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Implementing a Breast Cancer Registry and Treatment Plan/ Summary Program in Clinical Practice: A Pilot Program

Ann H. Partridge, MD, MPH¹, Virginia W. Norris, MCG², Victoria S. Blinder, MD³, Bruce A. Cutter, MD, MMM⁴, Michael T. Halpern, MD⁵, Jennifer Malin, MD⁶, Michael N. Neuss, MD⁷, and Antonio C. Wolff, MD⁸ on behalf of the ASCO Breast Cancer Registry Pilot Steering Group

¹Dana-Farber Cancer Institute and Brigham and Women's Hospital, Boston, Massachusetts
²American Society of Clinical Oncology, Alexandria, Virginia ³Memorial Sloan Kettering Cancer Center, New York, New York ⁴Group Health Cooperative, Spokane, Washington ⁵RTI International, Washington, DC ⁶VA Greater Los Angeles Healthcare System and Jonsson Comprehensive Cancer Center at UCLA, Los Angeles, California ⁷Vanderbilt-Ingram Cancer Center, Nashville, Tennessee ⁸Johns Hopkins Kimmel Cancer Center, Baltimore, Maryland

Abstract

BACKGROUND—There is a need to better measure and improve the quality of oncology care and improve communication with patients and other providers. The American Society of Clinical Oncology Breast Cancer Registry (BCR) pilot evaluated the feasibility and acceptability of prospective data collection for quality assessment in daily clinical practice. Data were used to create and share treatment plans/summaries (TPSs) at the point of care.

METHODS—Using a web-based tool, 20 diverse practices entered clinical data on each new early-stage breast cancer patient into the BCR for 14 months (September 2009 through November 2010). The tool created individual TPSs that were shared with patients. Practices received practice-specific and aggregate BCR quality measures data, participated in a survey, and received a participation stipend.

RESULTS—Twenty practices entered 2014 patients into the BCR, collecting demographic, clinical, and treatment information. Fifty-two percent of practice participants replied to an end-of-pilot survey: 73% were satisfied with the BCR and web-based tool, 31% expressed concern regarding time and effort, and 52% reported additional practice costs during the pilot. Among those who created or shared the TPSs, 90% thought the documents improved oncologist-patient communication, and 95% favored using BCR data for practice quality improvement.

CONCLUSIONS—Prospective data collection for quality assessment is feasible and allows sharing of TPSs with patients at the point of care. Future efforts should focus on decreasing implementation burden to practices, broadening participation, examining costs, and, most importantly, assessing its effects on patient outcomes.

Keywords

treatment plan; treatment summary; quality of care; quality assessment; breast cancer

Corresponding author: Ann H. Partridge, MD, MPH, Dana-Farber Cancer Institute, 450 Brookline Avenue, Boston, MA 02115; Fax: (617) 632-1930; ahpartridge@partners.org.

CONFLICT OF INTEREST

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INTRODUCTION

Over 207,000 women are diagnosed annually with breast cancer in the United States alone.¹ Treatment options for women with breast cancer have become increasingly complex, and care received can vary greatly among patients. Because studies have demonstrated that compliance with guidelines improves outcomes for patients with cancer, much emphasis is placed on measuring adherence to quality measures to evaluate this complex care.²⁻⁴ Several programs and studies, including the American Society of Clinical Oncology (ASCO) National Initiative on Cancer Care Quality, have revealed significant variation in the quality of care that cancer patients receive.^{2,5-7}

Variation in adherence to quality indicators for breast cancer care has also been observed among practices that participate in the ASCO's Quality Oncology Practice Initiative (QOPI).⁸ The QOPI provides a systematic quality measurement and improvement program for outpatient hematology-oncology practices.^{6,8-13} Through the QOPI, practice staff conducts retrospective chart reviews following a defined methodology and submits a limited data set via a secure online web application. The QOPI then provides detailed reports to participating practices, including doctor-specific, practice-specific, and national aggregate data on more than 90 quality measures. By early 2011, there were almost 700 practices registered in the QOPI. Similar to most existing efforts, this approach to quality assessment involves retrospective data collection that can then be used to develop initiatives to improve care, while the ideal system would facilitate real-time quality improvement efforts.

Previous work on the quality of care for individuals with cancer has also demonstrated a need for improved documentation in patient medical records regarding both planned treatment and a summary of the actual treatment received. The Institute of Medicine has made a compelling argument for the need for improved documentation to facilitate the transition to survivorship, specifically treatment summaries and survivorship care plans.¹⁴ Cancer patients often return to their primary care physicians (PCP) after completion of their cancer treatments. PCPs may be unaware of existing guidelines for the care of cancer survivors.¹⁵ Many PCPs feel they receive insufficient information about their patients' cancer diagnoses and treatments,¹⁶ and breast cancer patients feel that the communication between their oncologist and the PCP is inadequate.¹⁷ The use of treatment plans and summaries has the potential to affect clinical discussions, patient decision making, patient satisfaction, and coordination of survivorship care.¹⁸ Despite the increasing focus on the adoption of cancer treatment plans, summaries, and survivorship plans, there have been limited uptake and few studies to evaluate the burden and benefit of their widespread use in a clinical setting. Although electronic health records may make this process seamless in the future, currently data for quality assessment must be collected prospectively to allow the integration of quality improvement at the point of care. However, once the details of patient's cancer and treatment are systematically recorded in a registry database, this information can then be used to create a treatment plan and treatment summary (TPS). This is sometimes referred to as a survivorship care plan and that can be individualized for each patient.

Building on the QOPI's experience and success as well as the need for improved treatment documentation for individuals with cancer, the ASCO Breast Cancer Registry (BCR) was designed as a pilot project to evaluate the feasibility and acceptability of prospective data collection to support quality assessment in daily clinical practice. The BCR also allowed the implementation of a TPS program to provide customized treatment plans and summaries to be shared with patients at the point of care. This article describes the implementation and uptake of the registry and its perceived burden, value, and usefulness from the practice

perspective. A separate report describes the complementary and critical perspective of participating patients.¹⁹

MATERIALS AND METHODS

Practice Selection and Requirements

Practices were recruited from ASCO membership via announcement during the 2009 ASCO annual meeting and targeted e-mails to QOPI participants, ASCO Clinical Practice Committee members, and state affiliates. All applicant practices were required to indicate commitment to full participation by at least 2 medical oncologists (unless the practice involved a solo practitioner) and to have at least 1 ASCO member in the practice. Variation in other practice characteristics was desired to include a diverse selection of practices: (1) practice size (number of oncologists and number of new breast cancer patients seen per year); (2) type of practice (academic and community); (3) patient population mix (eg, languages spoken, insurance mix); and (4) participation in the QOPI. For the pilot, all practices had to be in the United States.

Twenty practices were selected for participation by the BCR steering committee members and ASCO staff, 2 of which were replaced by other practices because of their inability to meet minimum pilot requirements. Thirteen practices used the New England Institutional Review Board (IRB) as a central IRB, and 7 received local IRB approval. Selected practices were required to sign a study agreement and a registry participation agreement addressing Health Insurance Portability and Accountability Act compliance and data use; have their participating oncologists sign informed consent forms; undergo training; commit to using the web-based application and discuss the TPSs and share a copy with all eligible breast cancer patients for the duration of the pilot; and help all participating oncologists and staff complete online surveys. Practices were also required to obtain informed consent from a subset of patients to participate in a patient survey.¹⁹ A stipend of up to \$20,000 (prorated) was offered to compensate for time and costs.

Breast Cancer Registry Development and Implementation

The BCR was designed to be integrated into routine clinical care (ie, produce a TPS that could be used as a medical documentation and patient communication tool); to provide data and quality reports to the practices; for quality improvement activities; and for anonymous analysis of treatment patterns. Practice staff log on to a password protected centralized website (similar to the web-based interface used for QOPI data input). They input relevant clinical data regarding the patient, disease, and treatment into a user-friendly template screen including drop-down lists and some free text options. These data then are saved in the central registry and are used to populate the TPSs. The clinical data captured through the registry was stored as a limited data set. Individually identifiable patient information entered in the registry was stored in a separate and protected data table and was available to the practice and Outcome Sciences, Inc, but not to the ASCO, members of the steering group, or other participating practices (ie, practices could only view their practice data), and was not a part of the registry database. Each patient's name and contact information was captured for the purpose of populating the corresponding TPSs fields, and only the local practice had access to the individually identifiable patient information.

Prior to initiation of the BCR pilot, training of individuals at each practice occurred via webinar: a help desk provided ongoing support during the pilot, and the ASCO monitored practice staff for compliance. Participating practice members were instructed to enter data for all new patients with stage 0–3 breast cancer using the web-based application before treatment started. The content of the generated treatment plan was then printed and shared

with the patient. For patients who received chemotherapy, information on the actual treatment received was also entered into the web-based application upon completion of chemotherapy, triggering the creation of a treatment summary that was discussed and shared with the patients. In contrast, for patients who did not receive chemotherapy, the treatment plan and summary were administered at the same time in 1 document. In this article, we collectively refer to these documents as TPSs. Practices were also encouraged to share copies of completed TPSs with the patients' PCPs and other medical care providers.

Patient Surveys

Administration of patient surveys to assess patient response to TPSs began approximately 4 months into the pilot and was conducted by an outside vendor. Each practice was instructed to recruit and receive consent from patients to participate in telephone-based patient surveys (without compensation) until 10 patients from that practice had completed the survey process. These results are reported elsewhere.¹⁹

Feedback on Quality Measures and Survey of Practices

Practices received practice-specific and aggregate BCR data on 9 quality measures, such as percentage of patients with hormone receptor-positive disease who were offered endocrine therapy. These reports were provided to the practices approximately 12 months after the pilot was initiated. Future analyses will consider aggregate findings regarding quality measures among participating practices.

Participating practice members were asked to complete 2 surveys that were developed by the BCR steering committee to evaluate the perceived usefulness, value, and burden of the web-based registry and the perceived usefulness of the TPS in communication with the patient and other physicians. E-mail reminders and calls were used to enhance response rate. Practices were instructed to complete the survey twice during the pilot. We report the results of the second survey, which was conducted at least 10 months into the pilot after practices became more experienced with the registry and had received a report on the quality measures. All analyses are descriptive.

RESULTS

BCR Pilot Practice Population and Practice Survey Respondents

Eighty-three practice applications were submitted and 20 practices were selected and participated in the BCR pilot project (see practice characteristics in Table 1) Most practices were community-based. Three practices reported they had been using the ASCO templates for TPSs (available at (<http://www.asco.org/ASCOv2/Practice+%26+Guidelines/Quality+Care/Quality+Measurement+%26+Improvement/Chemotherapy+Treatment+Plan+and+Summary/Breast+Cancer+Treatment+Plan+and+Summary+Resources>)). Ten used templates from other sources, whereas 6 used none (1 did not respond).

Practice Participation in the BCR and Survey

Between September 2009 and November 2010, practices entered 2014 unique new patients with stage 0–3 breast cancer (median, 86; range, 9–276). Overall, 227 practice participants (128 staff and 99 physicians) signed informed consent to respond to the practice surveys, but 34 participants (24 staff and 10 doctors) did not participate in the pilot or had left the practice at the time of the survey. Fifty-two percent of the remaining participants completed the survey (52 physicians, 48 other staff members), were generally from larger practices, and half were from community practices (see characteristics of responders in Table 2). Survey responses were collected from at least 1 individual at each participating practice.

Satisfaction

Overall, 74% of respondents said they were satisfied with the BCR pilot, 14% expressed dissatisfaction, and 12% chose to reply not applicable or did not use the BCR. Satisfaction with the web-based application, treatment plan, and treatment summary were also separately assessed (Table 3). At the time of the end of pilot survey, 53% of respondents reported they had not yet used the summary measures report they received based on their BCR entries. Thirteen percent had used it, and 34% planned to use it. Most (95%) had a favorable view of using BCR data for practice quality improvement.

Perceived Utility to Patients

Ninety percent of those who helped create or communicate the TPSs found them helpful to improve provider/patient communication. Fifty-seven percent of respondents perceived that at least half of their patients found the treatment plan useful (33% not sure), and 56% perceived that at least half of their patients found the treatment summary (TS) useful (35% not sure). Thirty-eight percent of practice respondents shared copies of the TPSs with patients' other medical care providers.

Changes in Practice Routine, Care, and Costs

Practices indicated that they made changes in their practice routines to meet the requirements of the pilot: 43% did more work before appointments, 14% changed the length of appointments, 28% indicated other changes, and 38% made no changes. Changes were seen as positive by 22%, negative by 8%, and mixed by 43%. Only 8% indicated they made changes in patient care (29% unsure); among them, 88% indicated changes were positive, and some practices commented that the pilot helped them focus on improving documentation and patient communication.

Practice participants (52%) said they incurred additional costs to meet the BCR requirements; 25% had staff overtime costs, 6% hired additional staff, 4% updated computer systems, and 23% indicated other additional costs. Almost half incurred no additional costs. Thirty-one percent expressed concern regarding the time required to accomplish at least 1 aspect of the pilot.

DISCUSSION

In this report, we present results from the implementation and evaluation of a multisite pilot study of a quality improvement, treatment plan, and treatment summary program developed in conjunction with a corresponding registry of detailed patient-level data. To our knowledge, this is the first attempt to coordinate both real-time data entry for quality improvement with an intervention to improve the quality of care delivered in diverse oncology practices. We have demonstrated that prospective data collection for quality assessment is feasible and enables creation of TPSs that can be shared with patients at the point of care.

Prior limited research has suggested a great need for treatment plan and summary/survivorship documentation.^{20,21} Such plans may have substantial benefits for cancer patients. Griggs et al.²² reported that satisfaction with information provided during both treatment and survivorship among breast cancer patients is strongly associated with patient mental health and vitality; however, patients' satisfaction with treatment information was substantially greater than satisfaction with survivorship information. Patients view survivorship care plans as helpful, but may regard previously used plans as limited, incomplete, and too technical.^{18,23} It has been recognized that the lack of communication may contribute to poor care after treatment for many survivors of cancer,¹⁶ and information

exchange by physicians is strongly associated with the perceived quality of follow-up care among cancer survivors.²⁴

Prior research has also emphasized the importance of involving primary care physicians in the care of patients with cancer and survivors. Several experts have noted that summarizing treatment with a formal document allows for better awareness among the multiple doctors involved in caring for the average cancer patient.^{25,26} PCPs are often responsible for providing general medical services to patients with cancer, long-term care after treatment, surveillance for recurrence, and management of comorbid conditions. PCPs often feel untrained to provide long-term follow-up care for survivors of cancer¹⁵ and have concerns regarding communications with oncologists¹⁸ and transfer of care.¹⁶ Patients also have expressed concern regarding knowledge among PCPs of cancer survivorship care.¹⁷ However, cancer patients have indicated greater satisfaction when their PCPs have greater involvement in their cancer care.²⁷

The QOPI provides a systematic quality measurement and improvement program for outpatient hematology-oncology practices. Through the QOPI, practice staff conduct a retrospective chart review that follows a defined methodology and submits a limited data set via a secure online application. The BCR expands upon this program and uses a data submission process that is integrated into the clinical care process, avoiding the need for retrospective case identification and review. Like the QOPI, this registry provided data and quality reports to participating practices for use in data-driven quality improvement activities. However, the registry methodology allowed creation of a patient-specific treatment plan and treatment summary document that require no additional effort on the part of practice staff. Opportunity to study practice variation in the BCR is tremendous and complements other available databases for breast cancer health services research. Our future plans include formal analysis of this dataset regarding quality of care measures, such as the appropriateness of treatments planned and received for women with early breast cancer in the community oncology setting.

Our findings should be interpreted in light of the limitations of the research. This was a pilot study in selected, albeit diverse, practices with potential selection bias. Only half of the practice participants responded to survey requests, and we do not have demographic information on participants who did not respond to the survey for analysis of responder bias. Further, while we know that all practices entered patients into the BCR, we do not actually know that all practices used the TPS functionality and followed recommendations for sharing them with registry patients. Additionally, practices were required to consent a subset of patients enrolled in the BCR to participate in the patient survey, which undoubtedly added burden on the practices and may have influenced their perceptions of the pilot overall. Further, as would be the case in the “real world,” accuracy of data entered into the registry was dependent on practice input with limited oversight.

Nevertheless, we have demonstrated that implementation and evaluation of a multisite treatment plan and summary program with an associated breast cancer registry is feasible and generally well-received by practice participants. Future research should focus on broadening practice participation and assessing the cost and impact on practices and on patient outcomes as well as the quality of care delivered. Ongoing efforts to apply informatics solutions to limit practice burden, such as integration of treatment plan and summary templates with practices’ electronic medical records, may facilitate uptake of the program into standard clinical practice.

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Table 1

Characteristics of Practices Participating in the Breast Cancer Registry Pilot

Characteristic	Value
Practice type, no. (%)	
Total	20
Academic	4 (20)
Nonacademic	16 (80)
Geographic location, no. (%)	
Eastern time zone	10 (50)
Central time zone	6 (30)
Pacific time zone	4 (20)
Practice size, no. (%)	
Small (1–5 medical oncologists)	9 (45)
Large (6+ medical oncologists)	11 (55)
Practice volume,^a no. (%)	
Low (1–200 new patients)	11 (55)
High (> 201 new patients)	9 (45)
Participants per practice, median (range)	
Completed first survey	
Oncologists	4 (1–15)
Other staff ^b	4.5 (1–23)
Completed second survey	
Oncologists	1.5 (0–7)
Other staff ^b	2 (0–11)

^aNo. of new breast cancer patients per year; reported by practice.

^bIncludes advanced practice nurses, nurse practitioners, physician assistants, administrative assistants, and others.

Table 2

Characteristics of Individual Responders from Practices Participating in the Breast Cancer Registry Pilot

Characteristic	All Respondents	Medical Oncologist	Staff ^a
Practice type	N = 100	n = 52	n = 48
Academic	24 (24)	9 (17)	15 (31)
Nonacademic	76 (76)	43 (83)	33 (69)
Practice size	N = 100	n = 52	n = 48
Small (1–5 medical oncologists)	26 (26)	15 (29)	11 (22)
Large (6+ medical oncologists)	74 (74)	37 (71)	37 (78)
Practice volume^b	N = 100	n = 52	n = 48
Low (1–200 new patients)	52 (52)	25 (48)	27 (57)
High (> 201 new patients)	48 (48)	27 (52)	21 (43)
Years of experience	N = 96	n = 51	n = 45
1–6	24 (25)	10 (20)	14 (31)
7–12	25 (26)	15 (29)	10 (22)
13–23	24 (25)	17 (33)	7 (16)
24–52	23 (24)	9 (18)	14 (31)
Sex	N = 99	n = 52	n = 47
Women	63 (64)	21 (40)	42 (89)
Men	36 (36)	31 (60)	5 (11)
Age, y	N = 98	n = 51	n = 47
40	31 (32)	13 (25)	18 (38)
41–50	30 (31)	21 (41)	9 (19)
51–60	24 (24)	11 (22)	13 (28)
61	13 (13)	6 (12)	7 (15)
Ethnicity/Race^c	N = 96	n = 51	n = 45
Asian	14 (15)	13 (25)	1 (2)
African American/Black	4 (4)	3 (6)	1 (2)
White (non-Hispanic, non-Latino)	74 (77)	31 (61)	43 (96)
Hispanic or Latino (all races)	1 (1)	1 (2)	0 (0)
Unknown/Unreported	4 (4)	4 (8)	0 (0)

Data are presented as no. (%).

^aIncludes nurse practitioners, physician assistants, advanced practice nurses, administrative assistants, and other unidentified positions.^bNo. of new breast cancer patients per year; reported by practice.^cPercentage totals are >100% because respondents could select more than one category.

Table 3

Practice Satisfaction (N = 101)

Satisfaction	Satisfied	Dissatisfied	Not Applicable/ Did Not Use
With web-based application	57 (56)	6 (6)	38 (38)
With treatment plan	69 (68)	14 (14)	18 (18)
With treatment summary	71 (70)	13 (13)	17 (17)
With overall pilot project	75 (74)	14 (14)	12 (12)

Data are presented as No. (%).