)		35 (9.8)
\$35,001 - \$50,000	20 (15.5)	19 (13.3)	8 (9.3)		47 (13.1)
\$50,001 - \$75,000	21 (16.3)	37 (25.9)	13 (15.1)	0.0014	71 (19.8)
\$75,001 - \$100,000	23 (17.8)	24 (16.8)	11 (12.8)		58 (16.2)
Greater than \$100,000	22 (17.1)	31 (21.7)	10 (11.6)	_	63 (17.6)
Prefer not to answer	16 (12.4)	21 (14.7)	15 (17.4)		52 (14.5)

^a16 missing; ^b1 missing; ^c2 missing; ^d3 missing

Financial burdens were comparable across cancer types (**Table 14**), except for significant differences (*P*=0.0067) in worry about normal monthly living expenses, with more worry reported by colorectal cancer patients. Patients were neutral (neither dissatisfied nor satisfied) about their financial situation and did not report a high degree of financial stress. Very few (2.2%) patients did not have health insurance at the time of diagnosis.

	Breast	Prostate	Colorectal		Total
	(N = 130)	(N = 143)	(N = 88)	P value	(N = 361)
Hospitalized in Last 3 Months ^a , No. (%)	3 (2.3)	8 (5.8)	7 (8.1)	0.1429	18 (5.1)
Hours Spent Managing Conditions per Week ^b , mean (SD)	1.4 (1.9)	1.2 (1.3)	1.7 (2.7)	0.1707	1.4 (2.0)
Worry about Normal Monthly Living Expenses ^c : 0=Never worry - 10=Worry all the time, mean (SD)	2.4 (3.0)	1.9 (2.5)	3.2 (3.3)	0.0067	2.4 (2.9)
Satisfaction with Financial Situation ^d : 0=Very dissatisfied - 10=Very satisfied, mean (SD)	5.7 (3.3)	5.7 (3.3)	5.2 (3.4)	0.4609	5.6 (3.3)
Stress about Personal Finances ^c : 0=No stress at all - 10=Overwhelming stress, mean (SD)	3.1 (2.9)	2.5 (2.4)	3.2 (3.0)	0.1070	2.9 (2.7)
Health Insurance at Time of Diagnosis ^c					
Private health insurance offered through employer or union, No. (%)	70 (55.1)	67 (47.9)	42 (50.6)		179 (51.1)
Private health insurance purchased, No. (%)	11 (8.9)	17 (12.1)	7 (8.4)	_	35 (10.0)
Medicaid or state medical assistance for low-income, No. (%)	5 (3.9)	2 (1.4)	3 (3.6)	0.7374	10 (2.9)
Medicare or Medicare Advantage, No. (%)	37 (29.1)	45 (32.1)	27 (32.5)		109 (31.1)
Other National Government coverage (VA, etc.), No. (%)	4 (3.2)	9 (6.4)	4 (4.8)	_	17 (4.9)
Uninsured, No. (%)	2 (1.5)	2 (1.4)	4 (4.6)		8 (2.2)
20 missing $\frac{1}{2}$ missing $\frac{1}{2}$ missing $\frac{1}{2}$					

Table 14. Health and financial burden summary of follow-up respondents

^a8 missing; ^b7 missing; ^c3 missing; ^d2 missing

In survey #2 participants were asked about overall medication adherence and potential factors that could contribute to adherence problems (*Tables 15 and 16*).

Patient-reported adherence using an adapted version of the Morisky 8-item scale was generally higher than reported in the development sample of patients (Morisky et al J Clin Hypertens 2008;10:348-354), however 30.5% were considered to have low adherence according to the cutpoints suggested by the developer. There were no differences in reported adherence by cancer type. Similarly, there were few differences in potential adherence barriers by cancer type except that number of physicians prescribing medications (*P*=0.0009) and being bothered by side effects (*P*=0.0054) varied significantly by cancer type. Breast cancer patients reported more physicians prescribing and being bothered more by side effects.

Indicators of medication complexity include taking multiple dosage forms, taking medications multiple times per day, and having multiple physicians prescribe medications. Most patients took medications twice per day (52%) and saw two or three doctors (55%) (*Table 15*). Oral tablets, capsules, or pills were the most common (85.9%) dosage form reported. Injections (8.3%), ointments (6.4%), inhalers (5.8%), and nose sprays (5.3%) were sometimes used and 8.6% of patients were using three or more dosage forms (*Table 16*).

Having to travel far to a pharmacy or make many trips to a pharmacy are potential barriers to taking medication (*Table 15*). Most patients (57.5%) lived less than five miles from the pharmacy they used to get most of their medications. Most patients (89.1%) made four or fewer visits to a pharmacy in a three-month period, suggesting their refills were reasonably well synchronized to a monthly schedule.

Side effects of medications bothered 23% of patients at least somewhat with 9.6% of patients bothered quite a bit or very much (*Table 15*). Having to rely on medications bothered 15.2% of patients at least somewhat. Most patients (89.4%) did not find it difficult to pay for prescribed medications, however 5.6% found it difficult or very difficult.

Table 15. All medications summary of follow-up respondents

	Droast	Drestate	Coloratal		Total
	Breast (N = 130)	(N - 1/3)	(N - 88)	Pvalue	10tai (N = 361)
Medications Taken Regularly ^a mean (SD)	46(34)	39(31)	47(48)	0.2326	4 3 (3 7)
Morisky Adherence Score ^b	4.0 (3.4)	3.5 (3.1)	4.7 (4.0)	0.2320	4.5 (5.7)
Low Adherence, No. (%)	27 (23.3)	45 (36.3)	24 (32.0)		96 (30.5)
Medium Adherence, No. (%)	86 (74.7)	75 (60.3)	50 (66.7)	0.2197	211 (67.0)
High Adherence, No. (%)	3 (2.6)	4 (3.2)	1 (1.3)	-	8 (2.5)
"Do you sometimes forget to take your medication? ", No.	27 (22.2)			0.4070	
'Yes' (%)	27 (22.9)	45 (35.2)	23 (29.9)	0.1072	95 (29.4)
"Over the past 2 weeks, were there any days when you did	12 (11 0)	27 (21 1)	16 (21.1)	0.0710	$\Gamma C (17.4)$
not take your medication?" ^d , No. 'Yes' (%)	13 (11.0)	27 (21.1)	16 (21.1)	0.0718	56 (17.4)
"Have you ever cut back or stopped taking your medication	12 (10 2)	12 (10 2)	10 (12 2)	0 76/3	25 (10 0)
because you felt worse when you took it?" ^d , No. 'Yes' (%)	12 (10.2)	13 (10.2)	10 (13.2)	0.7043	35 (10.9)
"When you travel or leave home, do you sometimes forget to	5 (4 2)	10 (7 9)	5 (6 6)	0 4864	20 (6 3)
bring your medication?" ^e , No. 'Yes' (%)	5 (4.2)	10 (7.5)	5 (0.0)	0.4004	20 (0.3)
"Did you take all your medication yesterday?", No. 'Yes' (%)	112 (95.7)	117 (92.1)	75 (97.4)	0.2182	304 (94.7)
"When you feel like your symptoms are under control, do you	3 (2.5)	11 (8.7)	6 (7.8)	0.1127	20 (6.2)
sometimes stop taking your medication?"", No. 'Yes' (%)	· · ·	· · ·	()		· · ·
"Do you ever feel hassled about sticking to your treatment	10 (8.6)	12 (9.4)	11 (14.3)	0.3987	33 (10.3)
plan?"", No. 'Yes' (%)	. ,	. ,	. ,		. ,
"How often do you have difficulty remembering to take all					
your medication?	00 (76 2)	9E (66 A)	FF (71 A)		220 (71 2)
Onco in a while No. (%)	90 (76.3)		25 (71.4) 21 (27.2)	-	230 (71.2)
Sometimes No. (%)	25 (19.5)	56 (29.7)	21 (27.5)	0.3861	<u> </u>
	4 (5.4)	0	1 (1.5)	-	1 (0.2)
Number Doctors Prescribing	1 (0.9)	0	0		1 (0.3)
1 Doctor No. (%)	23 (22 3)	51 (48 1)	28 (43.8)		102 (37 4)
2 or 3 Doctors No. (%)	73 (70.9)	48 (45 3)	29 (45 3)	-	150 (55.0)
More than 3 Doctors No. (%)	7 (6.8)	4 (3.8)	6 (9 4)	0.0009	17 (6 2)
Not currently taking medications. No. (%)	0	3 (2.8)	1 (1.6)	-	4 (1.5)
Number Times Medication Taken on Typical Dav ^h		0 (1.0)	= (=:0)		. (1.0)
Once, No. (%)	46 (39.0)	36 (28.8)	21 (27.6)		103 (32.3)
Twice, No. (%)	55 (46.6)	72 (57.6)	39 (51.3)	-	166 (52.0)
Three times, No. (%)	12 (10.2)	11 (8.8)	6 (7.9)	0.0915	29 (9.1)
More than three times, No. (%)	5 (4.2)	6 (4.8)	10 (13.2)	-	21 (6.6)
Distance Pharmacy from Home ⁱ					
Less than 1 mile, No. (%)	31 (23.9)	29 (20.3)	15 (17.2)		75 (20.8)
1 - 2 miles, No. (%)	26 (20.0)	36 (25.2)	20 (23.0)	-	82 (22.8)
3 - 5 miles, No. (%)	21 (16.2)	19 (13.3)	10 (11.5)	0 7014	50 (13.9)
5 - 10 miles, No. (%)	18 (13.9)	17 (11.9)	11 (12.6)	0.7914	46 (12.8)
More than 10 miles, No. (%)	20 (15.4)	20 (14.0)	19 (21.8)	_	59 (16.4)
None of the above - Mail order, No. (%)	14 (10.8)	22 (15.4)	12 (13.8)		48 (13.3)
Pharmacy Delivery Service ^d , No. (%)	28 (24.1)	39 (32.2)	21 (28.0)	0.1870	88 (28.2)
Trips to Pharmacy in Past 3 Months ^j					
0 trips, No. (%)	24 (18.5)	34 (23.9)	20 (23.0)	-	78 (21.7)
1 - 2 trips, No. (%)	66 (50.8)	55 (38.7)	36 (41.4)	- 0 3615	157 (43.7)
3 - 4 trips, No. (%)	21 (16.2)	41 (28.9)	23 (26.4)	-	85 (23.7)
5 - 6 trips, No. (%)	11 (8.5)	7 (4.9)	4 (4.6)		22 (6.1)

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	Breast	Prostate	Colorectal		Total
	(N = 130)	(N = 143)	(N = 88)	P value	(N = 361)
7 - 8 trips, No. (%)	4 (3.1)	4 (2.8)	2 (2.3)		10 (2.8)
9 - 10 trips, No. (%)	1 (0.8)	0	1 (1.2)		2 (0.6)
More than 10 trips, No. (%)	3 (2.3)	1 (0.7)	1 (1.2)	-	5 (1.4)
"How bothered have you been by how much you have to rely					
on your medications?" ^k					
Not at all, No. (%)	66 (52.4)	84 (58.7)	47 (54.0)	_	197 (55.3)
A little bit, No. (%)	43 (34.1)	37 (25.9)	25 (28.7)	_	105 (29.5)
Somewhat, No. (%)	9 (7.1)	13 (9.1)	11 (12.6)	0.6968	33 (9.3)
Quite a bit, No. (%)	3 (2.4)	5 (3.5)	3 (3.5)		11 (3.1)
Very much, No. (%)	5 (4.0)	4 (2.8)	1 (1.2)	-	10 (2.8)
"How bothered have you been by side effects of your					
medications?"					
Not at all, No. (%)	52 (40.6)	86 (60.1)	52 (59.8)	_	190 (53.1)
A little bit, No. (%)	32 (25.0)	35 (24.5)	19 (21.8)	_	86 (24.0)
Somewhat, No. (%)	22 (17.2)	15 (10.5)	11 (12.6)	0.0054	48 (13.4)
Quite a bit, No. (%)	13 (10.2)	5 (3.5)	4 (4.6)		22 (6.2)
Very much, No. (%)	9 (7.0)	2 (1.4)	1 (1.2)	-	12 (3.4)
"How easy/difficult has it been for you to pay for prescribed					
medications?"					
Very easy, No. (%)	58 (45.0)	70 (49.0)	30 (34.9)	_	158 (44.1)
Easy, No. (%)	27 (20.9)	39 (27.3)	24 (27.9)	_	90 (24.1)
Neither easy nor difficult, No. (%)	27 (20.9)	24 (16.8)	25 (29.1)	0 1 4 7 5	76 (21.2)
Difficult, No. (%)	7 (5.4)	3 (2.1)	3 (3.5)	0.1475	13 (3.6)
Very difficult, No. (%)	2 (1.6)	2 (1.4)	3 (3.5)	_	7 (2.0)
Not applicable, No. (%)	6 (6.2)	5 (3.5)	1 (1.2)		14 (3.9)

^a8 missing; ^bOut of those who answered all questions (N = 315), per <u>Morisky et al.</u>; ^c38 missing; ^d39 missing; ^e41 missing; ^f40 missing; ^g88 missing; ^h42 missing; ⁱ1 missing; ^j2 missing; ^k5 missing; ^l3 missing

Table 16. Medication dosge forms taken, survey #2

		No. (%)		_	No. (%)
	Breast	Prostate	Colorectal	_	Total
"I take my medications by"*	(N = 130)	(N = 143)	(N = 88)	P value	(N = 361)
Number of Dosage Forms				0.7565	
One	84 (64.6)	89 (62.2)	59 (67.1)		232 (64.3)
Two	24 (18.5)	22 (15.4)	11 (12.5)		57 (15.8)
Three or More	10 (7.7)	15 (10.5)	6 (6.8)		31 (8.6)
None	12 (9.2)	17 (11.9)	12 (13.6)		41 (11.4)
Swallowing Tablet, Capsule, or Pill	118 (90.8)	119 (83.2)	73 (83.0)	0.1341	310 (85.9)
Swallowing Liquid	4 (3.1)	2 (1.4)	2 (2.3)	0.6418	8 (2.2)
Gargling	3 (2.3)	0 (0.0)	1 (1.1)	0.1911	4 (1.1)
Dissolving Tablet Under Tongue	1 (0.8)	1 (0.7)	2 (24.4)	0.4859	4 (1.1)
Injecting with Needle	11 (8.5)	11 (7.7)	8 (9.1)	0.9296	30 (8.3)
Spraying in Nose	7 (5.4)	8 (5.6)	4 (4.6)	0.9388	19 (5.3)
Inhaling through Mouth Using Inhaler	7 (5.4)	11 (7.7)	3 (3.4)	0.3880	21 (5.8)
Inhaling through Mouth Using Mask	0 (0.0)	3 (2.1)	0 (0.0)	0.997	3 (0.8)
Drops or Ointment in Eyes	9 (6.9)	9 (6.3)	4 (4.6)	0.7653	22 (6.1)
Drops or Ointment in Ears	0 (0.0)	2 (1.4)	0 (0.0)	0.2159	2 (0.6)

		No. (%)		No. (%)	
	Breast	Prostate	Colorectal	_	Total
"I take my medications by"*	(N = 130)	(N = 143)	(N = 88)	P value	(N = 361)
Drops or Ointment in Nose	0 (0.0)	0 (0.0)	1 (1.1)	0.2111	1 (0.3)
Ointment, Cream or Salve to Skin	5 (3.9)	11 (7.7)	7 (8.0)	0.3366	23 (6.4)
Dressing or Bandage Covering Wound	0 (0.0)	1 (0.7)	0 (0.0)	0.4656	1 (0.3)
Suppository, Cream, or Liquid Rectally or Vaginally	1 (0.8)	1 (0.7)	1 (1.1)	0.9344	3 (0.8)
Do Not Take Prescribed Medications	0 (0.0)	4 (2.1)	1 (1.1)	0.2546	4 (1.1)

*Participants were asked to check all that apply

As seen in survey #1, few survey #2 respondents reported currently receiving chemotherapy administered at a hospital or clinic (*Table 17*). Breast cancer patients but not prostate or colorectal cancer patients were commonly taking oral medications "prescribed by a doctor to cure cancer or to keep it from coming back."

Table 17. Cancer medications summary, survey #2

		No. (%)			No. (%)
	Breast	Prostate	Colorectal	•	Total
	(N = 130)	(N = 143)	(N = 88)	P value	(N = 361)
Chemo in Clinic	1 (0.8)	1 (0.7)	6 (6.8)	0.0034	8 (2.3)
Current Cancer Medications	93 (71.5)	8 (5.6)	2 (2.3)	<0.0001	103 (28.5)
"How often do you"*					
Forget to Take Cancer Medications					
None of the time	82 (88.2)	7 (87.5)	1 (50.0)	0 2742	90 (87.4)
Some of the time	11 (11.8)	1 (12.5)	1 (50.0)	0.2743	13 (12.6)
Decide not to Take Cancer Medications					
None of the time	91 (97.9)	8 (100.0)	2 (100.0)	0 9061	101 (98.1)
Some of the time	2 (2.2)	0 (0.0)	0 (0.0)	0.0901	2 (1.9)
"In the past 7 days"					
I took all doses	88 (94.6)	7 (87.5)	1 (50.0)	_	92 (92.9)
I missed or skipped 1 dose	4 (4.3)	1 (12.5)	1 (50.0)	0.0832	6 (6.1)
I missed or skipped 2 doses	1 (1.1)	0 (0.0)	0 (0.0)		1 (1.0)

*Following questions were asked only to those who answered "Yes" to currently taking a cancer medication (N = 103)

There was little clinical difference between survey #1 and survey #2 in either PROMIS physical health or mental health scores (*Figure 2*).



Figure 2. Patient-reported outcomes (PROMIS Global-10) from survey #1 and survey #2.

*Promis Global-10 (Patient-Reported Outcome Measurement Information System (<u>http://www.healthmeasures.net/</u>))

Symptom patterns reported by survey #2 respondents <u>in the past 7 days</u> (**Table 18**) were similar to those observed in survey #1, however some frequencies were higher on the second survey, likely attributable to the different time frame referenced (for survey #1 the reference period was "after diagnosis"). In particular, pain was much more frequently reported in survey #2 (62.6% vs. 24.5% in survey #1). In contrast, cancer worries were much less frequently reported in the recent 7 days (29.1% vs. 48.0% in the after cancer diagnosis period). *Figures 3-5* display the survey #1 and survey #2 symptom frequencies by cancer type. It is interesting that the proportion of people reporting pain and decreased range of motion increased from survey #1 to survey #2 for each cancer type, whereas cancer worries decreased in both breast and prostate cancers.

		No. (%)	_	No. (%)	
" <u>In the past 7 days</u> did you experience	Breast	Prostate	Colorectal	_	Total
any of the following?"	(N = 130)	(N = 143)	(N = 88)	P value	(N = 361)
Fatigue ^a	89 (69.0)	96 (67.6)	58 (66.7)	0.9339	243 (67.9)
Pain ^a	79 (61.2)	90 (62.9)	55 (64.0)	0.9158	224 (62.6)
Neuropathy ^b	44 (35.2)	45 (32.1)	50 (58.8)	0.0002	139 (39.7)
Cardiomyopathy ^c	0 (0.0)	1 (0.7)	3 (3.5)	0.0536	4 (1.1)
Trouble Thinking ^c	41 (32.3)	16 (11.4)	24 (27.6)	0.0001	81 (22.9)
Lymphedema ^d	10 (7.8)	3 (2.2)	3 (3.5)	0.0758	16 (4.6)

Table 18.	Symptom	inventory.	survev #2
TUDIC 10.	Symptom	mvencory,	Survey #2

		No. (%)			No. (%)
" <u>In the past 7 days</u> did you experience	Breast	Prostate	Colorectal	-	Total
any of the following?"	(N = 130)	(N = 143)	(N = 88)	P value	(N = 361)
Decreased Range of Motion ^e	34 (26.6)	48 (33.8)	24 (27.6)	0.3801	106 (26.7)
Rotator Cuff Problems ^d	7 (5.6)	16 (11.4)	15 (17.7)	0.0204	38 (10.8)
Bladder Problems ^e	15 (11.7)	39 (27.5)	15 (17.2)	0.0040	69 (19.3)
Frozen Shoulder ^c	0 (0.0)	3 (2.1)	4 (4.6)	0.0589	7 (2.0)
Other Shoulder Problems ^c	9 (7.0)	10 (7.2)	4 (4.6)	0.7089	23 (6.5)
Sexual Problems ^f	17 (13.3)	74 (52.1)	19 (22.1)	<0.0001	110 (30.9)
Distress ^f	38 (29.5)	26 (18.6)	26 (29.9)	0.0638	90 (25.3)
Worries about Cancer ^e	32 (24.8)	32 (22.7)	40 (46.0)	0.0003	104 (29.1)
Relationships or Body Image Worries ^g	34 (26.6)	31 (22.0)	17 (19.8)	0.4723	82 (23.1)

°3 missing; °11 missing; °7 missing; d9 missing; e4 missing; f5 missing; 86 missing



Figure 3. Symptom inventory* survey #1 and survey #2 – breast

*Top 10 endorsed symptoms only

Figure 4. Symptom inventory* survey #1 and survey #2 – prostate



*Top 10 endorsed symptoms only



Figure 5. Symptom inventory* survey #1 and survey #2 – colorectal

*Top 10 endorsed symptoms only

Questions were introduced about survivorship care plans at the time of survey #2 (**Table 19**). The ONWARD website included assistance for making a survivorship care plan. Before answering these questions, participants were presented with a definition of a survivorship care plan and explanation of the information it may contain. Almost a third of patients reported they had a survivorship care plan but 18.1% didn't know. Only two people reported using the ONWARD study website to create one. When asked about two key elements of survivorship care planning, a summary of treatments received and instructions about follow-up care, more people indicated they had received these (49.2% and 78.6%, respectively). Patients experience survivorship care planning even if they don't receive a formal survivorship care plan document. Only 62.6% of patients who received a summary of treatments still had it. Breast and prostate cancer patients more often reported being 'very certain' about which doctor was in charge of their follow-up care compared to colorectal cancer patients.

		No. (%)			No. (%)
	Breast	Prostate	Colorectal		Total
	(N = 130)	(N = 143)	(N = 88)	P value	(N = 361)
"Do you have a Survivorship Care Plan?" ^a					
Yes	49 (37.7)	41 (28.7)	26 (29.9)		116 (32.2)
No	57 (43.9)	80 (55.9)	42 (48.3)	0.2642	179 (49.7)
Don't Know	24 (18.5)	22 (15.4)	19 (21.8)	_	65 (18.1)
"Did you use or try to use the ONWARD study website					
to make your own Survivorship Care Plan?"b					

Table 19. Follow-up care, survey #2

		No. (%)			No. (%)
	Breast	Prostate	Colorectal	-	Total
	(N = 130)	(N = 143)	(N = 88)	P value	(N = 361)
Yes	1 (0.8)	0 (0.0)	1 (1.2)		2 (0.6)
No	127 (98.5)	140 (97.9)	85 (97.7)	0.6701	352 (98.1)
Don't Know	1 (0.8)	3 (2.1)	1 (1.2)	-	5 (1.4)
Did you receive a "written or computer print-out					
summary of the cancer treatments that you received?"					
Yes	64 (50.0)	69 (48.9)	42 (48.3)	_	175 (49.2)
No	41 (32.0)	39 (27.7)	29 (33.3)	0.7539	109 (30.6)
Don't Know	23 (18.0)	33 (23.4)	16 (18.4)		72 (20.2)
"Do you still have that written or computer print-out					
summary in your possession?"					
Yes	47 (73.4)	36 (52.9)	26 (61.9)	_	109 (62.6)
No	5 (7.8)	15 (22.1)	3 (7.1)	0.0339	23 (13.2)
Don't Know	12 (18.8)	17 (25.0)	13 (31.0)		42 (24.1)
Did you receive "written or computer print-out					
instructions about routine cancer check-ups after					
completing your cancer treatments?" ^e					
Yes	102 (79.7)	106 (75.2)	71 (82.6)	_	279 (78.6)
No	15 (11.7)	22 (15.6)	12 (14.0)	0.4481	49 (13.8)
Don't Know	11 (8.6)	13 (9.2)	3 (3.5)		27 (7.6)
"How certain were you about which doctor was in					
charge of your follow-up care?" ^f					
Very Certain	104 (80.6)	116 (81.7)	63 (72.4)	_	283 (79.1)
Somewhat Certain	18 (14.0)	18 (12.7)	15 (17.2)	0 01 21	51 (14.3)
Neither Certain nor Uncertain	6 (4.7)	1 (0.7)	8 (9.2)	0.0121	15 (4.2)
Treatment Not Complete	1 (0.8)	7 (4.9)	1 (1.2)		9 (2.5)

^a1 missing; ^b2 missing; ^c5 missing; ^dOnly asked to patients who responded "Yes" to receiving a summary (N = 175); ^e6 missing; ^f3 missing

E. Description of any problems encountered and resolution

Research team members logged all contacts from patients or their proxies. Calls were coded based on the nature of the contacts. Over the course of the study, the team received 23 contacts related to issues concerning the study website. Notably, the majority of such contacts (N = 15) were made after submission of Survey #1 and all involved issues related to accessing Survey #2 in their study account. The immediate action proposed by the team to such inquiries was to reset the user's password and communicate it to the patient over the phone or via mail. In all but one case, subjects completed Survey #2.

This volume of contacts related to website access in a short amount of time signaled a potential system problem, and we explored the username/password retrieval process further. The team identified issues related to the automated process of how forgotten usernames were retrieved and how passwords were reset. We implemented a fix soon thereafter. Thereafter, the volume of contacts related to account access issues fell, and the rates of Survey #2 completion increased.

Comments entered in Survey #2 in response to the question 'Please describe any problems you had with the ONWARD study website' reflected this observation. All but 6 of 34 responses entered cited issues with username/password retrieval and/or problems logging in to the website. The six remaining comments described difficultly or frustration with Survey #2, or indicated they were not aware of the full range of features available to them in the website.

F. Data collection instruments

We submitted the study data dictionaries and screen shots to NCI on June 18, 2018. Data dictionaries and screenshots of the instruments are included in Appendices 3 and 4 respectively.

G. Feasibility Assessment Report

I. Evaluation of methods used to contact and recruit patients

We used a mailed approach to inviting patients for this study for several reasons. First, the team did not have access to email addresses. If the Iowa Cancer Registry did collect email patient addresses, we likely would still have opted to mail invitations rather than send invitations via email, as there are many potential issues related to email recruitment (e.g., email goes to a spam or junk mail folder; recipient identifies email as spam/junk; lack of ongoing checking of email account for new messages; deleted by another user for email accounts; internet accessibility and data limits; obsolete email account, etc.).

We varied the envelope size and postage type across recruitment batches. Analyses of response rates suggested that larger envelope size (9" X 6" envelope vs. #10 envelope) and first-class postage (vs. bulk rate) may favorably impact response rate. However, given that mailings occurred in succession and not concurrently, the impact of time of year on response rate is not known. Future studies may benefit by using large envelopes and first class postage.

II. Evaluation of methods used to collect PGHD from participants. Includes:

a. Evaluation of potential efficacy of the PGHD approach and recommendations for the role of PGHD in future cancer surveillance research

In our prior experience, the response rate to a lengthy questionnaire mailed to breast cancer patients approached 70% (1 remailing, no telephone follow-up) with a \$10 incentive, the same amount as this

project. The online response rate in the present project was much lower. The low response rate does not appear to be attributable to difficulty using the tool, as the vast majority who went to the website and logged in ended up consenting and completing the survey and reporting it easy to use.

The data collection approach used an online personal health record (PHR) to collect patient-reported health data. Recruitment via mailed letter for an online survey introduces a barrier – people have to take the letter to a computer or access the website via mobile device before responding. Future cancer surveillance research could improve accessibility for some patients through a native mobile app available for download from app stores. E-mailed invitations could also remove the mail-to-device step. However, cancer registries do not maintain email lists. Another potential approach would be for cancer registries to recruit patients through reporting facilities, for example by partnering with hospital providers to distribute invitations via patient portals.

Important patient-reported data of value for cancer surveillance research (e.g. quality of life, questions about recurrence, and questions about cancer treatments) can fill gaps in current registry surveillance. A mixture of delivery through patient portals and brief mailed questionnaires may be the best approach.

b. Assessment of utility of the specified data collection method as a tool for longitudinal data collection

The PHR demonstrated good utility as a tool for longitudinal data collection. Of 395 subjects who completed Survey #1, 361 completed Survey #2 (91.4%), and an additional 5 subjects (1.3%) started but did not submit Survey #2. Of the 29 persons (7.3%) who did not start Survey #2, we made contact with 14 subjects, six had missing or invalid phone numbers, 2 persons were deceased, and the remaining seven were attempted but not reached after 3 attempts.

c. Information about burden the data collection method poses to patients

As described in section II.3. below, participants reported high ratings of ease and usability of the study website used to collect the data and only a minority (10%) reported having any problems with using the website, mostly related to password retrieval which was remedied. Taken together with the high continuing participation in the second survey (>90%), this indicates an acceptable respondent burden and generally pleasing experience.

d. Information about the extent of patient engagement with the study

We deployed log-tracking to collect information about patient engagement (*Tables 20-23*). Patients could explore the site at will. Use was completely voluntary. Patients were not told to do any specific tasks other than complete the survey but they were invited to explore and use the various features. The majority of patients (82.8%) engaged with the system twice. On those days the average number of items clicked was 5.9 and average minutes spent was 24.9. In addition to the home page, 69.6% viewed at least one other page. At least one report was viewed by 40.8% with 20.8% viewing survey #1 results and 8.6% viewing survey #2 results. Many (29.9%), but not most, users navigated to the current medications section and 15.7% used it to enter at least one medication. Symptom management information was accessed by 18.5%, 7.9% accessed an informational pamphlet, and 8.6% viewed 'my cancer care plan'. Breast cancer patients were most likely and prostate cancer patients least likely to view the cancer care plan (p=.014).

There were few differences in usage statistics by metro/nonmetro residence (*Table 21*), health literacy (*Table 22*), or age (*Table 23*). Nonmetro residents were more likely to view survey #2 results

(P=0.0267), and patients with high health literacy spent fewer minutes per session (20 vs 30, P=0.0005), as did younger individuals (21 v 28, P=0.0035).

	Breast (N = 144)	Prostate (N = 155)	Colorectal (N = 96)	P value	All (N = 395)
Interaction (Items Clicked) Per Day, mean (SD)	6.0 (7.4)	6.0 (9.5)	5.7 (6.9)	0.8688	5.9 (8.2)
Minutes Per Day, mean (SD)	24.7 (34.4)	24.5 (29.5)	26.0 (36.2)	0.8639	24.9 (33.0)
Separate Days Interacted					
1, No. (%)	9 (6.3)	12 (7.7)	7 (7.3)	_	28 (7.1)
2, No. (%)	120 (83.3)	132 (85.2)	75 (78.1)	0 5 2 6 7	327 (82.8)
3, No. (%)	13 (9.0)	8 (5.2)	13 (13.5)	0.5207	34 (8.6)
4+, No. (%)	2 (1.4)	3 (1.9)	1 (1.1)		6 (1.5)
Viewed Any Page in Addition to Homepage, No. (%)	107 (74.3)	107 (69.0)	61 (63.5)	0.2022	275 (69.6)
Viewed Any Report ^a , No. (%)	66 (45.8)	55 (35.5)	40 (41.7)	0.1869	161 (40.8)
Viewed Informational Pamphlet ^b , No. (%)	16 (11.1)	6 (3.9)	9 (9.4)	0.0545	31 (7.9)
Viewed Survey #1 Results, No. (%)	32 (22.2)	30 (19.4)	20 (20.8)	0.8296	82 (20.8)
Viewed Survey #2 Results, No. (%)	12 (8.3)	13 (8.4)	9 (9.4)	0.9535	34 (8.6)
Viewed "My Cancer Care Plan", No. (%)	20 (13.9)	7 (4.5)	7 (7.3)	0.0135	34 (8.6)
Navigated to "Current Medications", No. (%)	48 (33.3)	46 (29.7)	24 (25.0)	0.3840	118 (29.9)
Navigated to "Symptom Action Deck" Page, No. (%)	33 (22.9)	20 (12.9)	20 (20.8)	0.0661	73 (18.5)
Added a Medication, No. (%)	21 (14.6)	24 (15.5)	17 (17.7)	0.8050	62 (15.7)
Navigated to "Health Conditions Tab", No. (%)	17 (11.8)	10 (6.5)	12 (12.5)	0.1838	39 (9.9)
Clicked on an External Link ^c , No. (%)	17 (11.8)	9 (5.8)	11 (11.5)	0.1482	37 (9.4)

Table 20. Website use statistics by cancer type

^aReports Include: Current Medications Report, Medications History Report, Wallet Card Report, Informational Pamphlets (listed below), Survey #1 Results, Survey #2 Results, Cancer Care Plan, ONWARD Informed Consent Document, ONWARD Study Information Document, and ONWARD Study Info After Survey #2 Document

^bPamphlets include: "Making a Survivorship Care Pamphlet", "Use Medications Widely Pamphlet", "Talking with Doctors about Cancer Effects Pamphlet"

^cExternal links include symptom information links (survivorship.cancer.gov, smokefree.gov)

Table 21. Website use statistics by rurality

	Metro	Nonmetro		All
	(N = 211)	(N = 184)	P value	(N = 395)
Interaction (Items Clicked) Per Day, mean (SD)	5.9 (8.2)	5.9 (8.2)	0.9139	5.9 (8.2)
Minutes Per Day, mean (SD)	25.5 (39.8)	24.3 (23.0)	0.5813	24.9 (33.0)
Separate Days Interacted				
1, No. (%)	12 (5.7)	16 (8.7)		28 (7.1)
2, No. (%)	180 (85.3)	147 (79.9)	0 25 21	327 (82.8)
3, No. (%)	15 (7.1)	19 (10.3)	- 0.2531	34 (8.6)
4+, No. (%)	4 (1.9)	2 (1.1)		6 (1.5)
Viewed Any Page in Addition to Homepage, No. (%)	146 (69.2)	129 (70.1)	0.8437	275 (69.6)
Viewed Any Report ^a , No. (%)	81 (38.4)	80 (43.5)	0.3045	161 (40.8)
Viewed Informational Pamphlet ^b , No. (%)	15 (7.1)	16 (8.7)	0.5586	31 (7.9)
Viewed Survey #1 Results, No. (%)	40 (19.0)	42 (22.8)	0.3443	82 (20.8)

	•	·	•	
	Metro	Nonmetro		All
	(N = 211)	(N = 184)	P value	(N = 395)
Viewed Survey #2 Results, No. (%)	12 (5.7)	22 (12.0)	0.0267	34 (8.6)
Viewed "My Cancer Care Plan", No. (%)	19 (9.0)	15 (8.2)	0.7631	34 (8.6)
Navigated to "Current Medications", No. (%)	62 (29.4)	56 (30.4)	0.8199	118 (29.9)
Navigated to "Symptom Action Deck" Page, No. (%)	43 (20.4)	30 (16.3)	0.2980	73 (18.5)
Added a Medication, No. (%)	32 (15.2)	30 (16.3)	0.7563	62 (15.7)
Navigated to "Health Conditions Tab", No. (%)	23 (10.9)	16 (8.7)	0.4637	39 (9.9)
Clicked on an External Link ^c , No. (%)	24 (11.4)	13 (7.1)	0.1426	37 (9.4)

^aReports Include: Current Medications Report, Medications History Report, Wallet Card Report, Informational Pamphlets (listed below), Survey #1 Results, Survey #2 Results, Cancer Care Plan, ONWARD Informed Consent Document, ONWARD Study Information Document, and ONWARD Study Info After Survey #2 Document

^bPamphlets include: "Making a Survivorship Care Pamphlet", "Use Medications Widely Pamphlet", "Talking with Doctors about Cancer Effects Pamphlet"

^cExternal links include symptom information links (survivorship.cancer.gov, smokefree.gov)

Table 22. Website use statistics by health literacy

	Low	Medium	High	All	
	(N = 81)	(N = 112)	(N = 202)	P value	(N = 395)
Interaction (Items Clicked) Per Day, mean (SD)	5.6 (6.3)	5.9 (8.7)	6.0 (8.5)	0.8861	5.9 (8.2)
Minutes Per Day, mean (SD)	29.9 (45.2)	29.3 (38.5)	20.2 (21.5)	0.0005	24.9 (33.0)
Separate Days Interacted					
1, No. (%)	7 (8.6)	10 (8.9)	11 (5.5)		28 (7.1)
2, No. (%)	64 (79.0)	88 (78.6)	175 (86.6)	0 5 5 00	327 (82.8)
3, No. (%)	8 (9.9)	13 (11.6)	13 (6.4)	- 0.5500	34 (8.6)
4+, No. (%)	2 (2.5)	1 (0.9)	3 (1.5)		6 (1.5)
Viewed Any Page in Addition to Homepage, No. (%)	53 (65.4)	72 (64.3)	150 (74.3)	0.1205	275 (69.6)
Viewed Any Report ^a , No. (%)	36 (44.4)	41 (36.6)	84 (41.6)	0.5189	161 (40.8)
Viewed Informational Pamphlet ^b , No. (%)	5 (6.2)	13 (11.6)	13 (6.4)	0.2166	31 (7.9)
Viewed Survey #1 Results, No. (%)	18 (22.2)	24 (21.4)	40 (19.8)	0.8832	82 (20.8)
Viewed Survey #2 Results, No. (%)	11 (13.6)	11 (9.8)	12 (5.9)	0.1012	34 (8.6)
Viewed "My Cancer Care Plan", No. (%)	4 (4.9)	12 (10.7)	18 (8.9)	0.3603	34 (8.6)
Navigated to "Current Medications", No. (%)	21 (25.9)	34 (30.4)	63 (31.2)	0.6765	118 (29.9)
Navigated to "Symptom Action Deck" Page, No. (%)	15 (18.5)	20 (17.9)	38 (18.8)	0.9784	73 (18.5)
Added a Medication, No. (%)	10 (12.4)	19 (17.0)	33 (16.3)	0.6421	62 (15.7)
Navigated to "Health Conditions Tab", No. (%)	6 (7.4)	13 (11.6)	20 (9.9)	0.6275	39 (9.9)
Clicked on an External Link ^c , No. (%)	7 (8.6)	8 (7.1)	22 (10.9)	0.5338	37 (9.4)

^aReports Include: Current Medications Report, Medications History Report, Wallet Card Report, Informational Pamphlets (listed below), Survey #1 Results, Survey #2 Results, Cancer Care Plan, ONWARD Informed Consent Document, ONWARD Study Information Document, and ONWARD Study Info After Survey #2 Document

^bPamphlets include: "Making a Survivorship Care Pamphlet", "Use Medications Widely Pamphlet", "Talking with Doctors about Cancer Effects Pamphlet"

^cExternal links include symptom information links (survivorship.cancer.gov, smokefree.gov)

Table 23. Website use statistics by age

	Under 65	65 & Over		All
	(N = 187)	(N = 206)	P value	(n = 393) ^a
Interaction (Items Clicked) Per Day, mean (SD)	5.8 (7.9)	6.0 (8.5)	0.7510	5.9 (8.2)
Minutes Per Day, mean (SD)	21.2 (19.8)	28.0 (41.2)	0.0035	24.8 (33.0)
Separate Days Interacted				
1, No. (%)	10 (5.4)	18 (8.7)		28 (7.1)
2, No. (%)	162 (86.6)	163 (79.1)	0.2624	325 (82.7)
3, No. (%)	14 (8.5)	20 (9.7)	0.2034	34 (8.7)
4+, No. (%)	1 (0.5)	5 (2.4)		6 (1.5)
Viewed Any Page in Addition to Homepage, No. (%)	127 (67.9)	147 (71.4)	0.4579	274 (69.7)
Viewed Any Report ^b , No. (%)	75 (40.1)	86 (41.8)	0.7412	161 (41.0)
Viewed Informational Pamphlet ^c , No. (%)	13 (7.0)	18 (8.7)	0.5118	31 (7.9)
Viewed Survey #1 Results, No. (%)	36 (19.3)	46 (22.3)	0.4532	82 (20.9)
Viewed Survey #2 Results, No. (%)	13 (4.0)	21 (10.2)	0.2535	34 (8.7)
Viewed "My Cancer Care Plan", No. (%)	19 (10.2)	15 (7.3)	0.3106	34 (8.7)
Navigated to "Current Medications", No. (%)	58 (31.0)	59 (28.6)	0.6070	117 (29.8)
Navigated to "Symptom Action Deck" Page, No. (%)	34 (18.2)	38 (18.5)	0.9460	72 (18.3)
Added a Medication, No. (%)	27 (14.4)	35 (17.0)	0.4883	62 (15.8)
Navigated to "Health Conditions Tab", No. (%)	20 (10.7)	19 (9.2)	0.6260	39 (9.9)
Clicked on an External Link ^d , No. (%)	19 (10.2)	18 (8.7)	0.6296	37 (9.4)

^a2 unknown age at baseline submission

^bReports Include: Current Medications Report, Medications History Report, Wallet Card Report, Informational Pamphlets (listed below), Survey #1 Results, Survey #2 Results, Cancer Care Plan, ONWARD Informed Consent Document, ONWARD Study Information Document, and ONWARD Study Info After Survey #2 Document

^cPamphlets include: "Making a Survivorship Care Pamphlet", "Use Medications Widely Pamphlet", "Talking with Doctors about Cancer Effects Pamphlet"

^dExternal links include symptom information links (survivorship.cancer.gov, smokefree.gov)

e. Information about the ease and usability of the data collection tool or process from the patient's perspective

Participants were queried about the ease and usability of the ONWARD study website at the time of Survey #2. *Tables 24-27* display these responses by age, health literacy, metro/nonmetro residence, and cancer type. Overall, on a scale from 1 (worst) to 10 (best), respondents reported generally high ratings, finding the website generally satisfying (mean 7.0) and easy (7.6) to use. They found the website somewhat stimulating (mean 5.9), flexible (mean 6.4) and pleasant (mean 6.5 on a scale from terrible to wonderful). When asked about the screen display, they found it easy to read characters on the screen (mean 8.3), the information well-organized (mean 7.6), and the sequence of screens clear (7.7). Similarly, consistency of terminology (7.9) and clarity of prompts for input (7.9) were highly rated. Lastly, respondents found the website easy to learn (7.7) and task performance to be straightforward (7.7). Only 10% of respondents indicated having any problems using the study website (See Section G.II.e. for a description of these problems).

There was a tendency for older (65+) adults to report slightly lower ratings but this was statistically significant only for ease of use (55-64 years mean 7.8, 65+ years mean 7.3; *P*=0.0145) and

straightforward task performance (55-64 years mean 8.0, 65+ years mean 7.5; *P*=0.0265). Older adults were more likely to indicate having problems with the website (55-64 years mean 6.0%, 65+ years mean 13.9%; *P*=0.0146).

In contrast, lower health literacy was more consistently associated with lower ratings. Although evaluations of satisfaction with the website, how stimulating it was and pleasantness of experience were similar across all literacy levels, patients with lower literacy reported significantly poorer ratings on the remaining 9 metrics. Nevertheless, even among the 20% of patients in the lowest literacy group, mean ratings were typically 6.5 or greater. People with low health literacy were somewhat more likely to report problems using the study website (14.1% vs 6.6%, *P*= 0.0763).

Given potential concerns about internet performance in nonmetro areas, it was reassuring to observe no differences between metro and nonmetro residents in any of these ratings.

Table 24. Website feedback summary by age

	Under 65 (N =	Over 65		Total
	173)	(N = 186)	P value	(N = 359) ^a
Useful Information ^b				
Very useful, No. (%)	21 (12.5)	18 (9.8)	-	39 (11.1)
Somewhat useful, No. (%)	70 (41.7)	83 (45.1)		153 (43.5)
A little useful, No. (%)	50 (29.8)	60 (32.6)	0.0001	110 (31.3)
Not useful at all, No. (%)	27 (16.1)	23 (12.5)		50 (14.2)
"Have the information resources in the ONWARD study website helped you make a	24 (20 6)	26 (10 6)	0 0001	70 (20 1)
decision about how to treat or manage a symptom, illness or condition?" ^c 'Yes', No. (%)	34 (20.6)	50 (19.0)	0.8084	70 (20.1)
"Have you talked to a doctor, nurse, or other health professional about any kind of	2 (1 0)	5 (2 7)	0.5515	8 (2.2)
health information you have gotten from the ONWARD study website?"d , 'Yes', No. (%)	5 (1.8)	5(2.7)		
"Have the information resources in the ONWARD study website led you to ask a doctor	13 (7 7)	7 (3 8)	0 117/	20 (5 7)
new questions, or to get a second opinion from another doctor?" ^b , 'Yes', No. (%)	15 (7.7)	7 (5.8)	0.1174	20 (5.7)
Refer to Information from Website at Doctor's Visit ^e , 'Yes', No. (%)	1 (0.8)	1 (0.7)	0.8806	2 (0.8)
Show Information from Website at Doctor's Visit ^e , 'Yes', No. (%)	1 (0.8)	1 (0.7)	0.8806	2 (0.8)
Reactions to the ONWARD Website				
Terrible (1) - Wonderful (10) ^f , mean (SD)	6.5 (1.7)	6.5 (1.8)	0.9129	6.5 (1.8)
Difficult (1) - Easy (10) ^g , mean (SD)	7.8 (2.0)	7.3 (2.1)	0.0145	7.6 (2.1)
Frustrating (1) - Satisfying (10) ^h , mean (SD)	7.2 (2.0)	6.9 (2.1)	0.2704	7.0 (2.0)
Dull (1)- Stimulating (10) ⁱ , mean (SD)	5.9 (2.0)	5.9 (1.9)	0.8912	5.9 (1.9)
Rigid (1)- Flexible (10) ⁱ , mean (SD)	6.4 (2.0)	6.3 (2.2)	0.6049	6.4 (2.1)
Reading Characters ⁱ : Hard (1) - Easy (10), mean (SD)	8.4 (2.0)	8.3 (2.0)	0.6903	8.3 (2.0)
Organization ^k : Confusing (1) - Very Clear (10), mean (SD)	7.7 (2.0)	7.5 (2.1)	0.3273	7.6 (2.1)
Sequence of Screens ¹ : Confusing (1) - Very Clear (10), mean (SD)	7.9 (2.0)	7.6 (2.1)	0.1534	7.7 (2.1)
Use of Terms ¹ : Inconsistent (1) - Consistent (10) , mean (SD)	8.0 (2.0)	7.7 (2.1)	0.2288	7.9 (2.1)
Prompts for Input ⁱ : Confusing (1) - Clear (10), mean (SD)	8.0 (2.0)	7.8 (2.0)	0.2056	7.9 (2.0)
Learning to Operate ⁱ : Difficult (1) - Easy (10), mean (SD)	7.9 (2.1)	7.5 (2.2)	0.1100	7.7 (2.1)
Tasks were Straightforward ^h : Never (1) - Always (10), mean (SD)	8.0 (1.9)	7.5 (2.2)	0.0265	7.7 (2.1)
Problems Using Website ^m , 'Yes', No. (%)	10 (6.0)	25 (13.9)	0.0146	35 (10.1)

^a2 unknown age at baseline submission; ^b9 missing; ^c12 missing; ^d4 missing; ^eOut of those who reported a doctor's visit since baseline (N = 267); ^f8 missing; ^g11 missing; ^h15 missing; ⁱ16 missing; ^j17 missing; ^k19 missing; ^l18 missing; ^m14 missing
	Low	Medium	High		Total
	(N = 74)	(N = 99)	(N = 188)	P value	(N = 361)
Useful Information ^a					
Very useful, No. (%)	9 (12.3)	10 (10.3)	21 (11.4)	_	40 (11.3)
Somewhat useful, No. (%)	31 (42.5)	36 (37.1)	87 (47.3)		154 (43.5)
A little useful, No. (%)	25 (34.3)	36 (37.1)	49 (26.6)	0.5551	110 (31.1)
Not useful at all, No. (%)	8 (11.0)	15 (15.5)	27 (14.7)		50 (14.1)
"Have the information resources in the ONWARD study website helped you make a	20 (27 8)	12 (12 ⊑)	20 /1E E)		71 (20.2)
decision about how to treat or manage a symptom, illness or condition?" ^b 'Yes', No. (%)	20 (27.8)	25 (25.5)	28 (15.5)	0.0372	71 (20.2)
"Have you talked to a doctor, nurse, or other health professional about any kind of	1 (1 4)	2 (2 1)	1 (2 1)	0 7/82	8 (2 2)
health information you have gotten from the ONWARD study website?" ^c , 'Yes', No. (%)	1 (1.4)	5 (5.1)	4 (2.1)	0.7462	8 (2.2)
"Have the information resources in the ONWARD study website led you to ask a doctor	5 (6 0)	6 (6 2)	0 (1 0)	0 7817	20 (5 7)
new questions, or to get a second opinion from another doctor?" ^a 'Yes', No. (%)	5 (0.5)	0 (0.2)	5 (4.5)	0.7817	20 (5.7)
Refer to Information from Website at Doctor's Visit ^d , 'Yes', No. (%)	0 (0.0)	2 (2.6)	0 (0.0)	0.0859	2 (0.8)
Show Information from Website at Doctor's Visit ^d , 'Yes', No. (%)	0 (0.0)	1 (1.3)	1 (0.8)	0.6912	2 (0.8)
Reactions to the ONWARD Website					
Terrible (1) - Wonderful (10) ^b , mean (SD)	6.6 (1.8)	6.2 (1.9)	6.7 (1.7)	0.0657	6.5 (1.8)
Difficult (1) - Easy (10) ^e , mean (SD)	7.0 (2.1)	7.2 (2.2)	8.0 (1.9)	0.0004	7.6 (2.1)
Frustrating (1) - Satisfying (10) ^f , mean (SD)	6.7 (2.2)	6.8 (2.0)	7.3 (2.0)	0.0669	7.0 (2.0)
Dull (1)- Stimulating (10) ^g , mean (SD)	5.9 (1.9)	5.6 (2.1)	6.1 (1.9)	0.1359	5.9 (1.9)
Rigid (1)- Flexible (10) ^g , mean (SD)	6.1 (1.9)	6.0 (2.1)	6.7 (2.0)	0.0163	6.4 (2.1)
Reading Characters ^h : Hard (1) - Easy (10), mean (SD)	7.8 (2.3)	8.0 (2.1)	8.7 (1,8)	0.0003	8.3 (2.0)
Organization ⁱ : Confusing (1) - Very Clear (10), mean (SD)	6.9 (2.1)	7.3 (2.3)	8.1 (1.8)	<0.0001	7.6 (2.1)
Sequence of Screens ⁱ : Confusing (1) - Very Clear (10), mean (SD)	7.2 (2.1)	7.5 (2.2)	8.1 (1.9)	0.0041	7.7 (2.1)
Use of Terms ^j : Inconsistent (1) - Consistent (10) , mean (SD)	7.2 (2.2)	7.5 (2.2)	8.3 (1.8)	0.0002	7.9 (2.1)
Prompts for Input ^g : Confusing (1) - Clear (10), mean (SD)	7.4 (2.0)	7.7 (2.1)	8.2 (1.9)	0.0183	7.9 (2.0)
Learning to Operate ^h : Difficult (1) - Easy (10), mean (SD)	7.3 (2.1)	7.3 (2.4)	8.1 (1.9)	0.0010	7.7 (2.1)
Tasks were Straightforward ^f : Never (1) - Always (10), mean (SD)	7.3 (2.0)	7.1 (2.4)	8.2 (1.8)	<0.0001	7.7 (2.1)
Problems Using Website ^k , 'Yes', No. (%)	10 (14.1)	13 (13.7)	12 (6.6)	0.0763	35 (10.0)

 Table 25. Website feedback summary by health literacy

^a7 missing; ^b10 missing; ^c2 missing; ^dOut of those who reported a doctor's visit since baseline (N = 269); ^e13 missing; ^f17 missing; ^g18 missing; ^h19 missing; ^j21 missing; ^j20 missing; ^k12 missing

Table 26. Website	feedback summar	y b	y rurality	1
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	Metro	Nonmetro		Total
	(N = 194)	(N = 167)	P value	(N = 361)
Useful Information ^a				
Very useful, No. (%)	24 (12.6)	16 (9.8)		40 (11.3)
Somewhat useful, No. (%)	78 (41.1)	76 (46.3)	0 5 6 1 1	154 (43.5)
A little useful, No. (%)	58 (30.5)	52 (31.7)	0.5611	110 (31.1)
Not useful at all, No. (%)	30 (15.8)	20 (12.2)		50 (14.1)
"Have the information resources in the ONWARD study website helped you make a	27 (10 6)	24 (21 0)	0 7420	71 (20 2)
decision about how to treat or manage a symptom, illness or condition?" ^b 'Yes', No. (%)	57 (19.0)	54 (21.0)	0.7429	71 (20.2)
"Have you talked to a doctor, nurse, or other health professional about any kind of	2 (1 6)	5 (2 0)	0 2425	8 (2 2)
health information you have gotten from the ONWARD study website?" ^c 'Yes', No. (%)	5 (1.0)	5 (5.0)	0.3423	8 (2.2)
"Have the information resources in the ONWARD study website led you to ask a doctor	8 (1 2)	12 (7 4)	0 197/	20 (5 7)
new questions, or to get a second opinion from another doctor?" ^a n (Yes) (column %)	8 (4.2)	12 (7.4)	0.1974	20 (5.7)
Refer to Information from Website at Doctor's Visit ^d , 'Yes', No. (%)	1 (0.7)	1 (0.9)	0.8559	2 (0.8)
Show Information from Website at Doctor's Visit ^d 'Yes', No. (%)	2 (1.3)	0 (0.0)	0.2115	2 (0.8)
Reactions to the ONWARD Website				
Terrible (1) - Wonderful (10) ^b , mean (SD)	6.6 (1.8)	6.4 (1.7)	0.4505	6.5 (1.8)
Difficult (1) - Easy (10) ^e , mean (SD)	7.6 (2.1)	7.5 (2.1)	0.4446	7.6 (2.1)
Frustrating (1) - Satisfying (10) ^f , mean (SD)	7.2 (2.0)	6.9 (2.0)	0.1518	7.0 (2.0)
Dull (1)- Stimulating (10) ^g , mean (SD)	6.0 (2.0)	5.9 (1.9)	0.7219	5.9 (1.9)
Rigid (1)- Flexible (10) ^g , mean (SD)	6.4 (2.0)	6.3 (2.2)	0.5012	6.4 (2.1)
Reading Characters ^h : Hard (1) - Easy (10) , mean (SD)	8.4 (2.1)	8.3 (1.9)	0.5854	8.3 (2.0)
Organization ⁱ : Confusing (1) - Very Clear (10), mean (SD)	7.7 (2.0)	7.5 (2.2)	0.3761	7.6 (2.1)
Sequence of Screens ⁱ : Confusing (1) - Very Clear (10), mean (SD)	7.8 (2.0)	7.6 (2.1)	0.3406	7.7 (2.1)
Use of Terms ⁱ : Inconsistent (1) - Consistent (10) , mean (SD)	8.0 (2.0)	7.7 (2.1)	0.2551	7.9 (2.1)
Prompts for Input ^g : Confusing (1) - Clear (10), mean (SD)	8.0 (2.0)	7.8 (2.0)	0.3210	7.9 (2.0)
Learning to Operate ^h : Difficult (1) - Easy (10), mean (SD)	7.8 (2.1)	7.6 (2.2)	0.4733	7.7 (2.1)
Tasks were Straightforward ^f : Never (1) - Always (10), mean (SD)	7.9 (2.0)	7.5 (2.2)	0.0891	7.7 (2.1)
Problems Using Website ^k , 'Yes', No. (%)	18 (9.6)	17 (10.6)	0.7602	35 (10.0)

^a7 missing; ^b10 missing; ^c2 missing; ^dOut of those who reported a doctor's visit since baseline (N = 269); ^e13 missing; ^f17 missing; ^g18 missing; ^h19 missing; ^j21 missing; ^j20 missing; ^k12 missing

Table 27. Website feedback summary by cancer type

	Breast	Prostate	Colorectal		Total
	(N = 130)	(N = 143)	(N = 88)	P value	(N = 361)
Useful Information ^a					
Very useful, No. (%)	16 (12.5)	15 (10.6)	9 (10.6)	_	40 (11.3)
Somewhat useful, No. (%)	57 (44.5)	63 (44.7)	34 (40.0)	0 6777	154 (43.5)
A little useful, No. (%)	33 (25.8)	46 (32.6)	31 (36.5)	0.6777	110 (31.1)
Not useful at all, No. (%)	22 (17.2)	17 (12.1)	11 (12.9)		50 (14.1)
"Have the information resources in the ONWARD study website helped you make a					
decision about how to treat or manage a symptom, illness or condition?" ^b , 'Yes', No.	24 (10.1)	19 (22.4)	28 (20.0)	0.8390	71 (20.2)
(%)					
"Have you talked to a doctor, nurse, or other health professional about any kind of					
<i>health information you have gotten from the ONWARD study website?"</i> ^c , 'Yes', No.	1 (0.8)	4 (2.8)	3 (3.5)	0.3516	8 (2.2)
(%)					
"Have the information resources in the ONWARD study website led you to ask a					
doctor new questions, or to get a second opinion from another doctor?" ^a , 'Yes', No.	7 (5.5)	8 (5.7)	5 (5.8)	0.9955	20 (5.7)
(%)					
Refer to Information from Website at Doctor's Visit ^d , 'Yes', No. (%)	0 (0.0)	1 (2.0)	1 (1.5)	0.5178	2 (0.8)
Show Information from Website at Doctor's Visit ^d , 'Yes', No. (%)	2 (2.1)	0 (0.0)	0 (0.0)	0.1693	2 (0.8)
Reactions to the ONWARD Website					
Terrible (1) - Wonderful (10) ^b , mean (SD)	6.7 (1.9)	6.4 (1.6)	6.4 (1.9)	0.3925	6.5 (1.8)
Difficult (1) - Easy (10) ^e , mean (SD)	7.7 (2.1)	7.5 (1.9)	7.5 (2.3)	0.7699	7.6 (2.1)
Frustrating (1) - Satisfying (10) ^f , mean (SD)	7.2 (2.1)	7.0 (1.7)	6.9 (2.4)	0.5552	7.0 (2.0)
Dull (1)- Stimulating (10) ^g , mean (SD)	6.1 (1.9)	5.7 (1.7)	6.0 (2.4)	0.3364	5.9 (1.9)
Rigid (1)- Flexible (10) ^g , mean (SD)	6.6 (2.3)	6.2 (1.7)	6.3 (2.4)	0.3545	6.4 (2.1)
Reading Characters ^h : Hard (1) - Easy (10) , mean (SD)	8.4 (2.0)	8.3 (1.9)	8.2 (2.2)	0.7394	8.3 (2.0)
Organization ⁱ : Confusing (1) - Very Clear (10), mean (SD)	7.9 (2.0)	7.5 (1.9)	7.6 (2.4)	0.3646	7.6 (2.1)
Sequence of Screens ⁱ : Confusing (1) - Very Clear (10), mean (SD)	8.0 (2.1)	7.4 (1.9)	7.8 (2.2)	0.0553	7.7 (2.1)
Use of Terms ⁱ : Inconsistent (1) - Consistent (10), mean (SD)	8.1 (2.0)	7.7 (1.8)	7.7 (2.4)	0.1807	7.9 (2.1)
Prompts for Input ^g : Confusing (1) - Clear (10), mean (SD)	8.1 (1.9)	7.7 (1.9)	7.9 (2.3)	0.3019	7.9 (2.0)
Learning to Operate ^h : Difficult (1) - Easy (10) , mean (SD)	8.0 (2.0)	7.6 (2.0)	7.6 (2.5)	0.2144	7.7 (2.1)
Tasks were Straightforward ^f : Never (1) - Always (10) , mean (SD)	7.9 (2.0)	7.6 (2.1)	7.6 (2.3)	0.3561	7.7 (2.1)
Problems Using Website ^k , 'Yes', No. (%)	12 (9.7)	6 (4.3)	17 (20.2)	0.0006	35 (10.0)

^a7 missing; ^b10 missing; ^c2 missing; ^dOut of those who reported a doctor's visit since baseline (N = 269); ^e13 missing; ^f17 missing; ^g18 missing; ^h19 missing; ⁱ21 missing; ^j20 missing; ^k12 missing

f. Analysis of usefulness to patients of the data summaries provided to them

Participants were queried about the usefulness of the information they obtained from the ONWARD study website. **Tables 24-27** display these responses by age, health literacy, metro/nonmetro residence, and cancer type. The large majority of patients (85.9%) found the information to be at least a little useful with 54.8% finding the information somewhat or very useful. Perceived usefulness of information did not vary with age, health literacy, or metro/nonmetro residence.

To explore actionability of the information provided, we also asked about ways in which participants used the data. Twenty percent of people indicated that the information resources in the ONWARD study website helped them to make a decision about how to treat or manage a symptom, illness or condition and 5.7% indicated the information led them to ask a doctor new questions or to get a second opinion from another doctor. Low health literacy patients were somewhat more likely to say that the website information helped them make a decision (27.8% of low health literacy patients, 23.5% of medium health literacy patients, 15.5% of high health literacy patients; P=0.0572).

A caveat to this analysis is that many patients wrote in comments to indicate they had only used the website to complete the surveys and did not recognize they could use it to get information. This is surprising because patients landed on the main PHR page after they clicked 'Submit' at the end of the survey. The home screen contains a variety of informational sources. However log-tracking also indicated that the level of use of information and health tracking features of the tool were somewhat low. Some comments suggested that patients didn't expect to do anything more than complete a survey:

"I actually have not used the ONWARD site for information, I thought it was only for your survey."

"I didn't answer the questions about the ONWARD site. I wasn't aware – or remember about this. Please send me the info again so I can access this. It sounds like a good resource!"

"I never realized that this site had cancer treatment suggestions, etc....I thought it was just the survey. Now that I know, I may do some searching."

"Other than the survey, I was not aware if there was other information on an ONWARD website."

To more fully assess the value of the data summaries and other information, study recruitment could emphasize these features. Participants seemed pleased to complete the surveys without needing extras.

g. Info about the quality of data collected

Data completeness was generally high with the exception of items that required the user to type information in (e.g. number of doctors). In addition, there was more missing information for the questions about the ONWARD study website because many respondents either did not notice the information other than the surveys or did not understand what 'ONWARD website' meant.

Agreement of Iowa Cancer Registry data and patient-reported data are provided in **Tables 28-32**. Comparisons could only be made for data elements that were common to both, which included patient age, sex, race, ethnicity, and whether they had surgery for their cancer. All comparisons demonstrated high agreement of registry to patient-reported data.

Table 28: Difference in calculated age based on registry data and patient-reported survey responses*

	No.	Percent
Less than 1 year	389	98.48
1-2 years	3	0.76
More than 2 years	1	0.25
Missing	2	0.51

*Patient-reported date of birth was queried in Survey #1 and was used to calculate age as of the survey submission date.

Table 29: Concordance between registry and patient-reported sex

	No. of Participants					
Iowa Cancer Registry	Patient-reported*					
	Male	Female	Total**			
Male	203	0	203			
Female	3	184	187			
Total	206	184	390			

*Patient-reported sex was queried in Survey #1.

**5 subjects did not answer the sex item in the survey.

Table 30: Concordance between registry and patient-reported surgery for cancer

	No. of Participants					
Jowa Cancor Pogistry	Patient-reported*					
IOWA CALLER REGISTRY	Don't					
	Yes	No	know	Total		
Yes	301	14	2	317		
No	25	53	0	78		
Total	326	67	2	395		

*Patient-reported sex was queried in Survey #1 ("Have you had any surgery for your [TYPE] cancer? By surgery, we mean operation(s) for your [<u>SITE</u>] cancer that required you to be asleep and have some tissue removed.")

Table 31: Concordance of registry and patient-reported race

Jowa Cancer Registry		No. of Participants						
		Patient-reported*						
			American					
Iowa Callee Registry			Indian,					
		Aleutian or						
	White	Black	Eskimo	Unknown	Total			
White	356	0	0	1	357			
Black	0	1	0	0	1			
Native American	0	0 0 2 0 2						
Black and American Indian	0	0 1 0 0 1						
Total	356	2	2	1	361			

*Patient-reported race was queried in Survey #2.

Table 32: Concordance of registry and patient-reported ethnicity

	No. of Participants					
Jowa Cancor Bogistry	Patient-reported*					
Iowa Cancer Registry		Non-Hispanic /				
	Hispanic/Latino	Non-Latino	Total**			
White	1	341	342			
Hispanic	1	0	1			
Black	0	0	0			
American Indian/Alaskan Native	1	0	1			
Unknown	0	1	1			
Total	3	342	345			

*Patient-reported ethnicity was queried in Survey #2.

**16 subjects did not answer the ethnicity item.

h. Assessment of potential for interoperability of the data collection platform with informaticsbased registry systems

Our research builds on our prior work on the Iowa PHR, designed with and for older adults to help them keep track of medical conditions, medications (including providing multi-level warnings), symptoms, and health data (e.g., weight, exercise, blood pressure, including annotations). Through the Iowa PHR patients can also complete health assessments and get personalized recommendations on healthy habits. These features, together with in-app randomization and integrated online consent have enabled the Iowa PHR to be used in randomized trials for medication safety, cardiovascular disease (CVD), and cancer research. The Iowa PHR is available through the web, and through iOS and Android native apps.

For this project, the Iowa PHR was configured to accept seamless uploading of data from registry systems. Future uses of the Iowa PHR could obtain NAACCR-formatted data from registry systems and provide this information to patients. Future use could also obtain HL7 Consolidated Clinical Document Architecture (C-CDA) data from any personal health or electronic medical records system that decides to add a PHR module, or could also enable patients to obtain their own C-CDA document from a patient

portal. If the source of the C-CDA documents allows, the Iowa PHR can receive these routinely to take into account updates to patients' health. The Iowa PHR module can also send patient-generated data to the registry database routinely and during each use of the PHR. Information exchanges would follow the HL7 Context-Aware Knowledge Retrieval standard.

i. Information about what would be required to replicate the approach in larger studies, including any technical documentation or info needed to replicate procedures

The approach used to collect PGHD is highly replicable and readily scalable for future research or cancer surveillance efforts. Such efforts can be readily expanded to other cancer sites, institutional collaborators, and can be deployed to collect PGHD outside the cancer registry structure. For purposes of delineating broad guidelines for replication, the following discussion assumes replication of the current study population (three cancer types, two age groups), to collect roughly the same data, in oncology registry sites.

For larger studies involving multiple study sites, we envision workload to be distributed among a coordinating center (CC) and individual participating sites. In terms of procedures, both decentralized and centralized approaches are feasible; decisions about the relative fit of the approach and the specific roles and responsibilities of sites vs the CC would hinge in part on the scope and breadth of the research questions being asked as well as the desired level of integration with healthcare delivery systems.

Component	Decentralized	Centralized
Specified in Task Order		
Identify participants	Performed by participating sites; CC provides Study IDs and credentials for Iowa PHR; sites establish and maintain linkage between IDs and credentials, and patient identity.	Performed by participating sites. Site securely shares patient contact info with CC. CC establishes and maintains link between Study ID and credentials, and patient identify.
Contacting participants	Sites are trained by the CC* and conduct all aspects of invitation mailings: preparing address lists; formatting and printing cover letters; acquiring envelopes (and brochures if applicable); merging patient info and credentials into cover letters.	CC handles all aspects of invitation mailings with local info from sites (contacts, logos, etc.).
Recruit participants	Sites respond to all queries from patients about the study.	CC respond to all patient queries. Consider option to include local contact info.
Re-contact participants	CC automates email re-contact of participants. Sites mail letters to those who request them or who do not have email address.	CC automates email re-contact of participants. CC mails letters to those who request them or who do not have email address.
Collect data from participants	CC responsible for all data collection	CC responsible for all data collection
Other procedures		

Component	Decentralized	Centralized
IRB approval	Recent proposed changes to	UIOWA to serve as the IRB of
	human subjects regulations may	record with other sites relying on it
	require a centralized IRB model	for oversight
Data Sharing Agreement	Might be needed	Likely needed
Case tracking	Sites load patient data to REDCap	CC loads all patients to REDCap. CC
	and track their own cases. Sites log	logs all contacts and status
	all contacts and status changes.	changes.
Participant reimbursements	Sites issue reimbursements to	CC issues reimbursements to
	enrollees	enrollees
Meetings	Frequent, with all sites, to ensure	Periodic, to provide updates to
	protocol compliance	sites
Case reporting	Sites report enrollment status to	CC reports enrollment status to
	the CC. Can explore CC automation	sites
	of reporting via REDCap.	

*CC = Coordinating Center

i. Decentralized approach

In this instance, participating sites would play a substantial and active role. Site tasks would include establishing and storing the linkage between sampled patients and coordinating center-provided study IDs; mailing study invitations; responding to patient queries; logging mail and patient contacts in REDCap; processing subject reimbursements; and participating in frequent team meetings. The coordinating center would be responsible for providing study IDs and PHR credentials to sites; and training sites on mailing and case tracking protocols.

ii. Centralized approach

The main contrast with the decentralized approach is that sites would provide patient contact information (prior to enrollment) to the coordinating center, which would in turn implement recruitment and enrollment activities on behalf of sites. A REDCap project would be configured by the CC for sites to upload patient contact information. Sites would also provide letterhead and study contact info to the CC for incorporation into the mailed invitations. The CC would process subject reimbursements. Concentrating these resources at the CC level would streamline procedures and reduce materials and staff costs. A similar approach was successfully deployed in a recent study involving the Iowa PHR in partnership with three medical clinics ("Design and Testing of a Mobile Cardiovascular Risk Service With Patient Partners").

The approach used in the current study can be adapted to the contours of other research designs. If high response rates are needed to establish population parameters, the online survey can be supplemented with a mailed paper version of the survey, with results mailed to participants. This has the potential benefit of including PGHD from persons who cannot or will not use online means. Several options exist for central processing of paper questionnaires efficiently and the UIOWA specifically has experience in this area. If collection of PGHD from large health systems is desired, with some development, an approach mirroring that of the recent (and ongoing) PCORI-funded pragmatic ADAPTABLE study is feasible. The research design of the ADAPTABLE study leveraged EMR patient portals (e.g., EPIC MyChart) as a means of contacting prospective participants. A message containing a link to the study website and a 'golden ticket' (unique identifier) was sent to patient MyChart accounts. Finally, the ONWARD/Iowa PHR tool could be provided to patients via tablet devices in-clinic. Again, the purpose for collecting PGHD and available resources should guide the specific approach employed.

j. Recommendations for standard operating procedures for the selected approach

- Due to the relatively low rate of reply card return (N = 50 total), and the lack of substantial information conveyed, we recommend that future efforts do not use reply cards (and associated business reply envelopes). This should save on materials, postage, and staffing costs.
- Leverage REDCap for ensuring cohort data quality and enrollment efforts from participating sites. Forms can be configured to validate data fields (e.g., field names, valid values, etc.) before uploads can be successful. Account access can be provided to personnel from participating sites.
 - a. REDCap can also be used to efficiently collect information needed from a large number of sites, for example:
 - i. Project staff names, contact information, roles
 - ii. Contact info to be included on study materials
 - iii. Institutional logos
 - b. Real-time reports can be configured by the CC and made available to sites to track enrollment progress
- Several patients had questions about their cancer treatment sequelae. Future efforts might include resources for cancer registry staff to address subject questions. Iowa PHR can support secure messaging between research subjects and registry staff.
- Online prompts for use of the online tool to obtain cancer health information and for personal health information tracking should be emphasized.
- Since registries collect date of birth, this data element can be used in conjunction with assigned username to confirm the patient identity. Initial and ongoing user authentication is cited as a challenge to collection of PGHD (see "<u>Conceptualizing a Data Infrastructure for the Capture, Use,</u> <u>and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024</u>")

III. A detailed workload requirements report to include:

a. A cost breakdown per participant

We enrolled 395 patients from an initial sample of 2363. *Figure 6* shows the breakdown of costs per enrollee. The estimate excludes project leadership (Principal Investigator) and institutional infrastructure (e.g., phone, computing, F&A, etc.). Using these assumptions, we estimate the ONWARD study cost \$241 per participant enrolled. In contrast, *Figure 7* shows the breakdown of estimated costs to replicate the study at the Iowa Cancer Registry (ICR) using the same protocol. Cost per participant enrolled are estimated to be roughly half of the initial enrollment (\$120 / participant). Differences are largely due to reductions in staffing due to:

- Discontinuation of reply cards and #9 envelopes,
- Consolidation of mailing preparations into fewer and larger batches, and
- Fewer resources needed to develop, program, and test study instruments

The cost estimate for replicating the current study may result in a marginally higher (~5%) enrollment rate due to the use of larger envelopes and first class postage for all invitations. Use of bulk rate

postage and / or smaller envelopes would further reduce costs but potentially at the expense of a lower response rate.





Figure 7. Estimated allocattion of costs per participant to replicate the ONWARD study "as-is"



b. Breakdown of costs to 1) identify participants, 2) contact participants, 3) recruit participants, 4) re-contact participants, 5) collect data from participants

Tables 33 and *34* provide the detailed breakdown of costs to identify, contact, recruit, re-contact, and collect data from participants. The labor mix and number of hours per labor category is allocated across these categories. *Table 33* presents the cost breakdown for the current pilot and *Table 34* the projected breakdown as the data collection might be implemented as a registry process. Note the substantial savings on labor costs for data collection due to re-use of the developed tool.

Table 33. Costs to implement the current ONWARD study

					Collect data			
Derconnel	Identify	Contact	Recruit	Re-contact	from			
Personner	participants	participants	participants	participants	participants	Number of		
	(# hours)	hours	Hourly rate	Total				
Coordinator	10	14	40	40	0	104	\$63.35	\$6,588.25
Applications Developer (registry data)	40	0	0	0	0	40	\$55.46	\$2,218.56
Applications Developer (website)	0	0	10	30	480	520	\$60.22	\$31,314.16
Health Records Specialist	0	120	78	10	0	208	\$34.71	\$7,220.13
Research Specialist	0	300	100	200	24	624	\$42.46	\$26,496.20
Research Support Specialist	0	20	2	30	10	62	\$37.38	\$2,317.46
Database Administrator	0	0	40	21	22	83	\$57.67	\$4,786.51
Subtotal	50	454	270	331	536	1641		\$80,941.27
					Collect data			
Materials	Identify	Contact	Recruit	Re-contact	from			
Waterials	participants	participants	participants	participants	participants			
	(# units)	Total units	Cost per unit	Total				
Invitation packet expenses								
#9 business reply envelope	0	4275	0	0	0	4275	\$0.09	\$384.75
Cover letter	0	4394	0	279	0	4673	\$0.38	\$1,775.74
Address list cleansing, metering, letter	0	1232	0	0	0	1232	\$0.08	\$338 56
folding	0	4232	0	Ū	0	4252	Ş0.00	\$550.50
Reply card	0	4275	0	0	0	4275	\$0.08	\$342.00
Brochure	0	4275	0	0	0	4275	\$0.22	\$940.50
Outgoing envelopes								
#10 windowed envelope	0	2537	0	279	0	2816	\$0.15	\$422.40
9" X 12" windowed envelope	0	1857	0	0	0	1857	\$0.22	\$408.54
Outgoing postage								
Individual #10 envelope	0	663	0	279	0	942	\$0.47	\$442.74
Individual 9" X 12" envelope	0	346	0	0	0	346	\$1.21	\$418.66
Bulk #10 envelope	0	1874	0	0	0	1874	\$0.20	\$374.80
Bulk 9" X 12" envelope	0	1511	0	0	0	1511	\$0.47	\$710.17
Incoming postage								
Returned #10 envelope	0	64	0	0	0	64	\$0.47	\$30.08
Returned 9" X 12" envelope	0	106	0	0	0	106	\$1.21	\$128.26
#9 business reply envelope	0	50	0	0	0	50	\$0.50	\$25.00
Subject reimbursements								
Survey #1 payments	0	0	0	0	395	395	\$10.00	\$3,950.00
Survey #2 payments	0	0	0	0	361	361	\$10.00	\$3,610.00
Subtotal								\$14,302.20
Total of Personnel and Supplies								\$95,243.47
Cost per participant								\$241.12

Table 34. Costs to replicate the ONWARD study

					Collect data			
Demonstral	Identify	Contact	Recruit	Re-contact	from			
Personnei	participants	participants	participants	participants	participants			
	(# hours)	(# hours)	(# hours)	(# hours)	(# hours)	Total hours	Hourly rate	Total
Coordinator	10	0	0	0	0	10	\$63.35	\$633.49
Applications Developer	10	0	0	0	0	10	\$55.46	\$554.64
Applications Developer	0	0	0	0	20	20	\$60.22	\$1,204.39
Health Records Specialist	0	120	100	80	20	320	\$34.71	\$11,107.89
Research Specialist	0	240	50	80	20	390	\$42.46	\$16,560.13
Subtotal	20	360	150	160	60	750		\$30,060.53
					Collect data			
Materials	Identify	Contact	Recruit	Re-contact	from			
Waterius	participants	participants	participants	participants	participants			
	(# units)	(# units)	(# units)	(# units)	(# units)	Total units	Cost per unit	Total
Invitation packet expenses								
Cover letter	0	4394	0	279	0	4673	\$0.38	\$1,775.74
Address list cleansing, metering, letter	0	4232	0	0	0	4232	\$0.08	\$338 56
folding		1232	, , , , , , , , , , , , , , , , , , ,	•	•	1252	<i>\$0.00</i>	<i>\</i>
Brochure	0	4275	0	0	0	4275	\$0.22	\$940.50
Outgoing envelopes								
#10 windowed envelope	0	0	0	279	0	279	\$0.15	\$41.85
9" X 12" windowed envelope	0	4394	0	0	0	4394	\$0.22	\$966.68
Outgoing postage								
Individual #10 envelope	0	0	0	279	0	279	\$0.47	\$131.13
Individual 9" X 12" envelope	0	346	0	0	0	346	\$1.21	\$418.66
Bulk 9" X 12" envelope	0	2174	0	0	0	2174	\$0.47	\$1,021.78
Incoming postage								
Returned #10 envelope	0	64	0	0	0	64	\$0.47	\$30.08
Returned 9" X 12" envelope	0	106	0	0	0	106	\$1.21	\$128.26
Subject reimbursements								
Survey #1 payments	0	0	0	0	395	395	\$10.00	\$3,950.00
Survey #2 payments	0	0	0	0	361	361	\$10.00	\$3,610.00
Subtotal								\$13,353.24
Total of Personnel and Supplies								\$43,413.77
Cost per participant								\$109.91

Appendix 1. Detailed study recruitment and enrollment procedures

I. Invitation mailings

Invitations were mailed in batches between November 2017 and March 2018 (*see Table A1.1*) and envelope size and postage type varied by batch. Some mailed invitations were returned to the study team by the postal service with a new address for the intended recipient. A second invitation was sent approximately 1-3 months after the initial mailing to patients who did not reply in some manner. All such invitations were sent out in a #10 envelope with first class postage.

Batch Number	Envelope Size	Postage	Date Invitation Sent	Count
1	9" X 12"	First Class	11/15/2017	60
2	9" X 12"	First Class	12/01/2017	240
3	#10	First Class	12/15/2017	501
4	9" X 12"	Bulk Rate	01/12/2018	501
Remailing to Batches 1-4	¥ #10	Bulk Rate	02/23/2018	1048
5	9" X 12"	Bulk Rate	02/15/2018	1010
Remailing to Batch 5	#10	Bulk Rate	03/29/2018	826
6	9" X 12"	First Class	03/20/2018	46
Remailing to Batch 6	#10	First Class	04/18/2018	43

Table A1.1. Invitation mailing characteristics - envelope size and postage

II. Enrollment and online survey procedures

Mailed recruitment materials described how users could login to the website to review the consent document. Upon logging in, users were informed that clicking on an 'I agree' button would constitute their consent to enroll in the study.

After providing consent in the online tool, subjects were then asked to confirm that they were previously diagnosed with the cancer we were contacting them about ("This questionnaire is based on your [TYPE] cancer. To continue, please select (Yes, I was diagnosed with [TYPE] cancer / No, I was <u>not</u> diagnosed with [TYPE] cancer."). After confirming their cancer diagnosis, they were taken to a screen that invited them to take Survey #1. Subjects were informed they could save their responses and return to complete the survey at a later time, and that once completing and submitting Survey #1, they would be reimbursed \$10 for their time.

After submitting Survey #1, subjects were taken directly to the home page of their online account. A welcome message reminded them that their reimbursement would be processed, encouraged them to explore their account, and explained that a study team member would be contacting them when it was time to take Survey #2. An 'Action Center', displayed as a sidebar in the user interface, offered suggestions for activities related to optimal management of their cancer care and health generally. Actions included creating a list of current medications and health conditions, viewing reports and pamphlets on cancer care. An electronic copy of the informed consent document and a summary of study information were also available to users in their study account.

Three months after providing consent, subjects were emailed (if they provided an email address in Survey #1) or were mailed a letter inviting them to complete Survey #2 (all using a #10 size envelope).

Email notifications included a link to the study website; the website contained features for automated username and password retrieval. Letters mailed contained the subject's username and password. Both included research team contact information. For users who provided an email address and did not complete Survey #2 after 7-10 days, a second email was sent, followed by a mailed letter similar to the letter sent persons who did not provide an email address. Subjects who did not provide an email address and did not complete Survey #2 within 7-10 days were sent a second mailed letter. Those subjects who did not complete Survey #2 after seven additional days were queued to be contacted by phone to assess whether they received the invitations and had questions or encountered difficulties using the system. Voicemail messages were left when possible on the third phone attempt.

Upon login, subjects invited to complete Survey #2 were taken to a welcome screen that, like Survey #1, informed them of the reimbursement process upon completion of the survey. After submitting Survey #2, a thank you message that invited subjects to continue using the website, and confirmed they would be reimbursed was displayed. No firm end date after which subject accounts would be disabled was communicated.

Automated notifications were sent to research team members when users completed Survey #1 and Survey #2 and reimbursements were processed (a \$10.00 check was mailed to subjects after completing each, for a total of \$20.00).

The two study surveys were similar in length and were estimated to take 5-15 minutes each to complete. Surveys contained items about the patient's health conditions, quality of life, symptoms, medication adherence, cancer treatment, and demographics. Survey #1 included a field for subjects to enter an email address to be notified when it was time to take Survey #2. Survey #2 contained questions about the usefulness of the information provided to them in the online tool.

III. Number of invitation mailings

To help inform the replicability of and resources needed for using the current online tool to collect PGHD, we examined whether the number of invitation mailing attempts varied by cancer type, age group or rural status (*Table A1.2*). Invitations were remailed to persons if no outcome was ascertained after 4 or more weeks after the initial mailing. No statistically significant differences were found among cancer type or rural status. Patients diagnosed at age 65+ were significantly more likely to have been sent a second mailing compared to those diagnosed between age 50-64 (42.2% vs 35.5%, *P*=0.0412).

	N		
Characteristic		More than one	_
	One mailing	mailing	P value*
Cancer type			
Breast	93 (64.6)	51 (35.4)	
Prostate	96 (61.9)	59 (38.1)	0.7393
Colorectal	64 (66.7)	32 (33.3)	
Age group			
50-64	167 (67.9)	79 (32.1)	0.0412
65+	86 (57.7)	63 (42.3)	0.0412
Rurality			
Metro	136 (64.5)	75 (35.5)	0.8577

Table A1.2. Number of invitation mailing attempts

	N	Io. (%)	
Characteristic		More than one	
	One mailing	mailing	P value*
Nonmetro	117 (63.6)	67 (36.4)	
*Chi-square			

IV. Subject queries

Patients who returned a reply card or contacted the study team by phone or email were contacted and questions or concerns were addressed. Overall, 50 reply cards were returned to the study team. Most (N = 31) were returned with only a request to be contacted and no specific question for the research team. The remaining included questions about the study or study website (N = 9), patient experiences with cancer (not study related) (N = 4), or to decline participation (N = 6).

V. Nonresponse assessment

Phone calls were made to patients to assess reasons for nonresponse. A random sample of 70 patients, stratified by cancer type and age group (10 in each type * age group, except older colorectal cancer patients, where we selected 20 cases) who had not responded in any way to the study invitation(s) was selected for contact. A maximum of five contacts with each patient were attempted.

The research team was able to speak to the intended patient in just over half of all cases (N = 36; 51.4%). In 9 of such cases (12.9%), the patient requested that the invitation be remailed. Among 26 of 70 nonresponders (37.1%), the research team member did not make contact with the patient or other household member, with 11 of these cases due to wrong or missing phone number. The research team member left a voicemail message in 20% of cases.

In one-fifth of cases (N = 14), the patients who were successfully reached answered one or more questions asked about nonresponse (e.g., lack of internet access, more likely to complete survey if offered by mail, phone). Patients age 65 or older at the time of diagnosis were reached more often (58%; N = 23) than those who were 50-64 at diagnosis (43.3%; N = 13). Five persons reported that they would be more likely to complete the two study surveys if offered by mail, and three agreed to the same if offered by phone. Six persons reported not having regular internet access.

Eighty percent of contacts to patients diagnosed at age 65 or older were completed in 1-2 attempts; only 53% of those diagnosed between ages 50-64 were contacted in 1-2 attempts, with an additional 40% taking 4-5 attempts.

Appendix 2. Assessment of differences in completion of study procedures by patient and invitation mailing characteristics

To further assess replicability of this approach, we explored whether engagement in the study as measured by completion of select events varied by patient and mailing invitation characteristics (see **Table A2.1**). Four activities were examined – (A) logging in to the study website, (B) providing consent, (C) completion of Survey #1, and (D) completion of Survey #2. Number of completions of each of the first three activities as shown in Columns A-C in **Table A2.1** below were used as denominators for the latter three activities (Columns B-D) respectively. For example, we only considered those persons who consented (Column B) when comparing characteristics of Completion of Survey #1 (Column C).

Differences for rates of logging in the online tool were found for cancer type, and age group. Patients age 50-64 at the time of diagnosis were also more likely to consent after logging in (94% vs 87%, P= 0.0069). Analyses by number of mailings suggest that 9% of second invitations yielded logins.

We then assessed for differences within cancer types, by age group, for rates of logging in and consenting after logging in (See **Table A2.2**). Significant differences were found between younger and older age groups among breast and colorectal cancer patients respectively, but not prostate cancer patients, in terms of percent who ever logged in (breast: 24.5% vs 14.4%, *P*=0.0003; colorectal: 22.7% vs 11.5%, *P* <0.0001) with higher percentages observed for younger patients for both cancer types. Likewise, breast cancer patients who were 50-64 at the time of diagnosis were more likely to consent to the study after logging in compared to older breast cancer patients (97.0% vs 87.7%, *P*=0.0220).

Table A2.1. Comparison of patients and mailing characteristics to completion of select study activities

	No. (%)		No. (%)		No. (%)		No. (%)	
Characteristic	(A)	-	(B)	_	(C)	_	(D)	
	Ever logged in	P value*	Consented	P value*	Completed Survey #1	P value*	Completed Survey #2	P value*
PATIENT CHARACTERISTICS								
Denominator	Invitation delivered		Ever logged in		Consented		Completed Survey #1	
Denominator	(N = 2312)		(N = 445)		(N = 407)		(N = 395)	
Cancer type								
Breast	157 (19.6)	_	147 (93.6)		144 (98.0)	_	130 (90.3)	_
Prostate	173 (21.4)	0.0497	160 (92.5)	0.1245	155 (96.9)	0.6613	143 (92.3)	0.8252
Colorectal	115 (16.4)	-	100 (87.0)	_	96 (96.0)	_	88 (91.7)	
Age group								
50-64	267 (23.7)	< 0001	252 (94.4)	- 0.0060	246 (97.6)	- 0 2002	224 (91.1)	0 7600
65+	178 (15.0)	<.0001	155 (87.1)	0.0089	149 (96.1)	0.5662	137 (91.9)	0.7600
Rurality		0.5511		0.4467		0.3645		0.6760
Metro	237 (19.7)		219 (92.4)		211 (96.3)		194 (91.9)	
Nonmetro	208 (18.7)		188 (90.4)		184 (97.9)		167 (90.8)	
MAILING CHARACTERISTICS**								
Denominator	Invitation delivered		Ever logged in		Consented		Completed Survey #1	
Denominator	(N = 2266)		(N = 443)		(N = 405)		(N = 393)	
Envelope size (initial mailing)								
#10	96 (19.4)	- 0 0212	86 (89.6)	- 0.4673	83 (96.5)	- 0 7/61	80 (96.4)	0 0801
9" X 12"	347 (19.6)	0.9212	319 (91.9)	0.4073	310 (97.2)	0.7401	281 (90.6)	0.0894
Postage (initial mailing)								
Bulk rate	273 (18.5)	0 1000	250 (91.6)	- 0.8842	242 (96.8)	- 0 7200	218 (90.1)	0 102/
First class	170 (21.4)	0.1009	155 (91.2)	0.8842	151 (97.4)	0.7209	143 (94.7)	0.1054
Postage X envelope size (initial mailing)								
9" X 12" / First class	74 (24.7)	_	69 (93.2)	_	68 (98.6)	_	63 (92.6)	
9" X 12" / Bulk	273 (18.5)	0.0476	250 (91.6)	0.6925	242 (96.8)	0.7113	218 (90.1)	0.1872
#10 / First Class	96 (19.4)		86 (89.6)		83 (96.5)		80 (96.4)	
Number of invitations mailed***								
One	274 (69.9)	< 0001	255 (93.1)	- 0 1157	252 (98.8)	0.0057	232 (92.1)	0 8/19
More than one	169 (9.0)	\.0001	150 (88.8)	0.1157	141 (94.0)	0.0057	129 (91.5)	0.0410

*Chi-square

**Denominators for mailing characteristics comparisons were deprecated by exclusion of batch #6, which included only racial/ethnic minority patients.

***Excludes multiple mailings due to revised addresses.

	Activity					
Cancer type*age group	No. (%)		No. (%)			
	Ever logged in	P value*	Consented after logged in	P value*		
Breast 50-64	100 (24.5)	0 0002	97 (97.0)	0 0220		
Breast 65+	57 (14.4)	0.0005	50 (87.7)	0.0220		
Prostate 50-64	97 (23.8)	0.0044	92 (94.8)	0 1 9 2 5		
Prostate 65+	76 (19.0)	0.0944	68 (89.5)	0.1835		
Colorectal 50-64	70 (22.7)	<0.0001	63 (90.0)	0 2260		
Colorectal 65+	45 (11.5)	<0.0001	37 (82.2)	0.2208		
A						

Table A2.2. Comparison of cancer type * age group pairs by study activity completion

*Chi-square

TORFP: SEER 2016-07 Contract No. HHSN261201300020I Order No. HHSN26100014 Iowa: Elizabeth Chrischilles, Ph.D.

Appendix 3. Survey screenshots

(Begins on next page)

ONWARD Study Cancer Confirmation Survey and Survey #1 Screen Shots

The following images are a sequential series of screen clips taken from an ONWARD study test account. They illustrate what the on-line interface looked like for a user who visited the ONWARD study website, logged in with the unique credentials sent to them, reviewed and agreed to the study consent document, confirmed that were diagnosed with the cancer they were being contacted about, and navigated through Survey #1. The final page shows what a typical user would see after they submitted Survey #1.

Some items are shown or hidden based on the user's response to previous items. Thus, for simplicity of presentation, the following items do not encompass all possible items that any one user may see.

GNWARD	×

ONWARD ONline Way for F	Patients to A ugment R egistry D ata		Contact/About -	Welcome - A- A+
	Login			
	Please enter your username and Username	password and click "Login" to access your study account. Username		
	Password	Password		
		[forgot password] [forgot username]		

Institute for Clinical and Translational Science | University of Iowa

Supported in part by NIH grant U54TR001356 Version: 4.0.81 ONline Way for Patients to Augment Registry Data

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Contact/About - Welcome onwardaboo5 -

A

Important Information about this Research Study

Thank you for your interest in the ONWARD ("ONline Way for Patients to Augment Registry Data") study. The purpose of the study is to learn about experiences of Iowans who have had cancer.

We are inviting you to participate in this study based on your cancer diagnosis. We obtained your name and address through the Iowa Cancer Registry, which has the responsibility to collect statewide cancer information. Approximately 500 people will take part in this study at the University of Iowa.

If you agree to participate, we would like you to use a study website to complete two brief online surveys (the second survey a few (1-4) months after the first one). The study website – www.onwardstudy.org - is a "Personal Health Record" that was developed by researchers at the University of Iowa. It is intended as a tool for people to enter, store, and print reports about medications and other personal and health information. You will be able to enter as much or as little information in the study website as you like over the course of the next several months.

The two surveys will include basic questions about you (for example, your date of birth, gender, and education), questions about your health conditions, quality of life, and cancer medications you are taking/have taken. The second survey will also contain a few questions about the usefulness of the information provided to you in the study website.

To access the surveys, you will need to visit the study website and log in, using the username and password provided in the invitation letter you received. You may skip any questions you would prefer not to answer. Finally, we will link Iowa Cancer Registry data to how you use the study website, including your survey responses.

We may mail you up to two similar packages in the next few weeks if we do not receive a response from you. If you prefer not to receive these reminders, please let us know by sending an email to michele-west@uiowa.edu or calling us at (319) 335-7497 (toll-free: 800-613-3076). If you would like to receive more information about this study, please contact michele-west@uiowa.edu or call us at (319) 335-7497 (toll-free: 800-613-3076), or fill out the enclosed reply card and send it back to us in the envelope provided.

We will keep the information you provide confidential, however federal regulatory agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. If we write a report about this study, we will do so in such a way that you cannot be identified.

There are no known risks from being in this study, and you will not benefit personally. However, we hope that others may benefit in the future from what we learn as a result of this study. You will not have any costs for being in this research study.

You will be paid for participating in this research study. You may also need to provide your address if a check will be mailed to you. You will be paid \$10.00 for completing each of the two online surveys, for a total of \$20.00. A check will be mailed to you about 2-3 weeks after you complete each survey.

Taking part in this research study is completely voluntary. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you have any questions about the research study itself, please contact Michele West at michele-west@uiowa.edu or by phone at (319) 335-7497 (toll-free: 800-613-3076). If you experience a research-related injury, please contact Michele West at michele-west@uiowa.edu or by phone at (319) 335-7497 (toll-free: 800-613-3076). If you have questions about the rights of research subjects, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

Thank you very much for your consideration.

By clicking on "I Agree" below you are providing your consent to participate in the study.

Sincerely,

Elizabeth A. Chrischilles, PhD Professor and Principal Investigator

I Agree No Thanks



ONWARD ×		Θ – Φ	×
→ C 1 Secure https://www.onwardstudy.org/phr/form/take/37		☆	8
ONWARD ONline Way for Patients to Augment Registry Data	Contact/About -	Welcome onwardab005 • A- A+	
Confirm Study Eligibility		Save and Exit	1
Before we begin This questionnaire is based on your breast cancer. To continue, please select: O Yes, I was diagnosed with breast cancer. O No, I was not diagnosed with breast cancer.			
Institute for Clinical and Translational Science University of Iowa Supported in part by NIH grant U54TR001356 Version: 4.0.81			

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· → C ↑ Secure https://www.onwardstudy.org/phr/form/take/37			☆ 8
ONWARD	ontact/About 🗸 🛛 W	elcome onwardaboo	05 -
ONline Way for Patients to Augment Registry Data		A-	A+
Confirm Study Eligibility		Save and Exit	
Commin Study Englointy			
Before we begin			- 1
			n II.
Yes, I was diagnosed with breast cancer.			
To continue, please select: No, I was <u>not</u> diagnosed with breast cancer.			
			- 1
CONFIRMATION - Removal from the ONWARD study			
You indicated that you have <u>not</u> been diagnosed with breast cancer. Please click 'Submit' below to be removed from this study. We will not contact y	you any more.		
			- 11
	Submit	Cancel	
			11
Institute for Clinical and Translational Science University of Iowa			
Supported in part by NIH grant U54TR001356			
Version: 4.0.81 62			

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← → C ☆ 🔒 Secure https://www.onwardstudy.org/phr/form/take/37			☆	8
ONWARD		Contact/About -	Welcome onwardab005	•
ONline Way for Patients to Augment Registry Data			A- A	.+
			Save and Exit	
Confirm Study Eligibility				1
Before we begin				1
This questionnaire is based on your <u>breast</u> cancer.	• Yes I was diagnosed with breast cancer.			
To continue, please select:	• No. Lwas not diagnosed with breast cancer			
	U No, I was <u>not</u> diagnosed with breast cancer.			
	Click 'Submit' below to continue.			
		Cubra	it Cancel	
		Subm	Cancer	

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GNWARD

ONline Way for Patients to Augment Registry Data

ONWARD Study - Survey #1

INSTRUCTIONS

This questionnaire is based on your diagnosis of breast cancer. Even if you have been diagnosed with other cancers, please think back to your experiences with your breast cancer when answering the questions.

Click 'Next' below to continue.

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C 🗅 Secure https://www.onwardstudy.org/phr/form/take/133/12959?pagel	ld=550						<u> </u>	ζ 🖁
ONWARD Study - Survey #1							Save and Exit	
SECTION A: YOUR GENERAL HEALTH								
Please respond to each question by selecting one per row.								
In general, would you say your health is:	O Excellent	O Very good	O Good	O Fair	O Poor			
In general, would you say your quality of life is:	O Excellent	O Very good	O Good	O Fair	O Poor			
In general, how would you rate your physical health?	O Excellent	O Very good	O Good	O Fair	O Poor			
In general, how would you rate your satisfaction with your social activities and relationships?	O Excellent	O Very good	O Good	O Fair	O Poor			
In general, how would you rate your mental health, including your mood and your ability to think?	O Excellent	O Very good	O Good	O Fair	O Poor			
In general, please rate how well you carry out your usual social activities and roles. This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.	O Excellent	O Very good	O Good	O Fair	O Poor			
						Previous	Next	

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Image: Comparison of the part of th	~	Θ								Θ	<u>م</u>	-	~	5
SECTION A: Part II To what extent are you able to carry out your evrydae physical activities such as walking, climbing stairs, carrying geoeries, or moving a chair? Completely: Murthy Murthy Murthy Murthy Murthy Murthy Diving the past week, to what extent have arm, shoulder or hand problems interfered with your normal social activities with family. Not at all During the past week, were you limited in your work or other regular binded or band problems? Not at all limited Other past week, were you limited in your work or other regular binded or band? Not at all limited Murthy Murthy	<u></u> м	4								~	~		м	<u> </u>
To what sector are you able to carry out your everyday physical activities at welking, chabing stairs, carrying groeries, or moving a chair? Completely: Modely: Modely: During the past veek, to what extent have arm, shoulder or hand? Not at all Singht? Modely: Outing the past veek, to what extent have arm, shoulder or hand? Singht? Outing the past veek, to what extent have arm, shoulder or hand? Not at all Singht? Moderately: Outing the past veek, ower you limited in your work or other regular Not at all limited During the past veek, how much difficulty have you had sleeping Not at all limited During the past veek, how much difficulty have you had sleeping Not atfall limited During the past veek, how much difficulty have you had sleeping Not difficulty limited During the past veek, how often have you been bothered by emotional Not atfall During the past veek, how often have you been bothered by emotional Not atfall In the past 7 days, how would you rate your fatigue on average? Notes In the past 7 days, how would you rate your fatigue on average? Notes Midd Middentak Sometimes Often Always Not atfall In the past 7 d														
During the past week, to what extent have arm, shoulder or hand problems interfered with your normal social activities with family. Not at all Slightly Sli														
During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder, or hand problems? Sightly limited Very limited Very limited Vary limited Vary limited Vary limited Noderately limited Noderately limited Noderately limited Noderately limited Noderately limited Noderately Sightly limited Noderately Mild difficulty Severe difficulty So much difficulty that I can't sleep In the past 7 days, how would you rate your fatigue on average? None Nind Noderate Sightly limited Noterate Sometimes Often None Nind Noderate Severe Very severe In the past 7 days, how much did pain interfere with your day to day attivities?														
During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? No difficulty Mild difficulty Moderate difficulty Severe difficulty So much difficulty that I can't sleep In the past 7 days, how would you rate your fatigue on average? In the past 7 days, how would you rate your fatigue on average? In the past 7 days, how would you rate your fatigue on average? In the past 7 days, how much did pain interfere with your day to day activities? Not at all A little bit Somethat														
In the past 7 days, how often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?														
In the past 7 days, how would you rate your fatigue on average? None Mild Moderate Severe Very severe In the past 7 days, how much did pain interfere with your day to day activities? Not at all A little bit Somewhat O uits a bit														
In the past 7 days, how much did pain interfere with your day to day activities?														
In the past 7 days, how much did pain interfere with your day to day activities? O Not at all O A little bit O Somewhat														
O Guite a bit O Very much														
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SECTION A: Part II A		
In the past 7 days, how would you rate your pain on average? 0 = no pain 10 = worst pain imaginable $O \circ O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 2 O 3 O 4 O 5 O 6 O 7 O 2 O 3 O 4 O 5 O 6 O 7 O 7 O 2 O 3 O 4 O 5 O 7 O 6 O 7 O 7 O 2 O 3 O 4 O 5 O 7 O 6 O 7 O 7 O 7 O 7 O 7 O 7 O 7 O 7$) ⁸ O ⁹	O 10
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SECTION A: Part III								L
Please rate your <u>ability</u> to do the following activities <u>in the last</u>	week by selecting th	e appropriate respon	se.					II.
Open a tight or new jar	O No difficulty	O Mild difficulty	O Moderate difficulty	O Severe difficulty	O Unable			
Do heavy household chores (e.g., wash walls, floors)	O No difficulty	O Mild difficulty	O Moderate difficulty	O Severe difficulty	O Unable			
Carry a shopping bag or briefcase	O No difficulty	O Mild difficulty	O Moderate difficulty	O Severe difficulty	O Unable			
Wash your back	O No difficulty	O Mild difficulty	O Moderate difficulty	O Severe difficulty	O Unable			
Use a knife to cut food	O No difficulty	O Mild difficulty	O Moderate difficulty	O Severe difficulty	O Unable			
Recreational activities in which you take some force or impact through your arm, shoulder, or hand (e.g. golf, hammering, tennis, etc.)	O No difficulty	O Mild difficulty	O Moderate difficulty	O Severe difficulty	O Unable			
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SECTION A: Part IV								
Please rate the <u>severity</u> of the following symptoms <u>in the last</u>	week.							
Arm, shoulder or hand pain	O None	O Mild	O Moderate	O Severe	O Extreme			
Tingling (pins and needles) in your arm, shoulder or han	d O None	O Mild	O Moderate	O Severe	O Extreme			
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SECTION A: Part V		
The following questions relate to symptoms you migh	have experienced in the <u>past 4 weeks</u> in your <u>arm, breast, or chest.</u>	
Have you experienced <u>swelling</u> ?	Yes O No	
Have you experienced <u>heaviness</u> ?	O Yes O No	
The following questions relate to symptoms you migh	have experienced in the past 4 weeks in your leg, groin, hip, or lower body	
	nave experienced in the <u>past 4 weeks</u> in your <u>reg, grom, mp, or lower body.</u>	
Have you experienced <u>swelling</u> ?	O Yes O No	
Have you armovianeed bearinees?		
Have you experienced <u>neaviness</u> ?	O Yes O No	
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SECTION B: YOUR HEAI	LTH CO	NDITIONS				
<u>Before you were told you had breast c</u>	<u>ancer,</u> had y	you ever had any of the following conditions?	2			
A heart attack	O Yes	O No				
Heart failure (you may have been short of breath and the doctor may have told you that you had fluid in your lungs or that your heart was not pumping well)	O Yes	O No				
An operation to unclog or bypass the arteries in your legs	O Yes	O No				
Poor kidney function (blood tests show high creatinine)	O Yes	O No				
Used hemodialysis or peritoneal dialysis	O Yes	O No				
Received kidney transplantation	O Yes	O No				
Arthritis	O Yes	O No				
Rotator cuff, frozen shoulder or other shoulder diagnosis	O Yes	O No				
Do you have any of the following cond	litions?					
Lupus (systemic lupus erythematosus)	O Yes	O No				
Polymalgia rheumatica	O Yes	O No				
Alzheimer's Disease, or another form of dementia	O Yes	O No				
Cirrhosis, or serious liver damage	O Yes	O No				
Leukemia or polycythemia vera	O Yes	O No				
Lymphoma	O Yes	O No				
HIV/AIDS	O Yes	O No				
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ONWARD Study - Survey #1

SECTION B: Part II

<u>Before you were told you had breast cancer</u> , had you ever had a stroke, cerebrovascular accident, blood clot or bleeding in the brain, or transient ischemic attack (TIA)?	O Yes	O No	
Before you were told you had breast cancer, had you been told by a healthcare provider that you had depression? A healthcare provider could be a physician, physician assistant, nurse, or mental health professional such as a counselor.	O Yes	O No	
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L	SECTIO	ON B: Part III					1	
	Do you ha	ive asthma?	Ves No					
	a. If y	es, do you take medication for your asthma?	 Yes, I take medication regularly Yes, only with flare-ups of my asthma No 					
	Do you ha lung disea	ave emphysema, chronic bronchitis, or chronic obstructive ase?	Ves No					
	a. If y	es, do you take medication for your lung disease?	 Yes, I take medication regularly Yes, only with flare-ups of my lung disease No 					
	Do you ha	we stomach ulcers or peptic ulcer disease?	 Yes No 					
l	a. If ye doctor bariur rays a	es, has this condition been diagnosed by endoscopy (where a r looks into your stomach through a scope) or an upper GI or m swallow study (where you swallow chalky dye and then x- re taken)?	O Yes O No					
l	Do you ha	we diabetes (high blood sugar)?	Ves No					
	a. Is y	our diabetes treated by medication taken by mouth?	Ves No					
	b. Is y	our diabetes treated by insulin injections?	O Yes O No					
	c. Is y	our diabetes treated by modifying your diet?	O Yes O No					
	d. Has	s the diabetes caused problems with your kidneys?	O Yes O No					
	e. Has ophth	diabetes caused problems with your eyes, treated by an almologist?	O Yes A No					

C	Yes No Yes No Yes No Yes No No No Not sure or don't know MM YYYYY			
Do you have rheumatoid arthritis? a. If yes, do you take medication for it regularly? Not counting your breast cancer that was diagnosed in or around the year 2015, have you been diagnosed with other cancers? a. If yes, when was your first cancer diagnosed? b. What type of cancer was your first cancer?	Yes No Yes No Yes No No Not sure or don't know			
a. If yes, do you take medication for it regularly? Not counting your breast cancer that was diagnosed in or around the year 2015, have you been diagnosed with other cancers? a. If yes, when was your first cancer diagnosed? b. What type of cancer was your first cancer?	Yes No Yes No No Not sure or don't know			
Not counting your breast cancer that was diagnosed in or around the year 2015, have you been diagnosed with other cancers? a. If yes, when was your first cancer diagnosed? b. What type of cancer was your first cancer?	Yes No Not sure or don't know MM YYYY			
a. If yes, when was your <u>first</u> cancer diagnosed? b. What type of cancer was your <u>first</u> cancer?	MM YYYY			
b. What type of cancer was your <u>first</u> cancer?	∩ Breast			
	 Colorectal Lung Lymphoma Melanoma Ovarian Prostate Other 			
About how tall are you?	0R) feet) inches) meters		
About how much did you weigh <u>at the time of your breast cancer</u> <u>diagnosis?</u>	OR) pounds) kilograms		
About how much do you weigh <u>now</u> ?	OR) pounds		
How many different medications do you take daily on a regular basis? This would include any form of <u>prescribed</u> medication such as tablets, capsules, pills, liquids, injections, sprays, inhalers, creams and ointments, patches, suppositories, enemas.	medication(s)			
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Section B: Part IV						
How much of a problem has it been for you to						
organize your medications?	O Not at all	O A little bit	O Somewhat	O Quite a bit	O Very much	
take more than one medication every day?	O Not at all	O A little bit	O Somewhat	O Quite a bit	O Very much	
take your medications several times each day?	O Not at all	O A little bit	O Somewhat	O Quite a bit	O Very much	
refill your medications?	O Not at all	O A little bit	O Somewhat	O Quite a bit	O Very much	
adjust your medications (including the amount, type, or time when you take it)?	O Not at all	O A little bit	O Somewhat	O Quite a bit	O Very much	
take your medications as directed?	O Not at all	O A little bit	O Somewhat	O Quite a bit	O Very much	
plan your daily activities around your medication schedule?	O Not at all	O A little bit	O Somewhat	O Quite a bit	O Very much	
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ONWARD Study - Survey #1

SECTION C: YOUR CANCER DIAGNOSIS

Now, a few questions about your breast cancer.

During your breast cancer treatment, was there one health professional who COORDINATED your cancer care?	O Yes	O ^{No}	O Don't Know
Since your breast cancer was treated, has a doctor told you that your breast cancer has come back?	O Yes	O ^{No}	
To the best of your knowledge, are you now cancer-free?	O Yes	O No	
Have you had any surgery for your breast cancer? By surgery, we mean operation(s) for your breast cancer that required you to be <u>asleep</u> and have some tissue removed.	O Yes	O No	O Don't Know
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ECTION C: Part III			
fter your cancer diagnosis did you experience	any of the fe	ollowing?	
Fatigue	O Yes	O No	
a. Did you <u>get therapy</u> for fatigue?	O Yes	O No	
b. Did you <u>tell a doctor</u> about fatigue?	O Yes	O No	
c. Do you still have fatigue?	O Yes	O No	
Pain	O Yes	O No	
Neuropathy, tingling, burning, or numbness	⁵ O Yes	O No	
Cardiomyopathy or congestive heart failure	O Yes	O No	
Trouble thinking or concentrating	O Yes	O No	
Lymphedema	O Yes	O No	
Decreased range of motion	O Yes	O No	
Rotator cuff problem	O Yes	O No	
Frozen shoulder or adhesive capsulitis	O Yes	O No	
Other doctor-diagnosed arm or shoulder problem	O Yes	O No	
Urine, bladder, or kidney problems	O Yes	O No	
Sexual problems	O Yes	O No	
Distress, depression or anxiety	O Yes	O No	
Worries or concerns about cancer	O Yes	O No	
Worries about relationships or body image	O Yes	O No	
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SECTION D. MEDICATIONS FOR BREAST CANCER				
Are you now getting chemotherapy <u>administered at the hospital or</u>				
<u>clinic</u> ?				
doctor to cure cancer or to keep it from coming back?				
Which cancer medications do you take by mouth? Mark 'Yes' for all that apply.				
a. anastrazole (Arimidex [®]) O Yes O No				
b. capecitabine (Xeloda®) O Yes O No				
c. cyclophosphamide (oral) O Yes O No				
d. etoposide (oral) O Yes O No				
e. everolimus (Afinitor®) O Yes O No				
f. exemestane (Aromasin [®]) \bigcirc Yes \bigcirc No				
g. fluoxymesterone (Androxy [®]) O Yes O No				
h. lapatinib (Tykerb®) O Yes O No				
i. letrozole (Femara®) O Yes O No				
j. megestrol acetate (Megace®) O Yes O No				
k. methotrexate O Yes O No				
1. palbociclib (Ibrance [®]) O Yes O No				
m. raloxifene (Evista®) O Yes O No				
n. tamoxifen (Nolvadex [®] , Soltamox [®]) \bigcirc Yes \bigcirc No				
o. toremifene (Fareston®) O Yes O No				
p. Other medication by mouth for cancer O Yes O No				
How often do you <u>forget</u> to take your cancer medication?				
O Some of the time				
O Most of the time				
O All of the time				
How often do you decide not to take your cancer medication?				
O None of the time				
Most of the time				
O All of the time				
Which one of the following best describes you? In the nast = days:				
O I took all doses of my cancer medication				
I missed or skipped 1 dose of my cancer medication				
I missed or skipped 2 doses of my cancer medication I missed or skipped 2 or more doses of my cancer medication				

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Save and Exit ONWARD Study - Survey #1 SECTION E: CANCER FOLLOW-UP CARE After completing your breast cancer treatment, did any doctor, nurse, or other health O Yes O No O Don't Know professional give you a written or computer print-out summary of the cancer treatments that you received? After completing your breast cancer treatment, did any doctor, nurse, or other health O Yes $\bigcap N_0$ O Don't Know professional give you written or computer print-out instructions about where you should return or who you should see for routine cancer check-ups after completing your cancer treatments? After completing your breast cancer treatment, how certain were you about which doctor Very certain was in charge of your cancer follow-up care? This would be the doctor you would see to get followup medical tests or to treat symptoms and treatment-related side effects. O Somewhat certain Neither certain nor uncertain O Somewhat uncertain Very uncertain I have not yet completed my cancer treatment Next Previous

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Di	d you l	xnow?				
	(1211) (1	Today many cancer experts agree that personalized cancer Survivorship Care Plans are essential. They can help patients manage their treatment for cancer	health and well-b	eing after		
	Y					
	•	After you complete and submit this survey, you can read more about making your own Survivorship Care Plan on the ONWARD website in the 'Action Center'	er'.			
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Save and Exit ONWARD Study - Survey #1 SECTION F: HEALTH INFORMATION Please choose the one best answer for each of the following questions about your comfort with health information. How often do you have someone help you read hospital materials? Always Often Sometimes Occasionally Never How often can you fill out medical forms by yourself? Always Often O Sometimes Occasionally Never How often do you have problems learning about your medical Always Occasionally Often Sometimes Never condition because of difficulty understanding written information? How often do you have problems understanding medical statistics? Occasionally Always Often Sometimes Never How often do you have problems taking medications properly by O Sometimes Always Often Occasionally O Never yourself? Next Previous Institute for Clinical and Translational Science | University of Iowa

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SECTION G: A FEW FINAL QUESTIONS

What is the highest degree or level of school you have completed?	 Sth grade or less Some high school, but did not graduate High School Graduate or G.E.D. Some College or 2-year degree College Graduate More than a 4-year college degree Prefer not to answer
Were you employed <u>at the time your breast cancer</u> <u>was diagnosed</u> ?	O Yes O No
What was your marital status <u>at the time your breast</u> <u>cancer was diagnosed</u> ?	 Married Widowed Divorced Separated Never married Living with a partner/significant other
What is your sex?	O Male O Female O Other
What is your date of birth?	MM DD YYYY
If you would like us to notify you by email when it is time to take the second and final survey, please enter your email address:	
If you have any comments about this survey or your responses, please enter them here:	
Your \$10.00 payment will be processed after you submit thi Click below to	s form. Please allow 2-3 weeks for a check to be mailed to you.

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Appendix 4. ONWARD PHR screenshots

(Begins on next page)

ONWARD Study Online Personal Health Record (PHR) Account The following images are a sequential series of screen clips taken from an ONWARD study test account. They provide examples of the features in the on-line interface users would have encountered after completing Survey #1 or Survey #2.

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	Login		_		
	Please enter your username and	l password and click "Login" to access your study account.			
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My Medications more Update Now	Save
My Health Conditions more Update Now	[view blood pressure]
My Medication List Report more View Now	
My Wallet Card Report more View Now	
Talking with Doctors about Cancer Effects" pamphlet more View Now	
"Use Medications Wisely" pamphlet more View Now	
Making a Survivorship Care Plan" pamphlet more View Now	
Completed 0	
 My Survivorship Care Plan more (last accessed 07/03/17) Create plan 	
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Study Information more View Now	
Informed Consent Document more View Now	
 Symptom Action Decks more View Now 	

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Home / Current Medications Current Medications						
Use this page to enter your prescription and not	n-prescription medications	, vitamins, and dietary sup	plements.			
Order by Date Added/Updated Direction Ascending						
Name of Medication Example: Tylenol	What Strength do you take? Example: 325mg	How do you take it? Example: 2 tablets every 8 hours as needed	Why do you take it? Example: Arthritis			
Vau have no summent mediantions				s	ave	
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Medication History						
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click here for instructions view or print your medication history						
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Order by Date Added/Updated Direction Ascending						
Name of Medication	What Strongth do you take?	How do you take it?	Why do you take it?			
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You have no medication history.						
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Home / About Me

My Personal Information

Username	onwardab005	Address	• No address listed.	
Name		Phone Number(s)	No phone number listed.	
Date of birth				
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Edit Personal Information View or download your wallet sized card				

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What Are Decks?

Symptom Action Decks are collections of cards. Each card represents a specific topic relevant to cancer and treatment. The cards connect you to helpful tips, resources, and information.

Below are links to health topics that you might find useful (each opens up in a new window):

Symptoms

- Anemia and Bleeding
- Appetite Change
- Bladder Control Problems (Incontinence)
- Chemo-Brain and Memory Problems
- Constipation
- Diarrhea
- Fatigue
- Hair Loss
- Hot Flashes and Night Sweats
- Infections
- Infertility for Men
- Infertility for Women

- Lymphedema
- Mouth, Gum and Throat Problems
- Nausea and Vomiting
- Pain
- Sexual Problems for Men
- Sexual Problems for Women
- Skin and Nail Changes
- Sleep Problems
- Swelling (Edema)
- Tingling, Burning and Numbness (Neuropathy)
- Urine, Bladder and Kidney Problems
- Weight Gain

Stress and Mood

- Anxiety
- Coping with Cancer in Everyday Life
- Depression
- Distress
- Fear of Recurrence
- Practice Mindfulness and Relaxation

Wellness

- Be Active
- Healthy Eating
- Quit Smoking
- Sun Safety

Adopted from Springboard Beyond Cancer, joint venture between the National Cancer Institute and the American Cancer Society

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About the ONWARD Study

- The ONWARD study (Online Way for Patients to Augment Registry Data) is designed to answer the question: "Can patient-generated health data enhance cancer surveillance activities?"
- To do this, researchers at the Univerity of Iowa are using an online Personal Health Record (PHR) website that was developed for research on medication use to test whether it can be successfully used to collect information from patients in Iowa who were diagnosed with breast, prostate, or colorectcal cancer.
- Up to 500 patients across Iowa will participate in this study.
- This study is funded by the National Cancer Institute.

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If you have questions about the ONWARD (<u>ON</u>line <u>Way</u> for Patients to <u>Augment Registry Data</u>) study, please contact us toll-free at (866) 520-8983 or ICR-ONWARDStudy@uiowa.edu.

Thank you! The ONWARD Study Research Team

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Name	Value		
Email Alerts Enabled	Yes		
Notification Frequency	Daily		
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Save

Cancel