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Getting clinical trial results into practice: design, implementation, and process evaluation of the ALLHAT Dissemination Project

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Abstract

Background—Conventional dissemination of clinical trial results has inconsistent impact on physician practices. A more comprehensive plan to influence determinants of prescribing practices is warranted.

Purpose—To report the response from the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial to the National Heart, Lung, and Blood Institute's requirement for dissemination and evaluation of trials with potential immediate public health applicability.

Methods—ALLHAT's dissemination plan had two-components: 1) a traditional approach of media coverage, scientific presentation and publication; and 2) a theory-based approach targeting determinants of clinician behavior. Strategies included (1) academic detailing, in which physicians approach colleagues regarding blood pressure management, (2) direct patient messages to stimulate communication with physicians regarding blood pressure control, (3) approaches to formulary systems to use educational and economic incentives for evidence-based prescription, and (4) direct professional organization appeals to clinicians.

Results—One hundred and forty-seven Investigator Educators reported 1698 presentations to 18,524 clinicians in 41 states and the District of Columbia. The pre- and post-test responses of 1709 clinicians in the face-to-face meetings indicated significant changes in expectations for positive patient outcomes and intention to prescribe diuretics. Information was mailed to 55 individuals representing 20 professional organizations and to eight formulary systems. Direct-to-patient messages were provided to 14 sites that host patient newsletters and Web sites such as health plans and insurance companies, 62 print mass media outlets, and 12 broadcast media sites.

Limitations—It was not within the scope of the project to conduct a randomized trial of the impact of the dissemination. However, impact evaluation using quasi-experimental designs is ongoing.

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Conclusions—A large multi-method dissemination of clinical trial results is feasible. Planning for dissemination efforts, including evaluation research, should be considered as a part of the funding and design of the clinical trial and should begin early in trial planning.

Keywords

dissemination; translation research; physician behavior change; education; impact; implementation

BACKGROUND

Translational science includes both an interface between basic science (bench) and clinical medicine (bedside) and one between clinical medicine and ensuring that treatments based on evidence actually reach the appropriate patients and have an impact on the public's health (community) [1]. Results of clinical trials that objectively evaluate the safety and efficacy of medications and other interventions are the cornerstone of evidence-based practice. However, the impact on medical practice of these clinical trials may be less than optimal [2,3]. This issue may be particularly important for older interventions that lack corporate promotion, but are shown to be the best choices for therapy. Traditional dissemination of clinical trial results, especially presentation at scientific conferences and publication in scientific journals, may be inadequate to stimulate practice changes [4,1–14].

One effort to disseminate antihypertensive trial results was the National High Blood Pressure Education Program (NHBEP) of the National Heart, Lung, and Blood Institute (NHLBI). In 1971, the NHLBI organized this consortium of 47 professional and voluntary associations to create and maintain an education program to disseminate results from major multi-center clinical trials of antihypertensive treatment conducted since the 1960s, several with Federal sponsorship [15–18]. The NHBEP influenced the relatively steady progress in awareness, treatment and control of hypertension, and likely contributed to the dramatic declines in mortality from cardiovascular diseases [19,20]. Nevertheless, progress in translating clinical research advances into practice has fallen short of Healthy People 2000 [21] blood pressure goals. The NHLBI leadership had increasingly attempted to stimulate and direct innovative methods to accelerate this kind of translation, especially in the period immediately following additional major trials [22–24] and funded research in this area [25,26].

A recent clinical trial with major implications for public health was the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). ALLHAT was a randomized, double-blind, practice-based, multi-center clinical trial, designed to determine whether the occurrence of fatal coronary heart disease or nonfatal myocardial infarction is lower for high-risk hypertensive patients treated with a calcium channel blocker (CCB) (represented by amlodipine), an angiotensin converting enzyme (ACE) inhibitor (represented by lisinopril), or an alpha blocker (represented by doxazosin), each compared with a diuretic (represented by chlorthalidone) [27]. Secondary endpoints included stroke, heart failure (HF), all-cause mortality and renal disease. To evaluate differences in effects of the four treatments on cardiovascular and renal outcomes, ALLHAT was designed with a large sample size (40,000 participants) and long follow-up (up to 8 years). The doxazosin arm was discontinued in February 2000 in light of a significantly increased occurrence of cardiovascular disease, especially HF and because of futility for finding a difference in the primary endpoint (part of the a priori stopping guidelines for ALLHAT), when compared with the chlorthalidone arm [28]. The final results for the other two comparisons, reported in December 2002 [29], showed no differences for the primary endpoint or all-cause mortality. However, the trial showed that first-step treatment based on an inexpensive thiazide-type diuretic was superior to treatment based on other widely prescribed drug classes in preventing one or more major forms of CVD,

and recommended that, thiazide-type diuretics should be preferred for first-step antihypertensive drug therapy [29,30].

After the publication of ALLHAT results, there was some increase in prescriptions of thiazide-type diuretics at hypertension visits. However, the lack of a continued increase in thiazide prescriptions over the next year provided further evidence of the need for a more active dissemination plan as had been discussed by investigators at the time of the publication of the ALLHAT main results [31,32].

The purpose of this report is to describe the development, implementation and process (implementation) evaluation of a multifaceted, theory-informed intervention to disseminate the results of the ALLHAT trial and the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 7) guidelines beyond the standard publication and presentation of trial results. In addition to this design paper, the longer-term dissemination of ALLHAT was evaluated in two studies, one analyzing national prescription trends and another in the context of dissemination of hypertension guidelines in the Veterans Administration (VA) (In preparation).

METHODS

Intervention Development

Planning Framework and Core Dissemination Messages—We used the Intervention Mapping (IM) [33,34] framework to plan the ALLHAT/JNC 7 Dissemination Project, “Improving Blood Pressure Treatment in the Community: A Joint Project of the National High Blood Pressure Education Program and Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial Collaborative Research Group”. IM, a systematic process for health promotion program planning, has been used to guide development of numerous programs, several of which included change strategies for health care providers [35–37].

We began by identifying health care providers who manage hypertension as the priority population for practice behavior change and set an objective of reaching approximately 30,000 health care providers in the U.S. This is about 15% of the approximately 180,000 practicing internists and family practitioners in the U.S. [38]. According to Berwick (2003) [39,40], the tipping point for dissemination to occur is for 15% to 20% of a group to adopt the innovation. Although the priority population for behavior change was the health care providers, we also targeted change in their environment and the intervention was implemented both directly to providers and indirectly through messages to patients.

Dissemination Messages—The main dissemination messages articulated the treatment goals and expectations for hypertensive patients and were based on both the results of ALLHAT and the recommendations of the JNC7 report. The messages were reviewed and endorsed by the NHBEP to acquire broad-based consensus from among organizations that represent health care providers who treat hypertension [41]. They were the following:

1. The blood pressure (BP) goal for most patients with hypertension is <140/90 mm Hg.
2. Most patients diagnosed with hypertension should experience better BP control after adopting lifestyle modifications.
3. Most patients diagnosed with Stage 1 hypertension systolic blood pressure (SBP) 140–159 or diastolic blood pressure (DBP) 90–99 mm Hg should experience better BP control and better long term CVD risk while taking a thiazide-type diuretic.

4. Most patients with Stage 2 hypertension (SBP ≥ 160 or DBP ≥ 100 mm Hg) should experience better BP control and better long term CVD risk when taking a multi-drug regimen that includes a thiazide-type diuretic.
5. Most patients with uncontrolled hypertension should experience better BP control and better long term CVD risk when a thiazide-type diuretic is added to the patient's treatment regimen.

Although these were the agreed upon treatment recommendations, the messages were elaborated by combining the desired behavior goals with factors that influence health care provider behavior.

Theoretical Framework and Elaboration of Core Messages—Working from a Social Cognitive Theory (SCT) framework [39,40], we developed planning matrices (Tables 1 and 2) that combined detailed descriptions of the targeted health care provider behavioral change as well as expectations for communication by patients and other aspects of the providers' environments. We then worked from the matrices to develop plans for program delivery. We chose Social Cognitive Theory because it focuses on both individual cognitive influences on behavior and on social environmental influences. SCT provides a framework that incorporates categories of barriers and facilitators of the adoption of evidence-based practice changes [42, 43]. For example, Cabana and colleagues describe approximately 50 barriers and facilitators in categories of knowledge, attitudes, external barriers, guideline factors and environmental factors. SCT explicates similar categories of factors including cognitive and affective factors such as awareness of, or familiarity with guidelines, behavioral capability and skills (knowing what to do and how to do it), self-efficacy and outcome expectations for practice change. Social influences include patient behaviors such as adherence and follow-up for re-evaluation, commercial marketing, and presence of guidelines and standards of care. Barriers to practice change may also include the lack of opportunity for reinforcement, which most naturally should come from improvements in patient BP control, but may be lacking when patients are non-adherent, are not consistently followed, or the clinician lacks skills or resources to treat resistant hypertension. We developed matrices for both the priority population (providers) (Table 1) and the agents in the environment who provide the external influences on health care provider behavior (Table 2). The tables explain what health care providers should do (behavioral performance objectives in the left column) and hypothesized barriers and facilitators including external influences such as pharmaceutical company marketing (column heads). The cells of the matrices comprise change objectives, the immediate targets of the behavior change intervention and the basis of the elaborated messages.

Intervention Plan—A theory-based intervention method is a defined process by which theory postulates how behavior change may occur in an individual, a small group, or other social structure, whereas a strategy is a way of organizing and delivering the intervention methods [33]. An example of a theory-based method is modeling [39], which is frequently used to facilitate behavior change. In this step, we proposed a multi-level intervention to deliver change methods and practical strategies intended to influence the objectives in each matrix. The strategies involved direct and indirect approaches. The direct approach intended to influence physicians through academic detailing and their professional societies. The indirect approach intended to influence physicians through their patients and drug formulary systems.

The investigator educator (IE) approach was the primary strategy to achieve the objectives in the Table 1 matrix. It is based on academic detailing [44,45]. The plan was to reach providers using 180 investigator educators—mostly physicians who had participated in the ALLHAT trial as clinical investigators. Regional coordinators with clinical trial experience, including at least several years in ALLHAT, interviewed prospective educators to discuss their typical professional networks and the potential to reach providers beyond these routine contacts. They

also considered the ability of the investigator to recruit patients during the clinical trial, their success in retention and adherence during the trial, and their potential as persuasive behavior change educators. The project team attempted to recruit educators broadly from all regions of the U.S.

The change methods to be delivered through this personal contact strategy were 1. persuasion by presenting two-sided arguments and eliciting reservations of participants, 2. role modeling from a respected peer or opinion leader, and 3. provision of information and cues to action through materials given to providers at presentations. Investigator educators were trained in day-long face-to-face workshops to present the JNC 7 as the framework for BP control, describe the results of the ALLHAT trial, make the results relevant to personal practice, model the use of the guidelines and results, actively encourage use and stimulate questions and discussion. In the training, the educators were also asked to begin to plan potential venues for these presentations and discussions. The goal for the educators was for each one to make 12 presentations to small groups over 12 months and reach an estimated 156 providers (per IE) who prescribe drugs for hypertension. They were asked to make a special effort to reach opinion leaders, clinicians who influence the opinions of colleagues in their geographic areas. We explained that opinion leaders are physicians who are respected in the local community, trusted by their peers, and likely to be persuasive role models for colleagues regarding clinical practice; however, we did not provide a systematic process for the IEs to use to identify opinion leaders such as a survey or network analysis [46]. The proposed settings were medical practice staff meetings, hospital staff meetings, residency programs, local medical societies and other venues as identified by the educator, regional coordinator or central project coordinator. Investigator educators were compensated with \$400 per presentation to cover purchase of a light meal or snack for the participants at the session, travel to the venue and an honorarium. Prior to full implementation, we conducted a pilot phase with 24 investigator educators (IEs) for 6 months to test feasibility of the approach.

The IEs were to leave cues to action left with participants including a newsletter with examples of changes in blood pressure treatment (role model stories), pocket cards summarizing main blood pressure control messages and skills for encouraging lifestyle changes, JNC 7 reference cards, the JNC 7 Express report [47], reprints of two ALLHAT publications, tips for accurate BP measurement, and a copy of the Dietary Approaches to Stop Hypertension (DASH) diet. Participants were also offered exam room posters to encourage patients to talk with their doctors, and a small “prescription pad” to record recommendations for patient BP goals and plans for lifestyle changes.

The regional coordinators contacted educators periodically to assess progress, encourage contacts and help with finding venues. The ALLHAT Clinical Trials Center provided training, materials, and support for the coordinators and for the IEs. Brief reports on each completed venue were collected, data entered, and analyzed to provide ongoing process evaluation for this component of the dissemination effort.

A secondary strategy for reaching health care providers was through their professional associations. We solicited participation from 20 associations selected from members of the NHBPEP coordinating committee with a letter tailored to the focus of the association. We asked them to communicate project messages to their membership and we provided a sample letter, a model article for the association newsletter and reprints of the primary ALLHAT publications.

The interventions related to Table 2 were indirect influences on physician behavior. We sought to stimulate the ten pharmacy benefit systems that managed approximately 80% of prescription-covered lives to initiate education and incentives for prescribing according to JNC

7 guidelines. We provided formulary managers with letters including the project core messages, a summary of key ALLHAT results and JNC 7 recommendations, a statement of the importance of the ALLHAT results to formulary management, cost information and ALLHAT articles.

We also provided press kits to IEs to use with community media and stimulated the issuance of an NHLBI press release to stimulate community interest in the dissemination project and to highlight the commitment of local physicians to evidence-based treatment of hypertension. In addition we contacted both print and broadcast media outlets to assess their interest in running items on the project and to provide sample stories.

Process Evaluation Measures

We designed a protocol for process evaluation to assess the “reach” and “dose” of the implementation of the dissemination interventions. The University of Texas Institutional Review Board reviewed and approved the protocol under the exempt category. Reach is the proportion of the intended priority population who participated in the intervention [48]. We defined reach as the number of health care providers (clinicians) who attended face-to-face sessions with investigator educators. Based on IEs completing questionnaires, we recorded the number of IEs, the number of presentations, and characteristics of the presentations including geographic location and audience size. For each IE reporting over 15 venues as of October 2006 (8 IEs), we selected 20% of the reports to validate by calling participants or venue staff. These counts included both the pilot and full-scale phases of the strategy.

Another assessment was the dose. The “dose delivered” was the amount of intervention that was delivered or provided to the intended audience [49]. For dose-delivered calculations, the denominator was the population over 50 years of age in the metropolitan statistical areas (MSA) where the presentations occurred. We calculated the median ratio for IE presentations per MSA 10,000 population over 50 years. We also reported mean number of clinician-attendees per MSA 10,000 population over 50 years.

We assessed response of attending clinicians with pre-post measurement. Because we had targeted behavior change rather than strictly knowledge, we measured cognitive factors that may be related to behavior (influenced by knowledge) including intentions, self-efficacy and expectations of benefit from changing prescribing practices to be more congruent with the program messages. These pre-post questionnaires were distributed at the IEs’ discretion, which was dependent on the time allotted for the presentation, arrangements with the venue, and whether they had institutional review board (IRB) approval.

For the interventions targeted at patients, professional associations, and formulary managers, the quantitative process assessments for reach and dose were beyond the scope of the dissemination program except for description statistics of the number of contacts made to formulary managers, print and broadcast media and professional associations.

RESULTS

Reach and Dose

IE presentations are enumerated by regions in Table 3. The regional means are calculated from presentations in each MSA in the region. (The Table 3 detail by MSA is available from the corresponding author). The 147 educators (the number recruited from the goal of 180) reported a total of 1698 presentations to more than 18,500 participants in combined pilot and full implementation in 41 states and the District of Columbia between September 2004 and March 2007. Average attendance was 10.9. The median ratio of presentations to MSA population was 2.43 per 10,000 populations over 50 years of age (a denominator of older adults at increased risk of hypertension). The validation involved attempts to contact participants or staff at 29 of

the venues for 8 Investigator Educators; 21 were successfully contacted, and 19 presentations were verified (90%).

We mailed information to 55 individuals representing 20 professional organizations and to eight formulary systems that covered more than 80% of U.S. prescriptions as of July, 2005. Follow up mailings and phone calls were made to 34 individuals.

For the indirect approach to health care providers through patients, we contacted 14 sites that host patient newsletters and Web sites such as health plans and insurance companies, 62 print mass media outlets, and 12 broadcast media sites. In addition, an NHLBI press release highlighting the dissemination program and the importance of diuretic prescription was sent to the extensive NHLBI media list.

Participant Response

Questionnaires were completed by a convenience sample of 1709 respondents for the pre-test and 1617 respondents for the post-test. The response of the participants in the face-to-face meetings was positive. As shown in Table 4, the participants demonstrated statistically significant differences in mean scores between pre-test and post-test including their expectations for positive patient outcomes and their intention to prescribe diuretics.

DISCUSSION

Practice Change -- What Works?

Studies have yielded divergent results on how much and how rapidly clinical trial results have exerted a significant impact on physician prescribing. For example, changes in post-myocardial infarction treatment [13,50] and warfarin use in atrial fibrillation [51] have been attributed to publication of multiple clinical trials and have taken many years to be incorporated into clinical practice. In contrast, increases in statin prescribing preceded the publication of clinical trials, mostly sponsored by the industry, that demonstrated the specific benefit of statins on hard outcomes, and these trials had little effect on preexisting trends [52]. In an early study, Fineberg reviewed 28 studies on the effects of specific clinical trials on 19 practices and found only two instances where the clinical trial clearly influenced practice [53] and Kudesia and Chaturvedi (2002) [54] found little practical impact of negative clinical trials regarding intravenous heparin use in acute ischemic stroke. Moreover, a lack of influence of a randomized clinical trial even on its participating investigators has been suggested [55,56]. As mentioned above, the publication of the results of ALLHAT, shortly followed by the JNC 7 hypertension guidelines, were associated with a substantial initial increase in diuretic prescriptions, but the change apparently leveled out quickly [31] suggesting the need for intervention beyond the publication of trial results and their incorporation into newly published guidelines. A recent study showed some sustained increase in diuretic use in a large managed care organization, but suggested continuing opportunity to increase adherence to the JNC7 [57].

Intervention beyond the publication of trial results often has been limited to standard continuing medical education (CME), which has been recently described in two systematic reviews as having some impact on practice behavior [58,59]. However, effect sizes were small to moderate and the quality of intervention descriptions did not allow differentiations to be made between types of education except that interactive sessions are better than didactic sessions alone [58] and live media was more effective than print, multimedia more effective than single media and repeated exposure more effective than single exposure [59]. Other authors recommend that interventions should be more intensive than CME and suggest multilevel interventions (combinations of knowledge and skill enhancement, attitude change, behavioral feedback, patient specific guidance, and cues or reminders) may be necessary to improve physician and

patient adherence to guidelines and best medical practice [14,45,60–65]. To promote clinician adoption of recommended practices, efforts in addition to scientific publication should take into account a range of influences such as patient preferences, drug promotion, recommendations from clinical colleagues and guidelines, and features of particular pharmaceuticals, including their price and generic status, on clinician adoption of recommended practices [6–10]. Interventions using multiple methods including audit and feedback, detailing by local opinion leaders, patient components and community- and practice-based methods to target this range of influences have shown greater effectiveness than traditional continuing medical education [4,10–14].

In addition, a number of researchers have called attention to the need for theory- and evidence-based interventions [11,66,67]. For example, Davis and colleagues [11] have focused on evidence for multiple levels of causation in provider adoption of practice guidelines and have suggested that interventions focus on behavior through influencing factors at the provider, patient, practice, profession, and sociopolitical levels.

The intervention described in this report consisted primarily of persuasive communication regarding change in prescribing practices presented by colleagues in the community. We reached 18,524 care providers with face-to-face persuasive messages. Our goal was to focus on behavior change rather than focusing exclusively on improving physician knowledge. The IE strategy had characteristics of effective academic detailing including role modeling by peers, visits to individuals or practice groups and careful delineation of the target behavior [11,61]. The interactive sessions were based on Social Cognitive Theory and sought to influence behavioral capability and skills, attitudes toward ALLHAT and diuretic use, outcome expectations about drug effects and patient acceptance, self-efficacy for prescribing and cues, and reinforcement from patients and formularies in addition to improving knowledge. The intervention was designed to be more intensive than usual continuing medical education, but, it did not include individualized efforts such as initiation of practice- or network-based performance standards or audit and behavioral feedback strategies [68–70]. These more individualized strategies may be more powerful in producing behavior change but their implementation would have required individualized approaches to practices and practice systems, thus sacrificing the national reach of this project due to limited resources.

The intervention was intended to be multi-faceted and multi-level by stimulating communications to providers through professional societies, formularies and patients. However, we have little evidence that the intended communications occurred. Some media outlets, professional associations and formulary managers responded to their constituencies regarding BP control closer to the time of the JNC 7 and ALLHAT results release.

The intervention through formularies may have encountered additional barriers that were not measured in this study. When the ALLHAT Dissemination Project started, generic thiazide-type diuretics were already available as preferred antihypertensive drugs on most formularies. There was little opportunity for an intervention to increase the presence of diuretics on formularies. In addition to formularies, pharmacy benefit managers may use step-therapy programs to influence physician prescribing behavior. Step-therapy programs that were compatible with JNC 7 guidelines were extant before the onset of the ALLHAT Dissemination Project [71]. Pharmacy benefit managers may also influence prescribing behavior indirectly through drug co-payments charged to patients to change demand for and adherence to drugs [72,73]. When the dissemination project started, generic thiazide-type diuretics were already available to patients at the lowest tier for co-payment. The ALLHAT Dissemination Project did not have the capacity to change co-payment or step-therapy programs because they are governed by contracts between the pharmacy benefits managers and their clients who are employers, insurers, managed care organizations, and government agencies.

Limitations

The cost of the dissemination project, including the evaluation studies, was \$3.7 million, approximately 4% of the trial budget and a modest expenditure in the context of the annual cost of hypertension, estimated to have been 66.7 billion in 2007 [74,75]. It was conceived as an educational effort with an evaluation component rather than a research study. The evaluation plan included the implementation process questions reported in this paper. It was not within the scope of this implementation project to conduct a trial of the impact and outcomes of the dissemination. The assessment of change in physician intentions, expectations, and self-efficacy was conducted only on a convenience sample. No generalization to the full group of physicians reached can be made. However, we are conducting a comparison study of national prescribing trends between MSAs with varying intensities of dissemination activities (in preparation), and a report of a similar comparative study in the VA system (in preparation). The project would have been very resource intensive to carry out as a controlled trial on a wide scale, and trade-offs were made in evaluation rigor to achieve wide reach. Trial planners might consider both broad dissemination efforts and smaller dissemination sub-studies planned prior to the publication of trial results.

Even though the dissemination intervention targeted behavior and the barriers and facilitators of practice change, the project did not conduct a barrier assessment prior to developing the intervention, but instead relied on literature review and a theoretical framework to delineate barriers and facilitators to practice change. Furthermore, methods delivered did not include systems change or attempts to provide clinicians with practice data (audit and feedback). These strategies might have been indirectly included, had we prepared the IE's to teach how to implement audit and feedback and organizational change in the practices reached. However, we conceived of these approaches to require a more hands-on, individualized, resource-intensive interaction with providers and their practices and considered our intended reach and available budget to prohibit these strategies.

The intervention also did not include a sustainability component. Although the evidence is conflicting, practice change of the type targeted in this effort can be self-sustaining based on reinforcement from patient response and blood pressure control. For example, in acute stroke treatment, rates of therapy continued to increase after the intervention [39]. However, we acknowledge that acute stroke treatment change might be different than sustaining behavior change that is frequently challenged by outside influence such as drug marketing.

Lessons Learned

Outside Influences—The media can have a limited to dramatic effect on how the results of a study become known and interpreted. Articles about ALLHAT appeared in many major newspapers initially and less frequently as time progressed. The ALLHAT leadership made efforts to ensure that the study's findings and our dissemination efforts were presented fairly.

It is possible that limited dissemination efforts on the part of clinical trials cannot offset the vested interest and resources pharmaceutical companies bring to bear on the interpretation of a trial [76]. While the ALLHAT leadership was aware of the efforts of pharmaceutical companies to interpret the ALLHAT results in ways favorable to their products, it was not our intention to respond to or challenge marketing material counter to ALLHAT's message at every turn. However, we first countered these efforts in scientific forums [77,78] and by participating in presentations and debates at scientific conferences such as the American Society of Hypertension and the American Heart Association. Later dissemination efforts countered the efforts more directly within our academic detailing program albeit with comparatively limited resources.

Dissemination Partners—Another lesson learned regards considerations of the “who” in dissemination planning. Who might be available, effective and willing, at both the individual and organizational levels, to diffuse trial results? Glasgow and colleagues (2004) [48] suggest the need for dissemination planning early in the planning of the original trial so that partners who could participate in the dissemination have a stake in the trial from the beginning. These partners might be different from the clinical and other researchers who are necessary for the conduct of the research. In ALLHAT there was consideration of dissemination later in the trial, which is a typical scenario. However it might be questioned whether funders would be willing to invest in this early development of dissemination partners and strategies when trial results are unknown.

Initial dissemination training activities occurred at the final investigator’s meeting of the trial and focused on scientific presentation and media approaches rather than behavior change. In addition, the National High Blood Pressure Education Program was in place at the NHLBI its staff and principal advisors worked with the dissemination project to develop the core messages. When it became clear that further dissemination efforts might be needed to maximize the public health benefit of ALLHAT, the project was fortunate to have a large national network of trial investigators who could be recruited for dissemination activities. However, the question should be asked whether the network was the optimal one for dissemination. IEs in this dissemination had some problems seeking venues. Many were uncomfortable seeking invitations to make a persuasive presentation; they were used to being approached to speak rather than asking for invitations. The trial network members may not have had optimal professional reach or comfort with the tasks of dissemination.

Possible alternative networks might have included large professional associations that are routinely involved in disseminating practice information and guidelines. Also, public health networks should be considered for disseminating results from trials that have potential for widespread impact. For example, the Cardiovascular Health Council approached the dissemination project to use its network of state public health entities and its ties to both the NIH and CDC to provide valuable linkages to state high blood pressure initiatives. These types of public health networks could have been valuable partners from the beginning of the project. Another concern in the recruitment of dissemination partners is the optimal role model for the implementation of persuasive messages aimed at practice change. Theoretically, credible role models would be similar in practice characteristic and perhaps other attributes to the target practitioners [39]. At the same time, they would have characteristics of high status opinion leaders [79]. Some of the IEs for this project were academic physicians while others were community practitioners. Many of them may be opinion leaders in their communities, and they were encouraged to make presentations to other opinion leaders; however, no attempt was made to assess this type of characteristic in either presenters or participants.

Planning and Lead Time for Strategies—As we have discussed, one suggestion is to recruit dissemination partners early in the trial or even in the trial planning. Another issue is that strategies required longer implementation times than expected. For example, venues approached by IEs often required scheduling six months to a year in advance.

We tried to reach patients by interesting the media in stories for their audiences. This approach may have been more successful on a local level if we had prepared IEs to contact local media as a more central part of their role. Also, media outlets may have been more interested in the dissemination efforts if they had occurred closer to the publication of the ALLHAT results and the release of JNC 7 so that they were seen as newsworthy.

In conclusion, a large multi-method dissemination of clinical trial results is feasible. Woolf (2008) defines two types of translation research activities: the first is the “bench to bedside”

process to use knowledge from basic science endeavors to produce therapeutic modalities for patients while the second type is to ensure that new treatments reach priority populations and are implemented correctly [80]. In the U.S., until recently, focus on translation often underemphasized the second, or T2, activities of which the dissemination of the ALLHAT research results is an example. The work presented in this report suggests that planning for such T2 efforts, including evaluation research, should be seriously considered as a part of the funding and design of the clinical trial itself and should begin early in the trial planning process when possible.

Abbreviations

ACE	angiotensin-converting enzyme
ALLHAT	Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack
BP	blood pressure
CCB	calcium channel blocker
CDC	Centers for Disease Control and Prevention
CME	continuing medical education
CVD	cardiovascular disease
DASH	Dietary Approaches to Stop Hypertension
HF	heart failure
IE	investigator educator
IM	intervention mapping
IRB	Institutional Review Board
JNC7	Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure
MSA	Metropolitan Statistical Area
NHBPEP	National High Blood Pressure Education Program
NHLBI	National Heart, Lung, and Blood Institute
NIH	National Institutes of Health
VA	Department of Veterans Affairs

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Table 1

Intervention Planning Matrix for Provider Behavior

Performance Objectives	Awareness and Behavioral Capability	Skills and Self-Efficacy	Outcome Expectations	Pharmaceutical Marketing Influence	Perception of Social Norms and Standards of Care
1. Prescribe diuretic as first treatment (Stage 1 HTN)	<ul style="list-style-type: none"> Recognize the JNC 7 guideline to start with a diuretic for SBP 140–159 or DBP 90–99 mmHg Describe the results and conclusions of the ALLHAT study Recognize that patients with compelling indications need other or multiple drugs Describe ALLHAT as the largest head-to-head comparison relevant to Stage 1 HTN Recognize that normal blood pressure is <120 and <80 mm Hg 	<ul style="list-style-type: none"> Express confidence in prescribing according to JNC7 guidelines 	<ul style="list-style-type: none"> Expect that patients will have better BP control when treated with diuretic Expect better long-term CVD risk, especially for heart failure, with diuretic treatment Expect simplified first line treatment decisions when consistently prescribing diuretics Expect better adherence related to cost when prescribing diuretics 	<ul style="list-style-type: none"> Compare diuretics to other drugs regarding CVD outcomes and price Recognize messages that lobby against diuretic without scientific basis Reflect critically on origin of personal HTN drug preferences and biases 	<ul style="list-style-type: none"> Forecast that many other clinicians prescribe diuretics as first treatment Describe JNC7 as recommending diuretics as standard of practice for first treatment of Stage 1 HTN Expect that the monitoring required with diuretic is worked into practice routines by other physicians
2. Prescribe a 2-drug combination for Stage 2 HTN (Stage 2 HTN)	<ul style="list-style-type: none"> Discuss JNC 7 guidelines, ALLHAT conclusions, and dosing for a 2-drug combination usually including diuretic for patients with SBP $\geq$ 160 or DBP $\geq$ 100 mmHg Recognize that patients with compelling indications need other or multiple drugs 	<ul style="list-style-type: none"> Express confidence in prescribing for Stage 2 hypertension according to the JNC7 guidelines 	<ul style="list-style-type: none"> Expect that prescribing diuretics will enable Stage 2 HTN patients to have better BP control Expect that prescribing a diuretic will enable Stage 2 HTN patients to have better long term CVD risk 	<ul style="list-style-type: none"> Describe proportion of patient income represented by each regimen 	<ul style="list-style-type: none"> Recognize that other clinicians routinely prescribe 2- drug combinations for Stage 2 hypertension

Performance Objectives	Awareness and Behavioral Capability	Skills and Self-Efficacy	Outcome Expectations	Pharmaceutical Marketing Influence	Perception of Social Norms and Standards of Care
3. If patient is treated & uncontrolled, add a diuretic to the medication regimen	<ul style="list-style-type: none"> Describe ALLHAT conclusions, JNC 7 guidelines and dosing related to adding medications Describe that JNC 7 and ALLHAT suggest a diuretic as part of any multi-drug regimen 	<ul style="list-style-type: none"> Express confidence in adding diuretic to a regimen of uncontrolled patients 	<ul style="list-style-type: none"> Expect better BP control and long term CVD health by adding a diuretic when a patient is treated and uncontrolled 	<ul style="list-style-type: none"> Recognize that free samples are only a short term help 	<ul style="list-style-type: none"> Recognize that other clinicians are adding a diuretic to an uncontrolled patient's regimen
4. Discuss with patient benefits and side effects of diuretics	<ul style="list-style-type: none"> Describe goals and expectations of better blood pressure control and better long-term CVD health Describe side-effects as manageable 	<p>Express confidence in medication adherence counseling</p>	<ul style="list-style-type: none"> Expect that patient will appreciate discussion of BP control, long term CVD health and cost of drugs Expect that discussion will improve adherence 	<ul style="list-style-type: none"> Recognize that other providers discuss BP control and diuretics with patients 	
5. Recommend that hypertensive patient undergo lifestyle modification	<ul style="list-style-type: none"> Describe contributions of weight reduction, physical activity, moderate consumption of alcohol, and following the DASH eating plan to HTN control 	<ul style="list-style-type: none"> Express confidence in ability to deliver motivational messages 	<ul style="list-style-type: none"> Expect that brief clinician counseling can help patients commit to behavioral change 		<ul style="list-style-type: none"> Recognize other respected clinicians are recommending lifestyle modification

Table 2

Environmental Matrix Formulary and Patient Behavior Change

Performance Objectives	Awareness, Behavioral Capability	Skills and Self-efficacy	Outcome Expectations	Pharmaceutical Marketing Influence	Perception of Social Norms and Standards of Care
Pharmacy Managers					
1. Benefits managers implement formulary parameters to provide cues for diuretic use as first line HTN medication	<ul style="list-style-type: none"> Recognize that JNC 7 recommends starting with diuretic and diuretic as part of multi-drug regimen Describe ALLHAT results and conclusions Describe dosing recommendation 	<ul style="list-style-type: none"> Express confidence in asking about diuretic Express confidence in asking if a medication change is indicated 	<ul style="list-style-type: none"> Expect that patients will have better BP control and better long term CVD risk profile when treated with diuretic Expect cost savings to the pharmacy plan 	<ul style="list-style-type: none"> Compare diuretics to other drugs regarding CVD outcomes and price Recognize messages that lobby against diuretic without scientific basis Reflect critically on origin of personal HTN drug preferences and biases 	<ul style="list-style-type: none"> Recognize that other formulary drugs are changing to control HTN treatment costs and to achieve better outcomes
Patients					
1. Newly diagnosed patients and those with uncontrolled hypertension will ask providers about diuretics	<ul style="list-style-type: none"> Describe guidelines for diuretics as first step therapy and addition to regimen if uncontrolled Recognize that new recommendations suggest diuretics as first step therapy and as addition to regimen if uncontrolled Describe diuretics as having some adverse impact on blood sugar, nevertheless positive study results held for diabetics 	<ul style="list-style-type: none"> Express confidence in asking about diuretic Express confidence in asking if a medication change is indicated 	<ul style="list-style-type: none"> Expect providers to respond positively to communication about BP control and diuretics Expect communicating with provider about diuretic will result in better BP control and long-term CVD health Expect adding a diuretic may result in less need for expensive multi-drug regimens 	<ul style="list-style-type: none"> Recognize that guidelines suggest continuing to work on BP control until goals are met Describe friends and relatives as talking to the doctor about treatment for blood pressure 	<ul style="list-style-type: none"> Recognize that other formulary drugs are changing to control HTN treatment costs and to achieve better outcomes
2. Patients with diagnosed hypertension will engage in conversation about lifestyle modification with physician	<ul style="list-style-type: none"> Recognize that JNC 7 and ALLHAT results recommend that lifestyle modifications should be treatment for HTN Describe importance of weight reduction, physical activity, moderate consumption of alcohol, 	<ul style="list-style-type: none"> Express confidence in making lifestyle changes 	<ul style="list-style-type: none"> Expect that working with the physician can help with commitment to behavioral change Expect that physical activity and approaching 		<ul style="list-style-type: none"> Recognize that valued love ones, friends and colleagues think that making changes in weight and exercise is

Performance Objectives	Awareness, Behavioral Capability and following the DASH eating plan	Skills and Self- efficacy	Outcome Expectations	Pharmaceutical Marketing Influence	Perception of Social Norms and Standards of Care
			<div>normal weight will result in better BP control and better long term CVD risk</div> <ul style="list-style-type: none">• Expect that even modest changes can make a difference in BP		very important

Table 3

Investigator Educator Reach and Dose Delivered by Region

Region	Number of Presentations	Total # of Clinician Participants	Average # Clinician Participants per Presentation	Population age 50+/	Clinician Participants per 10,000 Population 50+
Total	1698	18524	10.9	76,381,962	2.43
			Range 1.0 – 106.8		Range 0.01 – 86.11
Midwest	542	4388	8.1	17,813,111	2.48
			Range 1.0–56.0		Range 0.01–86.11
Northeast	341	3274	9.6	15,661,538	2.09
			Range 1.4–72.0		Range 0.20–9.50
South	655	7898	12.1	27,530,500	2.87
			Range 1.0–106.8		Range 0.01–41.69
West	160	2964	18.5	15,376,813	1.93
			Range 1.0–32.0		Range 0.05–18.39

/ From: <http://datawarehouse.hrsa.gov/pcsa.htm>, files MSA1.DBF and COUNTY1.DBF, accessed 7/16/2007.

Table 4

Attitude and Intention Scores Pre- and Post- IE Presentations*

1 – Do not agree at all; 5 - Agree completely							
Total	1	2	3	4	5	Mean (sd)**	
Outcome Expectations							
I expect that my patients will have better BP control when treated with diuretic.							
Pre-test	1709	18 (1.1%)	61 (3.6%)	275 (16.1%)	692 (40.5%)	663 (38.8%)	4.12 (0.88)
Post-test	1617	5 (0.3%)	8 (0.5%)	80 (4.9%)	499 (30.9%)	1025 (63.4%)	4.57 (0.64)
I expect better long term CVD risk among diuretic treated hypertensive patients.							
Pre-test	1681	41 (2.4%)	108 (6.4%)	372 (22.1%)	669 (39.8%)	491 (29.2%)	3.87 (0.99)
Post-test	1595	36 (2.3%)	41 (2.6%)	113 (7.1%)	535 (33.5%)	870 (54.5%)	4.36 (0.89)
Attitude toward ALLHAT							
I believe the HF results from the ALLHAT clinical trial.							
Pre-test	1540	79 (5.1%)	191 (12.4%)	733 (47.6%)	320 (20.8%)	217 (14.1%)	3.26 (1.02)
Post-test	1535	144 (9.4%)	198 (12.9%)	379 (24.7%)	412 (26.8%)	402 (26.2%)	3.48 (1.27)
I anticipate good acceptance of diuretic treatment by patients.							
Pre-test	1688	28 (1.7%)	128 (7.6%)	421 (24.9%)	727 (43.1%)	384 (22.7%)	3.78 (0.94)
Post-test	1572	18 (1.1%)	36 (2.3%)	206 (13.1%)	695 (44.2%)	617 (39.2%)	4.18 (0.83)
I think diuretics can safely be used for diabetic patients.							
Pre-test	1674	76 (4.5%)	139 (8.3%)	365 (21.8%)	447 (26.7%)	647 (38.6%)	3.87 (1.15)
Post-test	1596	133 (8.3%)	135 (8.5%)	148 (9.3%)	371 (23.2%)	809 (50.7%)	3.99 (1.30)
Social Norms							
I think my colleagues are making changes in their practices regarding blood pressure management.							
Pre-test	1654	58 (3.5%)	114 (6.9%)	612 (37.0%)	585 (35.4%)	285 (17.2%)	3.56 (0.97)
Post-test	1576	25 (1.6%)	75 (4.8%)	423 (26.8%)	584 (37.1%)	469 (29.8%)	3.89 (0.94)
Intentions							
I expect to retrain my staff in proper blood pressure measurement techniques.							
Pre-test	1647	129 (7.8%)	140 (8.5%)	435 (26.4%)	432 (26.2%)	511 (31.0%)	3.64 (1.22)
Post-test	1519	88 (5.8%)	82 (5.4%)	252 (16.6%)	422 (27.8%)	675 (44.4%)	4.00 (1.16)
I anticipate beginning more newly diagnosed hypertensive patients on a diuretic as first line treatment.							
Pre-test	1673	72 (4.3%)	101 (6.0%)	334 (20.0%)	579 (34.6%)	587 (35.1%)	3.90 (1.08)
Post-test	1599	39 (2.4%)	36 (2.3%)	141 (8.8%)	468 (29.3%)	915 (57.2%)	4.37 (0.91)

1 – Do not agree at all; 5 – Agree completely						
	Total	1	2	3	4	5
Mean (sd)**						
<i>I add a diuretic, or plan to begin adding a diuretic, to the regimens of uncontrolled patients.</i>						
Pre-test	1678	30 (1.8%)	50 (3.0%)	234 (13.9%)	677 (40.3%)	687 (40.9%)
Post-test	1574	41 (2.6%)	23 (1.5%)	99 (6.3%)	450 (28.6%)	961 (61.1%)
<i>I anticipate providing lifestyle change counseling more often than is my current practice with hypertensive patients.</i>						
Pre-test	1686	86 (5.1%)	99 (5.9%)	370 (21.9%)	570 (33.8%)	561 (33.3%)
Post-test	1577	55 (3.5%)	55 (3.5%)	219 (13.9%)	489 (31.0%)	759 (48.1%)
* 18524 attendees						
2667 pretests (14.4% of attendees)						
2640 posttests (14.3% of attendees)						
Range of valid pretest responses is 8.3% to 9.2% of attendees.						
Range of valid posttest responses is 8.2% to 8.7% of attendees.						
** t-tests comparing mean pre-tests and mean post-tests are all significant at $p \leq .005$						