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Challenges to replicating evidence-based research in real world settings: Training African American peers as patient navigators for colon cancer screening

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Background

The translation of evidence-based research findings to practice that is effectively, appropriately and widely implemented has been described as one of the greatest challenges facing health promotion and disease prevention [1, 2]. There is a considerable gap in the continuum of diffusion and dissemination of evidence-based research to practice settings [3]. Glasgow, Marcus, Bull & Wilson [4] point out that successful and/or evidence-based programs do not and will not naturally diffuse into routine practice and that methods utilized

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[1]The protocol was amended twice. In the first amendment, we sought a waiver of informed consent, because due to the move to telephone-based navigation, we felt it would be difficult to obtain written informed consent via mail.

for dissemination are underreported in research studies. The process of disseminating research to practice is often discussed in conceptual terms, but the reality of applying this to practice is usually difficult, very complex, and time consuming. In recent years, more attention has been devoted to discussing the dissemination process, but few publications explicitly describe what this process may look like, especially the challenges that researchers are likely to face, how to address them, and how long the entire process takes. This is a serious problem in cancer research because "…the failure to transfer new, evidence-based findings into widespread delivery limits the impact of [advancing] cancer control research" ([3], p.1).

One of the major issues of concern within the field of dissemination research has been the lack of a standardized definition of terms. Dissemination research has been defined as "understanding the movement of evidence-based public health and clinical innovations into practice settings" ([5], p.474). Though this definition is certainly related to our research, in the current study, we refer to our efforts toward expanding evidenced-based interventions as replication. Specifically, as defined by the Conservation Company and Public/Private Ventures, replication is "a process that moves a tested prototype program to additional sites (or target populations) in keeping with the hard (invariable) and soft (variable) aspects of that program's components while remaining sensitive to the local context" (as cited in [4], p. 1240).

Evidence-Based Colorectal Cancer Screening Interventions

African Americans have the highest colorectal cancer (CRC) incidence and mortality of all ethnic/racial groups [6]. Compared to Whites, African American CRC incidence and mortality rates are, respectively, 20% and 45% higher [6]. Cancer health disparities related to race and ethnicity are among the most serious problems facing the US health care system. Given that CRC is preventable through screening colonoscopy, many of these disparities could be effectively reduced through greater African American participation in CRC screening and early detection. Research efforts have demonstrated many racial and ethnic minorities, including African Americans, face significant barriers to getting screened for CRC including interpersonal psychological factors such as fear and fatalism [7-13]. Patient navigation (PN) interventions [14, 15] have shown that providing patients with someone to help them navigate the health care system to complete a colonoscopy screening examination is effective, above and beyond standard scheduling procedures. Moreover, studies have demonstrated that trained volunteer laypersons can effectively carry out the same tasks as professional navigators [16, 17]. Despite this evidence, nationally, very few hospitals provide their patients with navigation assistance. According to a survey conducted by the National Cancer Institute, in 2003, over 200 nationwide cancer care programs had implemented some form of patient navigation [16][11], and this figure is growing each year. Through our prior work, we were successful in training peer navigators to work alongside our professional navigators [18, 19]. Thus, the goal of the current study was to replicate and disseminate our evidence-based training model to real-world practice settings, establishing a peer navigation system in other hospital settings. Throughout the course of this intervention, however, our dissemination efforts were met with several challenges. These challenges are not uncommon as many researchers within cancer prevention and control have discussed this and provided recommendations for addressing these challenges [1-5, 20-23]. From our perspective, however, it seems that many of these challenges are inevitable and thus in the current study we discuss the process of effectively maneuvering through the dissemination and replication process in real-world settings.

Methods

Identification of Participating Sites

In the Fall of 2008, with the assistance of the New York City Department of Health and Mental Hygiene (NYCDOHMH), 15 hospitals were identified as having existing patient navigation programs as well as a direct endoscopy referral system, also referred to as open access. The open access system was designed to allow physicians and nurse practitioners to medically clear and refer eligible patients directly for colonoscopy (http://www.nyc.gov/html/doh/downloads/pdf/cancer/cancer-colonoscopy-guide.pdf.)

In addition to having an existing patient navigation program, a hospital was also required to conduct a minimum of 400 colonoscopies per year and have a significant African American population. This would help to ensure that the goal of reaching the target population and proposed sample size (N=800) of the study was achieved. Of the 15 hospitals initially identified, six met these qualifications and were contacted about participating in the study. Meetings were held with hospital administrators, including the head and/or chief of the Gastrointestinal Department to discuss the possibility of conducting the study at their sites. This step alone took a significant amount of time as issues of prioritizing and scheduling with several of the physicians and at some locations, it took months to schedule a meeting. By April of 2009, three of the hospitals declined the offer to participate in the project, while three agreed to be a participating site for the study. However, due to communication issues, inter-hospital dynamics and other issues beyond our control, one of the locations became a non-participant. This further narrowed the number of participating sites to two. They will be referred to as Hospital A and Hospital B.

Institutional Review Board (IRB)

Initial IRB submission for the coordinating site occurred in March 2009 and was approved in June 2009. Initial IRB paperwork was submitted at Hospital A and Hospital B in April and June 2009, respectively. IRB approval at Hospital A was received in July 2009 and September 2010 at Hospital B. IRB submissions for Hospital B had to be approved twice because it has two Review Boards. Table 1 displays the timeline of events related to IRB approval.

Recruitment of Peers

At both Hospitals A and B, recruitment flyers were placed in the endoscopy suites with contact information for the project coordinator of the study. Additionally, internal recruitment was conducted at both hospitals by the Director of Patient Navigation Services. African American men and women over the age of 50 who had completed a colonoscopy from the two hospitals were recruited to be trained as peer patient navigators (PPN) for colonoscopy scheduling and completion.

Volunteer Offices

All peers selected to participate in the study had to complete mandated volunteer certification at their respective medical centers. The city's public hospital system has general requirements that all volunteers must complete (http://home2.nyc.gov/html/hhc/html/volunteer/volunteering.shtml). In general, volunteers are asked to commit to a set number of hours per week, complete all medical requirements (i.e., physical examination, PPD test for tuberculosis and immunization for tetanus, chicken pox, measles, mumps and rubella), and complete any applicable training (e.g. HIPAA training).

Navigation Procedures

Hospital A: Standard Professional Navigation—After referral by their primary care physician (PCP), a patient's information was given to a standard navigator who called the patient to schedule the colonoscopy appointment and give prep (e.g. laxative use and diet) instructions. The instructions along with the appointment time and date were mailed to the patient after the navigation call. If the navigator felt that the patient would benefit from a reminder, a phone call was provided two to three days prior to their appointment.

Hospital A: Peer Navigation—Peer navigators were also given a patient's information after a referral by the patient's PCP. The peer navigator called the patient to schedule a colonoscopy appointment, provide CRC education and prep instructions, and share their personal colonoscopy experience.

Hospital B: Standard Professional Navigation—After being referred by their PCP and obtaining financial clearance from the hospital financial office, a patient was instructed to either call or visit the office of the patient navigators. Financial clearance is the system at Hospital B in which a patient's medical insurance is verified. If a patient does not have medical insurance, they are asked to pay a fee (a sliding fee based on income). The first payment is due prior to the patient contacting the patient navigators. Upon the patient's arrival, the navigator ensured financial clearance within the hospital's electronic records. The navigator then provided the patient with CRC education and instructed them on how to take the laxative prep and medications. Finally, the patient was given an appointment date for the procedure. For patients who were navigated over the phone, the same procedure was followed, however the hard copy of the prep instructions were mailed to their home.

Hospital B: Peer Navigation—After financial clearance was ensured by the professional navigator, the peer navigator was given a patient's information. The peer navigator then provided the patient with CRC education, prep and medication instructions, an appointment date, and shared their personal experience with having a colonoscopy.

Results

Training of Peers

Six African American men and women over the age of 50 who had completed a colonoscopy from the participating two hospitals were trained as peer patient navigators (PPN) for colonoscopy scheduling and completion. Three peers (two men, one woman at Hospital A; two women, one man at Hospital B) were recruited at each hospital site. Training consisted of didactic discussion, observation, role playing, one-on-one sessions, and supervision via review of audio-tape recordings of PN. Trainees completed a paper and pencil knowledge test; both at the start of training and upon completion. In order to be placed in a hospital as a PPN, peers were expected to achieve at least 90% mastery of the materials as well as attend 90% of the training sessions. All six trainees were deemed proficient. In addition to our navigation training, peers were trained to become integrated into each respective hospital's colonoscopy screening navigation system. Some of the challenges faced in recruiting and training PPNs included developing professional etiquette in real-world settings (i.e., training volunteers to work within each hospital's standards) and recruiting "ideal" (i.e., professional, capable, dependable) community volunteers in a non-discriminatory manner.

Hospital A Challenges

Participant recruitment began in April 2010 after IRB approval was granted and volunteers were recruited and trained. The PPNs worked closely with Hospital A's staff to maximize recruitment of participants by talking with patients, explaining the study to them and going over informed consent. However, the patient population at Hosptial A is predominantly Hispanic/Latino, which is dissimilar to the target population of the study (African Americans) and resulted in recruitment numbers that were less than our projected goal. In an effort to ensure the highest possible recruitment, we placed a staff person at Hospital A to assist with the recruitment and consent process. Additionally, language issues with one PPN and scheduling difficulties in various clinics at the hospital were alsso significant challenges. Unfortunately, after approximately 14-15 months of recruitment efforts, we were unable to overcome this barrier, which was the greatest challenge we faced at this hospital, and decided to end recruitment due to lack of target population participation. Thus, we refocused our recruitment efforts to Hospital B, because their patient population is predominantly African-American. When recruitment ended, a total of 14 participants had been enrolled in the study, but only eleven (six randomized to the peer condition) were eligible to participate in the study.

Hospital B Challenges

Extensive IRB and Volunteer Approval Process—Because IRB documentation was required for two different boards (one for the hospital system and one for the affiliated academic institution) the process for IRB approval took about 15 months (see Table 1), which significantly delayed the start of participant recruitment. Beyond the lengthy IRB approval process, recruitment was also delayed due to complications with the hospital's volunteer office. Once volunteers completed peer navigation training, they were asked to complete the hospital's volunteer certification process (i.e. medical clearance, HIPAA training, background check), but because IRB approval for the study had not yet been granted by the hospital, the volunteers were unable to complete this training. During this period, there was some concern that the peer volunteers may lose interest in continuing their involvement in the study.

The research team met to discuss potential solutions for the peer volunteers' waning interest and enthusiasm and tried to think about the possible challenges that might further delay the progress of the study once IRB approval was granted. It was decided that, in addition to checking in periodocially with the volunteers (to update them on the status of the project), additional (paid) refresher trainings would be useful to ensure that peers were proficient enough to execute the core competencies of PN in which they had previously been trained. Thus, peer navigators at Hopsital B were trained on the hospital's navigation system. They were also given hospital computer access and training to facilitate navigation, received IRB/Human Subjects Research training at the coordinating site and were also added to Hospital B's IRB protocol to assist with the consenting process. After IRB and hospital volunteer approval had been granted, recruitment for navigation began, but unfortunately shortly after approval, one of the professional staff navigators at Hospital B died unexpectedly and recruitment was postponed.

Post-Approval Logistic Challenges—Following the death of the professional navigator, other challenges occured (see Table 2) including the lack of staff at Hospital B to faciliate the informed consent process, low recruitment, lack of space, and hospital-initiated changes. Finding adequate space to conduct interviews and telephone calls was difficult, but the professional navigators were very gracious and offered their offices to the peers and recruiters on alternating days and times when the professional navigators were not

physically in the office (e.g., there were days that the professional navigators went to the clinic to navigate patients instead of calling patients over the telephone).

Initially suggestions, such as asking a medical student from the affiliated academic institution and training PPNs to perform informed consent were posed to address the lack of staff at Hospital B to facilitate this process. It was decided, however, that two recruiters from the coordinating site would be placed at the hospital to explain informed consent, complete interview assessments in person and supervise the PPNs. Considering the large volume of colonoscopies performed each year at this hospital (on average as many as 2,000 per year), another challenge was that enrollment of eligible participants, at the point that we were recruiting, was suboptimal. Initially, on average we enrolled about three participants per week, which was less than 1% of the total number of colonoscopies performed in one year. We undertook a number of strategies to increase recruitment including shortening and eventually eliminating the assessment interview, offering a small incentive for patient participation and attempting to recruit participants immediately after their appointment with their PCP. Elimination of pre-surgical testing, which was initiated by the hospital, also helped to increase recruitment slightly. Ultimately, however, we learned that financial clearance (verfication of medical insurance) was the greatest barrier to recruitment. Regardless of whether a patient had met all other requirements, if he or she did not have insurance, an appointment for a colonoscopy could not be given.

Hospital-initiated changes to the navigation system to eliminate pre-surgical testing for colonoscopy screening eligibility and subsequently move from face-to-face navigation to telephone-based navigation also presented challenges. These changes, in other circumstances, would make PN much smoother and easier. However, because this is a research study, any change the hospital makes, consequently, also affects the original study protocol and it was difficult to execute PPN according to the original protocol. We also realized that given the low recruitment numbers, we would be unable to achieve our targeted sample size enrollment and contacted the NCI/NIH program director for the study for guidance and direction. The program director was very helpful in providing suggestions for how to proceed based on what her knowledge of what other grantees had recently done when these types of problems arose. Additionally, we also contacted the director of the IRB at Hospital B, to discuss possible options and solutions, which included several prospective options (e.g., mailing patients informed consent documents to sign and return to us before participating) as well as retrospectively collecting patient information. We assessed the specific aims of the project which included training the peers and evaluating whether peers could be as effective as professional patient navigators in helping patients complete a colonoscopy screening exam. Therefore, in consultation with the director of the IRB office at Hospital B and the NCI/NIH program director, the study protocol was amended[1] to be a clinical service instead of a research project. This would allow retrospective review of patients' medical charts (i.e., colonoscopy completion) so that informed consent could be waived to complement the hospital's telephone-based navigation. Approval was granted and average weekly recruitment has since improved (6-10 per/week). This option allowed us to gather colonoscopy completion data while maximizing the number of participants that could be enrolled in the study. The drawback to taking this approach is that we cannot collect any other research data regarding patients' attitudes, beliefs and feelings about the colonoscopy screening exam.

Discussion

Bridging the gap between evidence-based research and practice is critical to eliminating many cancer health disparities; therefore, it is crucial that researchers and practitioners continue to work to achieve both diffusion and fusion of evidence-based findings. It is

equally important that researchers better understand the processes and mechanisms through which cancer screening interventions and replication do *not* work. Overall, our experience in replicating a PPN training model in non-academic hospital settings demonstrates that the replication process is complex, requires significant contributions from collaborators and great flexibility. The purpose of this manuscript was to describe the replication process and highlight the challenges faced in attempting to disseminate an evidence-based intervention to a real-world setting. Table 2 summarizes the major challenges of the replication process and how we responded to these barriers. Although we were met with many challenges throughout the course of this project, we want to emphasize that we *were* able to address these barriers and come up with acceptable solutions for almost every problem.

Replicating the peer patient navigation training model in other settings has been challenging. First, it was difficult operating within multiple institutional settings' and their differing procedures and policies (i.e. IRB approval process; hospital volunteer training). This was the most time-consuming aspect of the project. Because the IRB process is an essential part of research and is known to be a lengthy process, it was helpful to have other training that the peers could participate in to keep them engaged and interested in the study. . Determining the best way to navigate within multiple institutional policies and procedures is more complex, and future dissemination, replication and implementation research may be able address this issue. Thus, it is important to anticipate a potentially long period of waiting before IRB approval is received. Future studies might consider waiting to train peer volunteers later in the process as well as begin other aspects related to the study (i.e., specific hospital navigation procedures, HIPAA and informed consent, etc.) that don't require IRB approval.

Second, a non-academic/research infrastructure is challenging for replication and implementation. The purpose of this project overall was to replicate evidence-based research in practice-focused, patient-oriented settings. Maintaining fidelity to the essential aspects of the original model/intervention while adapting the intervention to fit with current institutional policies and system is very challenging. Our experience shows that replication may be achievable with great flexibility and determination.

Third, the prevailing patient navigation practices made integrating the peer navigators into the hospitals' established navigation system challenging. Our research team attempted to overcome this challenge by choosing peers who demonstrated the utmost professionalism and integrity. Nonetheless, as mentioned earlier, there needs to be flexibility when attempting to implement additional navigation strategies into a pre-existing system. This point should be made clear when vetting potential collaborators, who will have to advocate on the project's behalf for possible changes (to scheduling procedures, record-keeping, etc.) at their institution.

Fourth, it was challenging to figure out how to obtain the support of hospital staff without overburdening them with additional responsibilities. We relied heavily on the professional staff navigators to execute the day-to-day aspects of the project. Although we felt that once the peer navigation system was in place, it would alleviate a significant portion of their navigation load, the staff navigators did not share our perspective and felt overburdened with extra work. We want to note that they were extremely helpful despite feeling this way and have worked with us to address many issues that arose.

Fifth, it was difficult to contend with competing time commitments of patient-focused medical professionals working within a practice setting. Because our collaborators were from non-academic institutions, they had limited time and resources available to dedicate to research activities. For example, being able to work with a research coordinator or a staff

person dedicated to the patient navigation program (without many other obligations) may have greatly reduced the burden on the professional navigators and eased the replication project. At Hospital A, for example, because there the patient navigation director helped to facilitate the coordinating site's interactions with the hospital volunteer office, this process was much simpler and shorter.

We offer the following recommendations for future replication projects. First, determine collaborators early on and involve them in proposal development and planning to be sure that there is market pull/demand. We attempted to do this, but uncertainty regarding funding makes this more complicated, as collaborators have their own agendas and priorities. Dedicating valuable time and resources to a not-yet-funded project may not be feasible. However, researchers may consider partnering with current collaborators (on ongoing projects) or other colleagues for replication projects to help with planning and proposal development. Second, choose and identify collaborators with institutional settings and characteristics that are most amenable for successful replication (i.e. flexibility of prevailing navigation practices and research focus). It was to our benefit that our collaborators were able to change some of their processes to facilitate better navigation and this helped to make recruitment easier. Third, ensure that the staffing pattern matches the intervention's requirements and if not, budget for additional staff and plan for ways to address this challenge. This is important for successful replication, because it is helpful to have a point person to coordinate activities in a multi-site intervention. Fourth, include hospital staff in proposal development whenever possible and consider offering incentives for staff participation. One of the comments from the staff navigators was that they were not involved in the planning of the proposal and protocol and felt they could have offered valuable insight about the operations of their hospitals' navigation system. Finally, be proactive. Identify possible challenges early and develop a plan to address them.

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Table 1
Timeline of IRB and Volunteer Approval Process

Date	Task/Event
September 08	Grant began; Meetings with potential sites
December 08	IRB submission at coordinating site
March 09	Meeting with chosen sites
April 09	IRB documentation given to IRB contacts at Hospitals A & B Recruitment of peer volunteers
June 09	IRB documentation submitted at Hospital B
July 09	IRB approval granted at Hospital A
September 09	Peer navigator training at coordinating site
October 09	Study approved by Board #1 at Hospital B
April 10	Peer patient navigation begins at Hospital A
May 10	IRB renewal submitted to Hospital B
July 10	IRB renewal approved at Hospital A
September 10	IRB approval granted by Board #2 at Hospital B
February 10	Coordinating site recruiter placed at Hospital A Peers approved by Hospital B volunteer office
April 11	Peer patient navigation begins at Hospital B

Table 2
Facilitators and Barriers to Effective Replication

Specific Challenge	Response/Solution
Extensive IRB approval process	During the waiting period, volunteers were recruited and trained as peers (initial PN training) Focused recruitment at Hospital A
Prolonged volunteer approval process	Postponement of start of study Informed volunteer office any forthcoming changes During the waiting period volunteers received additional PPN training
Unexpected death of professional staff navigator	Postponed recruitment
Lack of staff at Hospital B to facilitate informed consent process	Recruiters from coordinating site placed at hospital to perform informed consent and facilitate PPN PPNs completed training to facilitate informed consent
Low recruitment (due to appointment scheduling system)	Began randomizing by day of the week (instead of at level of participant) Elimination of pre-surgical testing before granting appointments Began recruiting at endoscopy suite (immediately after patients' appointment with PCP)
Lack of space for peer navigator/recruiters	Professional staff navigators offer their space PPNs navigate on days when PNs are not in
Telephone-based navigation	Petitioned IRB for waiver of informed consent
IRB not willing to approve waiver of consent	Sought advice from NCI/NIH program director and IRB administrator from Hospital B. Decided to forego research study and adopted clinical service approach to eliminate need for consent