Formative research methods to understand patient and provider responses to heart attack symptoms

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Received 1 April 1998; received in revised form 25 September 1998; accepted 3 October 1998

Abstract

Formative research is often required for program planning, and for reducing uncertainty about generalizability of program effects. This article describes and justifies methods of formative research conducted for the REACT study (Rapid Early Action for Coronary Treatment), a multi-center collaborative randomized community trial aimed at reducing patient delay in seeking care for acute myocardial infarction (AMI). Formative research cast light on patient and community members’ decision-making process in seeking help for AMI, as well as barriers and facilitators of this process. Investigators at all five REACT Field Centers participated in the formative research. The process consisted of: (1) developing a common theoretical framework for the study intervention; (2) conducting a literature review and qualitative research to identify and address gaps in knowledge; and (3) developing a common protocol for the REACT study that accommodated the diversity of the target communities in terms of services, resources, history, and ethnicity. Analysis employed triangulation, defined as an explicit search for heterogeneous data sources to reduce uncertainty about forces at work and opportunities for intervention across settings and populations. Because the collection and interpretation of data went in stages, staff of several REACT Field Centers had independent input to the overall synthesis, then shared and revised the results. Advantages and limitations of this approach are discussed. © 1999 Elsevier Science Ltd. All rights reserved.

Keywords: Acute myocardial infarction; Community trials; Community interventions; Focus groups; Formative research; Qualitative methods

1. Introduction

In program planning for multi-site evaluations, a formative research stage is often required. A formative stage is often useful to reduce uncertainty about a problem’s causes, by replicating previous findings and expanding knowledge where etiology is not as yet understood. A formative stage is also helpful to reduce uncertainty about the appropriateness and feasibility of strategies found to be effective in other settings. Finally, this stage is helpful to flesh out program theory, by tailoring the way that principles are made operational at specific sites that vary in terms of setting...
and population. Thus formative research can often serve to reduce uncertainty about program effects, prospectively, while assisting program personnel to tailor the program to local circumstances.

This article describes the process of formative research in a multi-center collaborative study aimed at reducing delay in seeking medical care for symptoms of acute myocardial infarction (AMI). The specific aim of the formative phase was to understand the patients' decision-making processes in seeking help, as well as barriers and facilitators to seeking help. The groups targeted for intervention all participated in formative research, including AMI patients, their families, those at high risk of AMI, and medical care professionals. The present article provides an overall assessment of the planning process, the advantages and limitations of the data collection methods, and the degree to which the formative information was useful to the study. Formative research was also conducted for other purposes (for example, profiles of study sites); however, the present work focuses exclusively on understanding the dynamics that occur when the target audiences seek (or do not seek) help for AMI.

Early treatment of acute myocardial infarction (AMI) offers great potential to improve the outlook for survival and reduced impairment among those experiencing coronary heart disease (CHD). When people seek help early, new drugs (thrombolytic agents) can cut the death rates, save heart muscle, and permit a more rapid and complete recovery (Anderson, 1992; Cannon, Antman, Walls & Braunwald, 1994; Hennekens, O'Donnell, Ridker & Marder, 1995; Lee et al., 1995). However, improvements in hospital and emergency medical services (EMS) (Atkins et al., 1995; Crampton et al., 1975) have limited effects when people delay their response to AMI symptoms in themselves and others. The patient or bystander's decision to seek care consumes by far the most time in the entire process of care (Dracup et al., 1995). Studies in the United States place median patient delay in a range of 2–4 h (Ho, Eisenberg, Litwin, Schaefer & Damon, 1989; Kereiakes et al., 1990; Goldberg et al., 1990; 1992; Yarzebski, Goldberg, Gore & Alpert, 1994; Avoidable Delay Study Group, 1992, 1995; Weaver, 1995).

Can intervention reduce delay time? In 1994 the National Heart, Lung, and Blood Institute (NHLBI) initiated the REACT study (Rapid Early Action for Coronary Treatment) with a goal of evaluating a community intervention to reduce patient delay time, defined as the period from onset of AMI symptoms until a patients' contact with the medical care system. REACT was a 4-year, multi-center collaborative community trial, with five Field Centers located in Alabama, Massachusetts, Minnesota, Texas, and Washington. New England Research Institute served as a coordinating center. Each Field Center studied 4 communities, for a total of 20. These were moderately sized cities with adequate media channels to get the message out. Ten pairs were matched on population, distribution of age, race/ethnicity, income and education. Paired cities did not overlap in terms of media markets. Pairs were randomly assigned either to receive community-wide education or to the control group. Further details are available in Simons-Morton et al. (1998).

2. Rationale for formative research in the REACT study

2.1. The challenge of formative research

REACT required a formative research phase because there were important areas of uncertainty about how best to encourage people experiencing MI symptoms to get attention quickly. Neither the individual forces at work, nor the system barriers and facilitators, were understood well enough to begin designing the intervention. Like REACT, many community education projects require a formative research phase, whether for public communication campaigns (Palmer, 1981), for social marketing (Andreasen, 1995), or for community-based health promotion (e.g., Higgins et al., 1996).

Formative research is an iterative, or cyclic process of exploring and confirming what is known about a problem; who is affected; the most important predisposing, enabling and reinforcing factors that determine behavior related to the problem; and the most effective general strategies for intervention (Andreasen, 1995). The methods employed are both qualitative and quantitative, and are usually less definitive than the methods a study would employ later to test hypotheses, establish external validity, or test empirical relationships among theoretical constructs. For example, the formative method of the focus group is limited in terms of accuracy and generalizability by the way in which groups are sampled and the extent to which they are replicated to avoid idiosyncratic results (Krueger, 1988). Key informant interviews are limited in much the same way (Rossi and Freeman, 1994). Even surveys have their limitations, when the goal is to obtain fresh insights, because they are limited by their close-ended content. In other words, surveys are limited by the sample of questions and response categories that are included. Formative research is limited by time (usually brief) and resources (usually small).

These limitations pose two challenges for formative research: (1) how can investigators increase their confidence that formative research findings are correct, even for the populations that are being directly studied and (2) how generalizable are the causal relationships that
are suggested by formative research, including the effects of existing interventions in the research literature and strategies for health promotion envisioned for the future intervention? Substantial effort and resources depend on the answers. Yet by definition, this phase “forms” something; the project is venturing into the unknown. The aim is not to answer questions about intervention definitively but, rather, to decrease uncertainty about what the intervention should be.

2.2. The process of triangulation

Triangulation is well-understood by the evaluation profession, but the special needs of the REACT formative research process make a review desirable. “Stripped to its basics, triangulation is supposed to support a finding by showing that independent measures of it agree with it or, at least, do not contra-
those at high risk of MI, in five geographic locations); by research method (REACT used focus groups and key informant interviews, while related research had used surveys, intervention studies, and epidemiologic studies); by researcher (five REACT centers collected data and independent analysis was performed by various REACT researchers); and by theory (REACT examined the logical consistency of data in light of an overarching theoretical framework).

The REACT investigators particularly emphasized behavioral theory as a basis for formative research and triangulation. A theoretical framework sharpens the research questions of formative research, either to confirm certain key findings of previous research (for new populations and settings), to qualify the conditions under which these findings hold, or to fill in gaps in knowledge. For some important research questions in REACT, such as the expectations and perceptions of those at high risk of AMI, there were no prior data. Theory is important for several other reasons: (1) it assists in articulating specific objectives and relating them logically to planned intervention activities; (2) theory is central to decrease uncertainty about the existence of potential causal relationships; (3) support for an elaborated theory makes alternative explanations increasingly less plausible (Cook and Campbell, 1979).

The REACT formative research took several iterations or cycles. Fig. 1 illustrates this process as applied to REACT formative research questions. Sources of information appear to the left, while synthesis and construct-building activities appear to the right. The first iteration involved synthesizing information about theory, existing research on the problem, and effectiveness of existing interventions. Although some of this work had occurred at the stage of proposal submission, the investigators spent substantial time sharing and incorporating each others’ suggestions and contributions. In the second iteration, the five research teams identified gaps in knowledge about the MI delay problem and potential interventions. In the third iteration, the investigators conducted focus groups and key informant interviews to add to the knowledge base.

3. First iteration: framing the problem

Planning began with the development of a consensus on the nature of the problem, general strategies to be employed, and the theoretical basis of intervention. At the proposal stage, the five REACT research teams had developed a strong information base. They employed two theories that together could explain delay. They were also well-acquainted with available strategies applied to other health problems and appreciated the importance of comprehensive, community-wide intervention (Simons-Morton, Simons-Morton, Parcel & Bunker, 1988). The first iteration of formative research incorporated these information sources.

3.1. Theoretical framework

The investigators developed a common theoretical framework to investigate the reasons people delay in seeking care for AMI (Simons Morton et al., 1998). Forces at individual, provider, systems and community levels can hinder or promote quick action in the face of AMI symptoms. Therefore intervention must be equally wide ranging and complex. The framework for understanding individual patient behavior is a synthesis of two theories. Social Cognitive Theory and the Theory of Self-Regulation together provided an overall framework for explaining the dynamic, reciprocal interaction among patient and bystander behaviors, personal factors, and environmental influences in the AMI delay problem. The Theory of Self-Regulation explains the way in which symptoms are experienced (Cameron, Leventhal & Leventhal, 1993; Leventhal, Meyer & Nerenz, 1980; Leventhal & Nerenz, 1985). Leventhal and colleagues discovered that people develop a common-sense representation of symptoms and of illness, upon which they base their plans for coping and action. They simultaneously cope with emotional states such as stress, aroused by the symptoms. An illness or symptoms may not be familiar, or if they are familiar they may not automatically be associated with an unfamiliar condition (such as heart attack). Patients may attribute the sensations they feel to several sources and try several coping responses before the problem is finally defined as one for which they need to seek medical care. Applied to the problem of delay in seeking AMI care, this process clearly adds to delay time and is amenable to change.

Social Cognitive Theory (Bandura, 1986) posits that individual decisions to take action, such as seeking medical care, occur within a community and social environment that shapes our perceptions and outcome expectations in the first place. Behavior change occurs in individuals largely through expectancies that behavior will result in personal benefit, and that one can successfully perform the behavior in question (self-efficacy). Collectively, these forces shape behavioral capabilities important to the decision to seek care. Points of intervention implied with respect to AMI delay suggest the potential of the community environment to shape and accelerate the decision-making process, by modeling appropriate behavior, reinforcing it, and increasing both outcome and self-efficacy expectancies.
3.2. Inventory of existing knowledge

Empirical research findings were inconsistent in important areas, including the individual and setting characteristics associated with delay, as well as the effectiveness of existing intervention studies. Several kinds of information were available to the REACT planners, including: studies of how people interpret symptoms of heart attack; studies of existing interventions; epidemiologic studies; and surveys of health care seeking. NHLBI had previously commissioned market research as part of the National Heart Attack Alert Program (Porter & Novelli, 1994a, 1994b). NHLBI's work included nine key informant interviews with medical providers in various parts of the country who worked regularly with AMI patients; six focus groups of white, African American and Hispanic patients who had an AMI within the previous 7 years; and eight focus groups with white, African American and Hispanic members of the general public who had not experienced AMI, had not had bypass surgery or angioplasty, and had no family members or close friends with AMI in the previous 3 years. The Minnesota Field Center had conducted two pilot focus groups, one with individuals who had experienced heart attack or heart attack-like symptoms during the past year, and one with spouses or companions of patients (Porter & Novelli, 1994a, 1994b). Although several regions were included in the work by NHLBI, REACT investigators wanted to make sure that additional qualitative data confirmed the conclusions of this work.

3.2.1. Factors that predict delay

People vary in how they experience symptoms of MI; this influences help-seeking (Meischke, Ho, Eisenberg, Schaeffer & Larsen, 1995; Raczenski et al., 1994; Schmidt & Borsch, 1990). Expectations about the heart attack experience have been linked to delay (Johnson & King, 1995). While the general public seems to have good awareness of the most severe heart attack symptoms (Porter & Novelli, 1994a, 1994b; Hall & Foushee, 1993; Raczenski et al., 1996) apparently they do not anticipate less severe symptoms. Other factors may add to the process of cycling through symptom representation, coping attempts, and reappraisal. These include processes of denial, suppression, fear, loss of control, embarrassment, poor advice from others, and not communicating with others about AMI symptoms, all of which have been linked to longer delay in seeking care (Hall & Foushee, 1993; Kenyon, Ketterer, Gheorgiade & Goldstein, 1991; Matthews, Siegel, Kuller, Thompson & Varat, 1983; Porter & Novelli, 1994a, 1994b). Consultation with family members and friends is often a part of the appraisal process (Porter & Novelli, 1994a, 1994b; Hall & Foushee, 1993), yet their influence can either increase or shorten delay time, so that this was an important issue for focus groups.

Results were mixed concerning several relationships with delay, including age, gender, SES and whether a medical history of CHD or prior AMI would cause someone to delay longer than others (Alonzo, 1986; Clark, Bellam & Feldman, 1989; Cooper, Simmons, Castaner, Prasad & Fenlinz, 1986; Dracup et al., 1995; Gilchrist, 1973; Hackett & Cassem, 1969; Hoffgren et al., 1988; Kenyon et al., 1991; Matthews et al., 1983; Meischke et al., 1995; Montague et al., 1992; Moss, Wyner & Goldstein, 1969; Pagley et al., 1993; Pagley & Goldberg, 1995; Rawles & Haites, 1988; Schmidt & Borsch, 1990; Schroeder, Lamb & Hu, 1978; Simon, Feinleib & Thompson, 1972; Turi et al., 1986; Weaver et al., 1991; Weilgosz, Nolan, Earp & Biro, 1988). Ethnicity has been linked to delay, such that African-Americans and Hispanic-Americans are likely to delay longer than Whites in seeking medical care (Alonzo, 1986; Clark et al., 1989; Cooper et al., 1986; Kathleen, Haywood, Sobel, Deguzman & Ning, 1994; Raczenski et al., 1994). Because African Americans and Hispanic-Americans are over-represented among the poor, it is possible that race and ethnicity may be confounded with SES. However, AMI symptom presentation appears to differ by race (Johnson, Lee, Cook, Rouan & Goldman, 1993; Raczenski et al., 1994) and cultural differences may mediate help-seeking behavior. NHLBI focus groups gave a preliminary understanding of help seeking among Hispanics (Hall & Foushee, 1993). Hispanic AMI patients were very concerned about the cost of treatment, lack of insurance, and fear of action against undocumented immigrants. Other race and ethnic groups did not uniformly cite cost as an obstacle. Hispanic women indicated that they did not find the concept of “warning signs” to be meaningful; symptoms would have to be severe before they would take action. Hispanic focus groups of the general population mentioned that family is an important motivator and messages might stress the consequences for the family if a member had a fatal MI (Porter & Novelli, 1994a, 1994b).

Existing interventions suggested potential to decrease patient delay time (Blohm et al., 1992; Rustige, Burczyk, Schiele, Werner & Senges, 1990). Therefore, the investigators planned a comprehensive community education program, implemented through multiple channels and settings (Green and Kreuter, 1991). Existing interventions focused on mass-media approaches, ranging in length from 1 week (Bett, Aroney & Thompson, 1993; O’Rourke, Thompson & Ballantyne, 1989) to 2 years (Moses et al., 1991). Such campaigns often noted a response by the public within the first week (Gaspoz et al., 1993; Herlitz et al., 1991) but a dwindling in response if campaigns are not main-
Table 1
Formative research questions and data sources

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<tr>
<th>Research questions</th>
<th>Theoretical application</th>
<th>Prior research</th>
<th>REACT focus groups—types</th>
<th>REACT key informants</th>
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<td><strong>About patient-level forces:</strong></td>
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<td>What is the process by which people experience MI?</td>
<td>Self-regulation</td>
<td>In-depth interviews</td>
<td>MI patients</td>
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<td>Focus groups</td>
<td>Providers</td>
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<td>What is the process by which people seek help for MI?</td>
<td>Social cognitive theory</td>
<td>Surveys</td>
<td>MI patients</td>
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<td>Does coping offer an intervention point?</td>
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<td>All focus groups</td>
<td>All key informants</td>
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<td>Does interpretation of symptoms offer an intervention point?</td>
<td>Social cognitive theory</td>
<td>Self-regulation</td>
<td>Social cognitive theory</td>
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<td>What patient characteristics are associated with delay? (and what should be done about them?)</td>
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<td><strong>About interpersonal community forces:</strong></td>
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<td>How do spouses and bystanders perceive AMI?</td>
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<td>What environmental forces are associated with delay? (and what should be done about them?)</td>
<td>Self-regulation</td>
<td>Epi studies</td>
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<td>Which components of intervention are important to include?</td>
<td>Self-regulation</td>
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<td>Social cognitive theory</td>
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<td>Focus groups</td>
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<td>What message content is important? for which target audiences?</td>
<td>Self-regulation</td>
<td>Focus groups</td>
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<td>Social cognitive theory</td>
<td>Surveys</td>
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<td>How should intervention be adapted to local REACT communities?</td>
<td>Social cognitive theory</td>
<td>Focus groups</td>
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<td>All key informants</td>
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<td><strong>About medical systems forces:</strong></td>
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<tr>
<td>How can medical care settings facilitate REACT goals?</td>
<td>Social cognitive theory</td>
<td>Interventions</td>
<td>All focus groups</td>
<td>All key informants</td>
</tr>
<tr>
<td>How can medical providers encourage short delay time?</td>
<td>Social cognitive theory</td>
<td>Not addressed</td>
<td>All focus groups</td>
<td>All key informants</td>
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tained (Bett, Aroney & Thompson, 1993; O’Rourke et al., 1989). Public education campaigns of six months and longer (Blohm et al., 1992; Eppler, Eisenberg, Schaeffler, Meischke & Larsen, 1994; Gaspoz et al. 1993; Rustige et al., 1990) have tended to produce fewer mixed results, more durable results, and larger effect sizes than those of shorter duration (Ho et al., 1989; Moses et al., 1991). Promising results were obtained in the only study employing patient education for men and women in specific medical practices, (Rowley, Hill, Hampton & Mitchell, 1982), and in the only study that has specially targeted those over 50 and those at high risk of AMI (Eppler et al., 1994).

Message content was a special concern for REACT investigators in planning additional qualitative research. Campaigns have generally focused on information concerning symptoms of heart attack, on the importance of seeking help quickly, and on ways to activate the emergency system (e.g., dial 9-1-1). However, the theoretical framework, as well as prior focus group information, led REACT investigators to see a need for other messages addressing barriers and facilitators, as well as local conditions. Focus groups of the general population appeared to favor a message emphasizing the potential cost of ignoring a heart attack, while AMI patient focus groups preferred a message that was specific in the actions required and described several symptoms (Hall & Foushee, 1993). The preliminary focus groups conducted in Minnesota (Hall & Foushee, 1993), as well as Hispanic females in NHLBI marketing research (Porter & Novelli, 1994a, 1994b), favored messages that conveyed urgency of action.

3.2.2. Medical system factors

Specific barriers and facilitators, both real and perceived, were predicted to affect delay in seeking care for AMI. The setting for an intervention affects barriers and facilitators at many levels: through community resources for medical care, through the behaviors and attitudes of medical professionals, and through communities’ capacity to support and enhance the messages. Most of the prior intervention studies were conducted outside the US, making generalizability difficult. Only three took place in this country: two in Seattle (Eppler et al., 1994) and one in rural Illinois (Moses et al., 1991). The REACT communities were chosen with an eye to their variation, because it was felt that this would be most informative about the conditions under which education to reduce delay time would be effective in the US as a whole. However, this variation made it imperative to understand how messages and programs would need to be adapted to local circumstances, within an overall protocol.

Previous studies were conducted in countries with medical care systems very different from that of the US. The REACT planning group realized that even within the US, some critical dimensions of the medical care system differentiated the regions under study. For example, the three northern regions reflected the inroads made by managed care, while the southeast and southwest were less affected. Managed care may affect the amount of time physicians and other professionals have for patient education (Zapka et al., 1998). The emergency care systems were also likely to differ in sophistication if not quality.

The project also anticipated challenges in the process of gaining commitment of medical professionals. A substantial literature on influencing the practice of medical professionals (Agency for Health Care Policy and Research, 1992) and gaining commitment for specific preventive measures (Burns, Cohen, Gritz and Kottke, 1993) helped the project to outline a general approach. However, specific information was very limited about provider behavior with AMI patients. NHLBI’s prior marketing research included nine providers who worked regularly with AMI patients: physicians, nurses, paramedics, and 9-1-1 dispatchers (Porter & Novelli, 1994a, 1994b). Providers said they looked for clues to people’s condition and consulted with third parties, if there was any problem in communicating symptoms. They also believed that financial barriers to care caused in delay in seeking help, although the community and patient focus groups did not corroborate this point.

4. Second iteration: identifying gaps in knowledge

Investigators debated the meaning of the existing information and identified priorities for additional study, within the theoretical framework. Table 1 presents the key questions for planning, the role of prior research and theory, and the areas addressed by new data collection. To identify the best opportunities for intervention, REACT investigators planned additional focus groups and interviews, setting priority on replication, expansion to new questions, and focus on additional populations.

One promising area for intervention involved people’s expectations about symptoms. Gradual onset of AMI symptoms is far more common than the sharp severe and sudden pain that most people expect. Coping processes offered another opportunity. It was possible that patients’ decision to seek care would be accelerated if families, friends and bystanders were quicker to challenge patients’ representation of symptoms and their outcome appraisal of self-treatment. Verifying the importance of specific service delivery and community factors also became a goal: past work had revealed that certain AMI patients were embarrassed to call 9-1-1, believed that seeking medical care...
was bothering health care providers, or were concerned about cost of care and lack of insurance. These expectations were most likely to be affected through an interaction between patient perspectives and outside events: personal experience, stories related by AMI patients concerning their experiences, and providers’ verbal communication. It became critical, therefore, to understand the populations most likely to have these concerns, the reality of those concerns in different communities, and the willingness of medical care providers to address those concerns.

Prior study had not addressed people who were at high risk, but had not yet had an AMI. REACT investigators therefore planned focus groups including people with a history of CHD and those with several CHD risk factors, regarding their perceptions of personal risk, expectations of heart attack symptoms, likelihood of taking specific actions and perceptions of benefits and barriers to taking action. Also, very little was known about how health care providers view the issue of patient delay, nor about their opinions and ideas about how to influence patients’ health care seeking behavior for AMI. Yet, patient education is key for individuals who already have experienced an AMI and are therefore at greater risk of experiencing subsequent events. Additionally, providers may vary in their education of patients who are known to be at high risk of heart attack. Provider beliefs about why people seek help, why they call 9-1-1 or not, patient information needs, and provider roles and responsibilities all became the focus of REACT attention.

5. Third iteration: new data collection

5.1. Patient and community focus groups

REACT investigators conducted 34 focus groups, consisting either of patients or community members. REACT conducted its focus groups based on the protocols suggested by Krueger (1988). Investigators discussed the content areas, developed individual questions and then revised them, taking care to include that core questions common to all ethnic, gender, and age groups. Centers then negotiated the division of labor for conducting focus groups. It was agreed that, to the extent the budget permitted, Centers would replicate focus groups with particular characteristics (e.g., gender, age, prior MI); however, the replication would take place in a different REACT region from the first focus group.

The Centers recruited adults over 30 years old (the target population) through a variety of strategies: through heart attack and CVD/CHD registries; through existing research projects; through local hospitals and primary care settings; and through Southern African American churches. Participants were paid $25 for their time and travel, either directly or through gift certificates. Between April and July 1995, 207 persons participated in focus groups in the states of Alabama, Mississippi, Massachusetts, Minnesota, Texas, and Washington. Participants resided in the same regions as the study communities, but not in the project communities themselves.

In Table 2, the plan for data collection, groups actu-
5.2. Provider interviews and focus groups

Each REACT Field Center conducted key informant interviews with cardiologists \( (N = 11, 91\% \text{ male}) \) and with emergency physicians \( (N = 13, 62\% \text{ male}) \). This method was used rather than focus groups, because it was hypothesized that the practitioners each held unique perspectives that required exploration. Moreover, it is logistically difficult to assemble groups of these specialists, especially in regions where they might be thinly dispersed. Each REACT Field Center also conducted 3 focus groups of providers for a total of 15 groups. Centers conducted five focus groups of primary care physicians \( (N = 26, 73\% \text{ male}) \), five groups of nurses working in inpatient settings \( (N = 36, 92\% \text{ female}) \), and five groups of nurses working in outpatient settings \( (N = 29, 97\% \text{ female}) \). Focus groups were developed and conducted using the same methods and principles as the community and patient focus groups. As in the case of community focus groups, providers resided in the same regions as the study communities, but not in the communities themselves. Investigators recruited respondents through their contacts and professional networks.

The analysis of provider data occurred in stages. Investigators from each Center provided transcripts of the focus groups conducted. They also provided initial summaries (along with original notes) of the key informant interviews of cardiologists and emergency physicians, respectively. Each Center was then assigned to summarize the data on one of the five types of providers. Summarizers first reviewed each Center summary, and each interview or group transcript in its entirety to understand themes emerging from each session and to understand the flow and emphasis that can be lost in a question by question analysis. This “vertical read” helped to identify issues that might be especially important in certain REACT regions. Then REACT investigators analyzed themes that emerged across summaries and transcripts in question by question fashion (a “horizontal” read). A preliminary report was sent from the primary analyst to a secondary reader at another REACT Field Center, along with the data. The secondary reader read the transcripts, reviewed the preliminary report and commented on any errors of commission and omission.

6. How well did react formative research meet its objectives?

6.1. Assessment: adequacy of new data collection

REACT’s new data collection relied on key informant interviews and on focus groups. If they had stood alone (without the theoretical framework and without preexisting empirical information), neither method would have been satisfactory to plan REACT. In the context of other information, however, they
become more persuasive: the principle of triangulation. They filled specific information gaps, corroborated findings, and verified the importance of certain intervention components. They assisted the prospective task of generalizing about existing interventions and potential causal relationships. Only examples of each can be offered here. Detailed findings are fully described in Finnegan et al. (1998), and Zapka et al. (1999).

While the advantages of these methods are considerable, there are also limitations. Focus groups cannot be fully representative of population subgroups. Usually, they are not composed randomly from the population; participants may often be more involved in the research issue of interest than most members of the population subgroup. Also, the group members affect each other; their statements are conditioned by the group. Generalizing from focus groups to the population therefore must be tentative. In addition, the analysis and interpretation of key informant interviews and focus groups, while systematic, may be variable among investigators or idiosyncratic to their interests and beliefs; hence the role of multiple syntheses by a variety of REACT investigators.

Focus groups were appropriate at this stage of planning because they highlighted key intervention issues and problems. As an audience-centered qualitative data gathering method, they permitted in-depth discussion of social and behavioral processes. The focus groups sharpened the goals of REACT messages in several ways: to change expectations about what a heart attack would feel like; to make specific appeals to family members; to increase awareness that women get heart attacks; and to better define what is meant by a plan for heart attack (“like a fire drill”).

Key informant interviews contributed in much the same way. Cardiologists and emergency physicians are in a unique position to know about trends and forces at work in delay time for AMI. There were no published or informal reports of systematic interviews with these groups. Therefore, the stage of research development justified open-ended interviewing of a limited number of informants. The objective was to explore the diversity of beliefs about several key areas of inquiry. Informants confirmed and expanded upon points critical for REACT intervention: improvements in the description of symptoms; encouragement to seek care regardless of hesitations and doubts; importance of the family members.

6.2. Assessment: filling information gaps

The formative research process was successful in filling some critical gaps. While these are addressed in Finnegan et al. (1998) and Zapka et al. (1994), some examples make the point. Researchers learned about:

- the expectations of people at high risk of AMI and their degree of preparation for the possible event;
- various provider experiences, beliefs and commitment to encouraging early intervention;
- how various ethnic groups interpreted symptoms and responded to educational messages.

In addition, the REACT team discovered that certain concerns identified in the literature held for some subgroups and not others. For example, professionals serving low-SES groups perceived that their patients used 9-1-1 with little embarrassment, while those serving higher-SES groups believed that embarrassment was a major obstacle. Focus groups tended to confirm this pattern.

6.3. Assessment: triangulating about findings

The quality of REACT triangulation differs by type (Denzin, 1978). Regarding triangulation on data sources (types of people, settings, time periods, regions), REACT formative research did fairly well within the limitations of budget and the use of convenience samples. Planning incorporated a variety of insider and outsider perspectives. Five different types of providers generally corroborated each other regarding beliefs, practices, and factors at work in AMI delay (Zapka et al., 1999). Corroboration on some points also typified patients and families across regions, gender and ethnicity (Finnegan et al., 1998). However, data sources were weaker in other respects. In planning focus groups of high-risk individuals, we placed priority on replication by intervention study site and by gender (e.g., four groups of women at risk), and did not replicate across ethnicity (though minorities were represented in these groups). Given the budget, as well as the limited information available about those at risk of AMI, the decision seems warranted. Our ability to triangulate data sources is most limited in the case of Hispanics. We were able to conduct only four focus groups of Hispanics, and only replicated focus groups of Hispanic men with previous AMI. For African Americans, in contrast, prior research illuminated many important points, and we replicated findings about several subgroups.

Triangulation across methods is also adequate, in that previous findings derived from surveys and intervention studies were often corroborated with focus group and key informant information. However, within the second phase of formative research, REACT relied on focus group information almost exclusively. It is possible that some target groups might have answered differently had they been interviewed one-on-one; or the cardiologists and emergency physicians might have answered differently had they been part of a group of colleagues who might challenge their statements (Krueger, 1988). In other words,
an interaction of two sources of bias, data sources and methods, may limit triangulation.

Triangulation across researchers is viewed as a particular strength of REACT formative research. Five different sets of investigators with somewhat disparate interests recruited participants, collected data, and then shared the findings. Several different analysts interpreted various portions of the data and defended their final reports against challenge by the REACT investigators as a group. Finally, we achieved a degree of triangulation based on theory. Certain findings, especially in the patient focus groups, fit the combined framework, but would not really fit either Social Cognitive Theory or Self-Regulation Theory taken alone, quite as well.

6.4. Assessment: reducing uncertainty about the REACT intervention

Existing interventions looked promising; but the REACT information was prospective; to the extent possible, planned intervention needed insights about likely effectiveness at specific intervention sites. In reality, this is a generalization issue. Cronbach (1982) redefined external validity when he observed that for practitioners, generalization is always prospective and always specific: “will my revised version of the intervention protocol work in my setting with my population?”. This concept of external validity is quite different from that of the behavior theorist who wants to generalize about classes of interventions, settings, and populations (Cook and Campbell, 1979).

According to Cronbach (1982), several sources of variation affect external validity (and uncertainty about the new interventions): populations, which are rarely identical to those of past studies; settings, which may affect implementation or interact with treatments to affect outcomes; the interventions themselves, which are seldom if ever exactly replicated; and the methods of observation, including experimental or quasi-experimental design and outcome measures. Formative research can address the first three sources of variation. Cronbach also recommends that, when a population cannot be sampled, it makes sense to study modal or typical situations, as well as those variations that are known to be important. For example, REACT formative research did not sample from the US population at large—that would have been incompatible with rich and detailed description from a select group of respondents, to gain insights for implementation. Instead, participants were recruited insofar as possible from modal situations (e.g., those known to be at high risk of heart attack) and from specific ethnic subgroups in similar geographic areas.

REACT formative research is satisfactory to answer the prospective generalization question, because it was planned specifically with the study sites in mind. It is less satisfactory for generalizing about large classes of intervention, populations and settings. It is probably the case that one can generalize to similar communities or medical care settings, within some boundaries. For example, it is fairly clear that managed care limits provider time, and therefore the ability to provide patient education. Also, the information about white AMI patients may be suitable for this larger purpose. However, given the number of focus groups available, it is more difficult to generalize about African Americans, and particularly, Hispanics. Southern and Southwestern Centers conducted these focus groups because their planned study sites had large populations of these minority groups. Therefore, these groups were studied within the Southern and Southwestern regions, exclusively. This study cannot provide information about northern African Americans or about northern Hispanics, whose national origins may in any case differ from those of REACT communities. For different reasons, we cannot generalize about medical care providers, since our respondents were recruited through REACT investigator professional networks. Such providers may be very different from those outside our networks.

7. Summary

Formative research was employed in the REACT project to decrease uncertainty about effective strategies to reduce delay in seeking help for AMI symptoms. A theoretical framework focused investigator discussions of the role that focus groups and key informant interviews would play. An inventory of available studies revealed several gaps in knowledge, thus sharpening the priority given to certain interview questions over others. The formative research served its primary purpose, to assist in planning the REACT intervention. It also contributed to a better understanding of how communities, medical care settings, and population characteristics can affect the outcomes of educational efforts to reduce AMI delay.

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