Feasibility and Acceptability of Conducting a Randomized Clinical Trial Designed to Improve Interpretation of Screening Mammography

Patricia A. Carney, PhD, Andy Bogart, MS, Edward A. Sickles, MD, Robert Smith, PhD, Diana S. M. Buist, PhD, Karla Kerlikowske, MD, Tracy Onega, PhD, Diana L. Miglioretti, PhD, Robert Rosenberg, MD, Bonnie C. Yankaskas, PhD, Berta M. Geller, EdD

Purpose: To describe recruitment, enrollment, and participation in a study of US radiologists invited to participate in a randomized controlled trial of two continuing medical education (CME) interventions designed to improve interpretation of screening mammography.

Methods: We collected recruitment, consent, and intervention-completion information as part of a large study involving radiologists in California, Oregon, Washington, New Mexico, New Hampshire, North Carolina, and Vermont. Consenting radiologists were randomized to receive either a 1-day live, expert-led educational session; to receive a self-paced DVD with similar content; or to a control group (delayed intervention). The impact of the interventions was assessed using a preintervention–postintervention test set design. All activities were institutional review board approved and HIPAA compliant.

Results: Of 403 eligible radiologists, 151 of 403 (37.5%) consented to participate in the trial and 119 of 151 (78.8%) completed the preintervention test set, leaving 119 available for randomization to one of the two intervention groups or to controls. Female radiologists were more likely than male radiologists to consent to and complete the study ($P = .03$). Consenting radiologists who completed all study activities were more likely to have been interpreting mammography for 10 years or less compared to radiologists who consented and did not complete all study activities or did not consent at all. The live intervention group was more likely to report their intent to change their clinical practice as a result of the intervention compared to those who received the DVD (50% versus 17.6%, $P = .02$). The majority of participants in both interventions groups felt the interventions were a useful way to receive CME mammography credits.

Conclusions: Community radiologists found interactive interventions designed to improve interpretative mammography performance acceptable and useful for clinical practice. This suggests CME credits for radiologists should, in part, be for examining practice skills.

Key Words: Screening mammography; physician education; interpretive accuracy.

Acad Radiol 2013; 20:1389–1398

From the Departments of Family Medicine and Public Health and Preventive Medicine, Oregon Health & Science University, 3181 SW Sam Jackson Park Rd, Mail Code: FM, Portland, OR 97239 (P.A.C.); Group Health Research Institute, Group Health Cooperative, Seattle, WA (A.B., D.S.M.B., D.L.M.); Department of Radiology, University of California, San Francisco, San Francisco, CA (E.A.S.); Cancer Control Science Department, American Cancer Society, Atlanta, GA (R.S.); Departments of Medicine and Epidemiology and Biostatistics, University of California, San Francisco, San Francisco, CA (K.K.); Department of Community and Family Medicine, Geisel School of Medicine at Dartmouth, Lebanon, NH (T.O.); Department of Public Health Sciences, University of California Davis School of Medicine, Davis, WA (D.L.M.); Department of Radiology, University of New Mexico, Albuquerque, NM (R.R.); Department of Radiology, University of North Carolina, Chapel Hill, NC (B.C.Y.); and Department of Family Medicine, University of Vermont, Burlington, VT (B.M.G.). Received July 22, 2013; accepted August 21, 2013. **Address correspondence to:** P.A.C. e-mail: carneyp@ohsu.edu

http://dx.doi.org/10.1016/j.acra.2013.08.017

Continuing medical education (CME) has traditionally been a requirement for maintaining qualifications for practicing physicians (1). Physicians who interpret mammography are required by the Mammography Quality Standards Act (MQSA) to obtain at least 15 hours of Category 1 CME units in mammography every 36 months to maintain their qualifications (2). Justification for continuing CME activities under MQSA is based on a belief that gains in knowledge will lead to improved patient care and outcomes (3). However, despite the significant level of participation and resources applied to CME, there are two persistent concerns. First, conventional, lecture-based CME may have little, if any, effect on physician performance (3–6). Second, 20 years after Congress passed the MQSA, there remains a sizable gap between actual and ideal interpretative performance (7,8).

In 1992, the definition of traditional CME had expanded beyond classic passive lectures or grand rounds, as physicians and CME providers were undertaking more complex learning activities such as computer-based simulations using actual patient problems, reading materials, and visits to practice sites by health care professionals trained to improve performance using academic detailing (3). Several such approaches have been described as positive interventions because they prepared physicians for further learning and improvements in clinical practice (3). In addition, subsequent studies (5,6,9,10) of more discrete interventions consistently identified three important features of effective CME: (i) assessment of learning needs is a necessary precursor to effective CME, (ii) the importance of interaction among physician-learners with opportunities to practice the skills learned, and (iii) the importance of multifaceted educational activities (5,6,9–12).

Several studies have tested approaches to improve interpretive performance of screening mammography, the most of which combined several strategies, including performance data review, participation in a self-assessment and case review program, and increasing interpretive volume (13–16). What is less well understood in educational intervention research is how feasible it is to engage clinical practitioners to participate in complex educational research. Understanding the characteristics of those who consent to educational research as well as the characteristics of those who complete all study components compared to those who drop out can assist in tailoring future recruitment efforts and in interpreting findings from educational interventions.

We conducted an interpretive skills assessment using mammography test sets before and after testing two educational strategies designed to improve interpretive performance of screening mammography relative to a control group. Here, we report what we learned about the feasibility and acceptability of conducting a large, complex randomized controlled trial (RCT) to assess educational interventions.

METHODS

This study enrolled radiologists to (i) complete a brief survey and complete one of four mammography preintervention test sets designed to assess their baseline performance, (ii) be randomized to receive one of two interventions or serve as a control group (delayed intervention), (iii) complete the intervention if randomized to one, and (iv) complete a postintervention test set. The larger study is described in detail elsewhere (17,18). Briefly, we developed four image-based test sets designed to assess interpretative performance at baseline, conducted an RCT to evaluate two educational interventions designed to improve interpretation of screening mammography, and designed a single test set to test performance postintervention. A third study arm served as a control group. The development of the test sets is described elsewhere (17), and the content of the interventions was based on what we learned about participants' performance on the preintervention test sets, which were administered the year before the interventions were developed and deployed. The interventions included a self-paced DVD and a live expert-led 8-hour educational session that included a review of 40 cases (18–20). If radiologists had a compelling reason for being unable to attend the live intervention after the initial randomization, they were re-randomized to either the DVD group or the control group. This occurred for 13 participants (6 moved from live to DVD, and 7 moved from live to control; see Fig 1). One other participant was mistakenly invited to attend the live intervention, despite having been randomized to the DVD group. This person was reassigned to the live intervention. To evaluate the interventions, we compared participants' performance on a postintervention test set administered at least 90 days after the interventions were completed. The impact of the interventions on radiologist performance is reported elsewhere (18).

Study Population

During enrollment, which occurred in 2009 and 2010, we invited 403 radiologists to participate. Eligibility included those who interpreted mammograms at a facility contributing to a National Cancer Institute Breast Cancer Surveillance Consortium (BCSC) mammography registry (21) between January 2005 and December 2006. We also invited 103 non-BCSC radiologists from Oregon; Puget Sound, WA; North Carolina; San Francisco, CA; and New Mexico. As an incentive to participate, all participants received up to 24 Category 1 CME credits through the University of Vermont for completing the three components: (i) the preintervention test set, (ii) either of live or DVD intervention being tested (or delayed DVD intervention for the control group), and (iii) the postintervention test set. Potential participants were notified that they could receive up to 24 AMA PRA Category 1 credits CME.

Each BCSC registry and the Statistical Coordinating Center (SCC), where analyses were performed, received institutional review board approval for all study activities, including active consent to enroll radiologists and perform analytic studies. All registries and the SCC follow procedures that are Health Insurance Portability and Accountability Act (HIPPA) compliant to obtain films and patient information and also have received a federal certificate of confidentiality and other protections for the identities of women, physicians, and facilities that are related to the films used in this research (22).

Data Collection

Study coordinators at each site were provided with a tracking database, which was used to maintain records of all study activities including participant recruitment, administration of the preintervention and postintervention test sets, and all activities related to randomization and implementation of